Innovation and Regulation of Emerging Technologies: Safety and Data Security

FDA's Evolving Policy on Personalized Medicine Tests

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Clinical and Patient Decision Support Software

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on: December 8, 2017

You should submit comments and suggestions regarding this draft document within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register.

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Preface

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Table of Contents

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I. Introduction

The Food and Drug Administration (FDA) has long regulated software that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including software that is intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of diseases or other conditions (often referred to as clinical decision support software). This draft guidance provides clarity on the scope of FDA's regulatory oversight of (1) clinical decision support software intended for healthcare professionals and (2) patient decision support software intended for patients and caregivers who are not healthcare professionals.

FDA recognizes that the term "clinical decision support" or "CDS" is used broadly and in different ways, depending on the context. This draft guidance defines "CDS" in the context of and using language from Section 3060(a) of the 21st Century Cures Act (Cures Act), which amended section 520 of the FD&C Act and excludes certain software functions from the device definition.

The purpose of this guidance is to identify the types of decision support software functionalities that: (1) do not meet the definition of a device as amended by the Cures Act; (2) may meet the definition of a device but for which FDA does not intend to enforce compliance with applicable requirements of the FD&C Act, including, but not limited to, premarket clearance and premarket approval requirements; and (3) FDA intends to focus its regulatory oversight on.

This guidance does not address other FDA statutory or regulatory requirements that may apply to certain decision support software, including software disseminated by or on behalf of a sponsor, for use with one or more of its drugs or biologics, such as requirements applicable to drug or biologic labeling or combination products.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance documents means that something is suggested or recommended, but not required.

II. Background

Section 3060(a) of the Cures Act amended the FD&C Act to add section 520(o) of the FD&C Act, which excludes certain software functions from the definition of device in section 201(h) of the FD&C Act. Specifically, section 520(o)(1)(E) of the FD&C Act excludes, from the definition of device, software functions that meet all of the following four criteria:

(1) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system (section 520(o)(1)(E) of the FD&C Act);

(2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) (section 520(o)(1)(E)(i) of the FD&C Act);

(3) intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition (section 520(o)(1)(E)(ii) of the FD&C Act); and

(4) intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient (section 520(o)(1)(E)(iii) of the FD&C Act).[1]

[1] The Cures Act provides that a software function described in section 520(o)(1)(E) of the FD&C Act will not be excluded from the device definition under 201(h) if the software meets the criteria under section 513(a)(1)(C) of the Act or if the software is used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; Section 520(o)(4)(B) and (C) of the FD&C Act.

To explain FDA's interpretation of section 520(o)(1)(E), this guidance discusses each element of section 520(o)(1)(E) below. FDA is defining the term CDS based on section 520(o)(1)(E) as follows:

> **Clinical Decision Support (CDS):** For the purposes of this guidance, FDA is using the term "CDS" to mean those software functions that meet the first, second, and third criteria of section 520(o)(1)(E) as listed above. CDS is not always excluded from the device definition by the Cures Act. Only when a CDS function also meets the fourth criterion of section 520(o)(1)(E), which relates to enabling independent review of the basis for recommendations, is the CDS function excluded from the definition of a device.

Relatedly, some software functions may have CDS functions, but are intended for use by patients or non-healthcare professionals. For purposes of this guidance, FDA is using the term "patient decision support software" ("PDS") to mean those software functions that are intended for patients or caregivers who are not healthcare professionals and that also are: (1) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system; (2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as information derived from peer-reviewed clinical studies and clinical practice guidelines) and (3) intended for the purpose of supporting or providing recommendations to a patient, in terms that are understandable to the patient, about prevention, diagnosis, or treatment of a disease or condition. FDA's regulatory approach to PDS functions is described in section V below.

III. Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act

(1) Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system

Under section 520(o)(1)(E), software functions that are intended to acquire, process, or analyze a medical image, a signal from an in vitro diagnostic device, or a pattern or signal from a signal acquisition system remain devices and therefore continue to be subject to FDA oversight. Products that acquire an image or physiological signal,[2] process or analyze this information, or both, have been regulated for many years as devices. Technologies that analyze those physiological signals and that are intended to provide diagnostic, prognostic and predictive functionalities are devices. These include, but are not limited to, *in vitro* diagnostic tests, technologies that measure and assess electrical activity in the body (e.g., electrocardiograph

[2] Physiological signals are those signals that require use of either an in vitro diagnostic device (e.g., assay or instrument) or signal acquisition system. A signal acquisition system is the electronic circuitry and control processor that receives, as inputs, signals from sensors that are within, attached to (e.g., EEG, ECG), or external to (e.g., CT, MRI) the human body or sample from the human body (e.g., digital pathology). The fidelity with which a physiologic signal is captured, processed, and analyzed is often critical to the overall performance of a device.

(ECG) machines and electroencephalograph (EEG) machines), and medical imaging technologies. Additional examples include algorithms that process physiologic data to generate new data points (such as ST-segment measurements from ECG signals), analyze information within the original data (such as feature identification in image analysis), or analyze and interpret genomic data (such as genetic variations to determine a patient's risk for a particular disease).

(2) Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information

Section 520(o)(1)(E)(i) of the FD&C Act describes software functions that are intended to display, analyze, or print medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines). FDA interprets this to include software functions that display, analyze, or print patient-specific information, such as demographic information, symptoms, and test results, and/or medical information, such as clinical practice guidelines, peer-reviewed clinical studies, textbooks, approved drug labeling, and government agency recommendations. In general, this is the kind of information that health care professionals may use to make decisions about prevention, diagnosis, or treatment of a disease or condition for an individual patient.

(3) Intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition

Section 520(o)(1)(E)(ii) describes software functions that are intended to support or provide recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition. This means that software functions that support or provide recommendations to patients – not health care professionals – are not excluded from the definition of device. However, FDA does not intend to enforce compliance with applicable regulatory requirements with respect to analogous devices described in Section V below that provide similar recommendations for patients or caregivers who are not healthcare professionals.

(4) Intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional relies primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

Section 520(o)(1)(E)(iii) states that, in order to be excluded from the definition of device by operation of section 520(o)(1)(E) of the FD&C Act, the CDS function must be intended to enable health care professionals to independently review the basis for the recommendations presented by the software so that they do not rely primarily on such recommendations, but rather on their own judgment, to make clinical decisions for individual patients.

FDA interprets 520(o)(1)(E)(iii) to describe software functions that clearly explain:

1) The purpose or intended use of the software function;
2) The intended user (e.g., ultrasound technicians, vascular surgeons);
3) The inputs used to generate the recommendation (e.g., patient age and gender); and
4) The rationale or support for the recommendation.

In order for the software function to be excluded from the definition of device, the intended user should be able to reach the same recommendation on his or her own without relying primarily on the software function. The sources supporting the recommendation or underlying the rationale for the recommendation should be identified and easily accessible to the intended user, understandable by the intended user (e.g., data points whose meaning is well understood by the intended user), and publicly available (e.g., clinical practice guidelines, published literature). A practitioner would be unable to independently evaluate the basis of a recommendation if the recommendation were based on non-public information or information whose meaning could not be expected to be independently understood by the intended health care professional user.

IV. Examples

A. Examples of CDS Functions that are not Devices

Applying these interpretations, below are examples of CDS functions that do not meet the definition of device in section 201(h), as amended by the Cures Act, because they meet all four criteria described in section 520(o)(1)(E), as described in Section III.

- Software that provides recommendations to health care providers by matching patient-specific information (e.g., diagnosis, treatments, allergies, signs or symptoms) to reference information the medical community routinely uses in clinical practice (e.g., practice guidelines)[3] to facilitate assessments of specific patients. Examples include:
  - Software that uses a patient's diagnosis to provide a health care professional with current practice treatment guidelines for common illnesses or conditions such as influenza, and provides the source of the guidelines; and
  - Software that helps to identify drug-drug interaction and drug-allergy contraindication alerts, based on FDA-approved drug labeling and patient-specific information, to prevent adverse drug events;

- Software that provides health care professionals with recommendations on the use of a prescription drug[4] that are consistent with the FDA-required labeling.[5]

[3] The type of information provided in this software is from authoritative medical sources, as recognized by the field or discipline that is the subject of the software.

[4] Information relied upon by the software should be kept up-to-date while prominently displaying the source of the information (e.g., FDA approved labeling), and provide options to users to obtain up-to-date information. (For

- Software that suggests an intervention or test, consistent with clinical guidelines and/or drug labeling, based on or in response to a physician's order, such as, for example, software suggesting that a health care professional order liver function tests before starting a statin.
- Software that makes chemotherapeutic suggestions to a health care professional based on patient history, test results, and patient characteristics, including, for example, software suggesting a platinum-based chemotherapy for BRCA-positive individuals that is consistent with the drug labeling.
- Software that uses rule-based tools that compare patient-specific signs, symptoms, or results with available practice guidelines (institutions-based or academic/clinical society-based) to recommend condition specific diagnostic tests, investigations or therapy.
- Software that contains tools, calculators, guidelines, and protocols for ordering total parenteral nutrition (TPN), enteral nutrition, or other alimentation procedures. This would include, for example, software recommending increased protein in TPN for patients with active infection, consistent with generally accepted clinical practice.
- Software that provides health care professionals with a report based on arterial blood gas results that includes a calculated anion gap and recommends whether the patient has high anion gap metabolic acidosis and possible next steps, based on practice guidelines.
- Software that presents and prioritizes alternatives to orders, drugs, or therapies using practice guidelines and other generally accepted practices, such as rule-based tools allowing health care professionals to efficiently select diagnostic tests, drugs, devices or therapies in accordance with their approved or cleared labels.
    - A specific example is software providing a ventilator guideline suggestion based on patient-specific blood gas readings and current condition, such as "unless the FiO2 is already 1.0, suggest increasing the FiO2 by 0.1 if the PaO2 is >50 but <60 mm Hg in adult patients with acute respiratory distress syndrome."
- Software intended for use by health care professionals to aid in diagnosing patients suspected to have diabetes mellitus. The healthcare practitioner enters patient parameters and laboratory test results (i.e., fasting plasma glucose, oral glucose tolerance test results, and/or hemoglobin A1c test results), and the device suggests whether the patient's condition meets the definition of diabetes based on established guidelines.

example, software that provides alerts for potential drug-drug interactions, should provide a link directly to a trusted and up-to-date source for that information (e.g., DailyMed for drug labeling)).

[5] Drug labeling includes prescribing information (also referred to as package insert or physician labeling); patient labeling, including patient package inserts and Medication Guides; the product's immediate container label; outer container; the outside package; and other written, printed, or graphic information that accompanies the product. For non-prescription drugs, labeling includes the Drug Facts Label.

B. Examples of CDS and Other Software Functions for Health Care Professionals that Remain Devices

Examples of devices FDA intends to focus its regulatory oversight on include:

- Software that uses a patient's image sets (e.g., computed tomography (CT), magnetic resonance (MR)) to create an individual treatment plan for patients undergoing radiation therapy treatment with external beam or brachytherapy, and the health care professional is intended to rely primarily on the treatment recommendations in determining the radiation therapy plan for the individual patient.
- Software that manipulates or analyzes images and other data obtained from a radiological device (e.g., CT, bone density, and distance) to create 3D models of the region intended to be used in planning orthopedic/dental surgical treatments with a device.
- Software that manipulates or interpolates data from a patient's CT scan, providing 3D reconstruction for visualization of the interior of the bronchial tree to aid in the placement of catheters in lung tissue; and placement of markers into soft lung tissue to guide radiosurgery and thoracic surgery. The surgeon relies primarily on the recommendations to make decisions about the placement of catheters and markers during surgery.
- Software that customizes the patient-specific surgical plan and instrumentation based on analysis of imaging and device characteristics for orthopedic or dental implant procedures.
- Software that analyzes multiple physiological signals (e.g., sweat, heart rate, eye movement, breathing – from FDA-regulated devices) to monitor whether a person is having a heart attack or narcolepsy episode.
- Software that analyzes sound waves captured when users recite certain sentences to diagnose bronchitis or sinus infection.
- Software that analyzes near-infrared camera signals of a patient intended for use in determining and/or diagnosing brain hematoma.
- Software that calculates the fractal dimension of a lesion and surrounding skin image and builds a structural map to provide diagnosis or identify whether the lesion is malignant or benign.
- Software that analyzes CT images to compute and/or approximate fractional flow reserve. In this case the software performs and provides the user an image analysis that the user could not independently derive.
- Software that is intended to perform image analysis for diagnostically differentiating between ischemic and hemorrhagic stroke.

- Software that analyzes breathing patterns from a sleep apnea monitor to diagnose sleep apnea or other conditions in patients.

- Software that analyzes signals from a FDA-cleared trans-abdominal electromyography device and a FDA-cleared fetal heart rate, intrauterine pressure catheter intended to determine a C-section intervention for an "at term" pregnant woman.

- Software that performs analysis of cerebrospinal fluid (CSF) spectroscopy data to diagnose tuberculosis meningitis or viral meningitis in children.

- Software that analyzes images of body fluid preparations or digital slides (digital pathology) to perform cell counts and morphology reviews.

- Software intended for health care professionals that uses an algorithm undisclosed to the user to analyze patient information (including noninvasive blood pressure (NIBP) monitoring systems) to determine which anti-hypertensive drug class is likely to be most effective in lowering the patient's blood pressure.

- Software that analyzes a patient's laboratory results using a proprietary algorithm to recommend a specific radiation treatment, for which the basis of the recommendation is unavailable for the HCP to review.

There are many types of software intended to support health care professionals that are not affected by section 520(o)(1)(E) of the FD&C Act or this guidance. Some of these, such as software that perform calculations routinely used in clinical practice, are devices for which FDA maintains its existing policy of not intending to enforce compliance with applicable regulatory requirements. FDA also provides additional examples of such software in the Mobile Medical Applications (MMA) guidance (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf) and on its website (https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm).

FDA is providing clarification of section 520(o)(1)(A)-(D) of the FD&C Act in a separate guidance, which details changes to existing guidance documents that relate to the regulation of the software functions described in those provisions, and describes certain software functions for which FDA intends to continue to exercise enforcement discretion.

V. Patient Decision Support Software

Section 520(o)(1)(E) of the FD&C Act only pertains to products intended for health care professionals, not patients. There are certain types of decision support software intended for patients or caregivers who are not healthcare professionals (PDS) that are low risk devices and fall outside of the set of functionalities upon which FDA intends to focus its regulatory oversight. As a result, FDA intends to adopt an enforcement discretion policy for PDS that generally parallels the CDS for health care professionals excluded from the device definition under section 520(o)(1)(E) of the FD&C Act. FDA does not intend to enforce compliance with applicable regulatory requirements for PDS that meets all of the following factors:

1) Do not acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
2) Display, analyze, or print medical information about a patient or other medical information (such as information derived from peer-reviewed clinical studies and clinical practice guidelines);
3) Support or provide recommendations to patients or non-health care professional caregivers about prevention, diagnosis, or treatment of a disease or condition; and
4) Enable the patient or non-health care professional caregiver to independently review the basis for the recommendation so that it is not the intent that such patient or non-health care professional rely primarily on any of such recommendations to make a decision regarding the patient.

In order to enable the patient or non-healthcare professional to independently review the basis of the recommendation, the software function should clearly explain:

1) The purpose or intended use of the software function;
2) The intended user (e.g., patient, non-health care professional caregiver);
3) The inputs used to generate the recommendation (e.g., patient age and gender); and
4) The rationale or support for the recommendation.

The intended user should be able to reach the recommendation on his or her own without primarily relying on the software function. Therefore, the sources supporting the recommendation or underlying the rationale for the recommendation should be identified for the intended user, understandable by the intended user, and publicly available. The kinds of explanations that a health care professional may be able to understand and apply are different than the kinds of explanations that a patient may be able to understand and apply, given the differences in clinical education and experience.

Examples of such types of software functionalities include:

- Software that provides information to a patient about the use of a prescription drug that is consistent with the FDA-required labeling,[6] such as reminding the patient how or when to take a prescribed drug. Such software does not recommend changes in dose or drug discontinuation that healthcare providers do not oversee (unless drug labeling includes such recommendations).
- Software that assists a patient in choosing an appropriate over-the-counter (OTC) cold or allergy medication based on symptoms. For example, once a patient or non-healthcare professional caregiver inputs the symptoms of the person needing the cold or allergy medication, the software provides a prioritized list of OTC medications that match the

[6] Information relied upon by the software should be kept up-to-date while prominently displaying the source of the information (e.g., FDA approved labeling), and provide options to users to obtain up-to-date information. (For example, software that provides alerts for potential drug-drug interactions should provide a link directly to a trusted and up-to-date source for that information (e.g., DailyMed for drug labeling)).

person's symptoms. In this example, inclusion of appropriate warnings about products with overlapping active ingredients (e.g., multiple products containing acetaminophen) would be an important mechanism to prevent risks to patients that might arise from using this software.

FDA intends to focus its regulatory oversight on PDS that do not follow the recommendations outlined above. Below is an example of such a software functionality:

- For patients performing home blood testing required with use of warfarin, an anticoagulant ("blood thinner"), the software makes recommendations for dosing adjustments based on the outcome of the home blood test (i.e., the International Normalized Ratio (INR)) and published algorithms, without the patient seeking consultation with their healthcare provider.

VI. Conforming Changes to Existing Guidance

Once this guidance is finalized, FDA intends to make conforming edits to the MMA guidance document[7] to make it consistent with the interpretations and policies in this guidance. For example, mobile apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling and preventative recommendations from well-known and established authorities (listed in Appendix B of the MMA guidance) are not devices.

[7] Available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

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When final, the content of this guidance will be incorporated into the following guidance documents: General Wellness: Policy for Low Risk Devices, issued July 29, 2016; Mobile Medical Applications, issued February 9, 2015; Off-The-Shelf Software Use in Medical Devices, issued September 9, 1999; Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, issued February 9, 2015

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Preface

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Table of Contents

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I. Introduction

Section 3060(a) of the 21st Century Cures Act (Cures Act) amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) on December 13, 2016, removing certain software functions from the definition of device in section 201(h) of the FD&C Act. This draft guidance provides FDA's current thinking regarding the amended device definition and the resulting effect the amended definition has on FDA's guidances related to medical device software. Upon finalization, the concepts detailed in this draft guidance will also be made through Level 2 updates to the following guidance documents:

- General Wellness: Policy for Low Risk Devices, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm429674.pdf
- Mobile Medical Applications, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263366.pdf
- Off-The-Shelf Software Use in Medical Devices, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, available at

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm401996.pdf

The following guidance document will be withdrawn, for the reasons described in Section IV.D:

- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073720.htm

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II. Background

On December 13, 2016, the Cures Act was enacted. Section 3060(a) of this legislation, titled "Clarifying Medical Software Regulation," amended the FD&C Act to add section 520(o), which describes software functions that are excluded from the definition of device in 201(h) of the FD&C Act. Section 3060(d) of the Cures Act amended section 201(h) of the FD&C Act to state that the term device does not include the software functions excluded pursuant to section 520(o). This draft guidance focuses on section 520(o)(1)(A)-(D) of the FD&C Act, reproduced below.

> Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j)
>
> (o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—
>
> (1) The term device, as defined in section 201(h), shall not include a software function that is intended—
>
> (A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;
>
> (B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;
>
> (C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—
>
> (i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;
>
> (ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

> (iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;
>
> (D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings…

III. Scope

This draft guidance details the changes to existing guidance documents that relate to the regulation of the software functions described in section 520(o)(1)(A)-(D) of the FD&C Act. These sections describe software functions that do not meet the device definition in 201(h) of the FD&C Act. Section 3060 also describes limited circumstances when software functions described in 520(o)(1)(A)-(D) would remain devices.[1, 2]

FDA intends to provide clarification of its interpretation of section 520(o)(1)(E) of the FD&C Act, which is for software functions intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of disease or other conditions (often referred to as clinical decision support software), in a separate guidance document. Section 520(o)(2) of the FD&C Act describes the regulation of a product with multiple functions, including at least one device function and at least one software function that is not a device. FDA also intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.

IV. Interpretation of the Cures Act and Modifications to Existing Guidance Documents

FDA's interpretation of each provision of Section 520(o)(1)(A) – 520(o)(1)(D) of the FD&C Act, as amended by the Cures Act, described in Sections A – D below will be added to the

[1] The Cures Act also provides that a software function described in section 520(o)(1)(A)-(D) of the FD&C Act will not be excluded from the device definition under section 201(h) of the FD&C Act if FDA makes a finding that the software function would be reasonably likely to have serious adverse health consequences and certain substantive and procedural criteria are met. Section 520(o)(3) of the FD&C Act.

[2] The Cures Act further provides that a software function described in section 520(o)(1)(A)-(D) of the FD&C Act will not be excluded from the device definition under section 201(h) of the FD&C Act if the software meets the criteria for class III classification under section 513(a)(1)(C) of the FD&C Act. (Section 520(o)(4)(C) of the FD&C Act). The Cures Act also states that this statutory provision shall not be construed to limit FDA's authority to regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans. (Section 520(o)(4)(B) of the FD&C Act).

Background sections of the indicated guidances that will be revised, after consideration of timely filed comments, through Level 2 updates to incorporate the changes detailed in this guidance. Similarly, FDA will make changes to the examples in the guidances, after consideration of comments, through level 2 updates, as described below.

Section 3060 of the Cures Act created a function-specific definition, and as such, the functions excluded from the device definition under section 520(o) of the FD&C Act are independent of the platform on which they might run. In order to clarify this, once this guidance is finalized, we will make changes to the relevant guidances, through Level 2 updates, to clarify, where appropriate, that the policies in the guidance documents are function-specific and apply across platforms. For example, as appropriate, instances of "mobile application" in the Mobile Medical Applications (MMA) guidance will be changed to "software function," and the title of the guidance will likely be revised to "Mobile Medical Applications and Software Functions."

A. Software Function Intended for Administrative Support of a Health Care Facility

Section 520(o)(1)(A) of the FD&C Act states that the term "device" does not include a software function that is intended "for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow." FDA has not historically considered most of these software functions to be devices; however, we propose the following modification in order to provide additional clarity.

Section 3.2.2 of the Guidance for Off-the-Shelf Software Use in Medical Devices, titled "Exemption of Laboratory Information Management Systems," will be removed from the guidance. As software with functions intended for administrative support of laboratories and/or for transferring, storing, converting formats, or displaying clinical laboratory test data and results, Laboratory Information Management Systems (LIMS) are not within the definition of the term device, according to 201(h) of the FD&C Act, as amended by the Cures Act (*see* section 520(o)(1)(A) and (D) of the FD&C Act). Therefore, these products are not subject to requirements under the FD&C Act.

B. Software Function Intended for Maintaining or Encouraging a Healthy Lifestyle

Section 520(o)(1)(B) of the FD&C Act states that the term device does not include a software function that is intended "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition." FDA considers a product with an intended use for maintaining or encouraging a "healthy lifestyle" to

mean a product with an intended use that encourages or maintains a "general state of health or healthy activity," as defined in the FDA guidance General Wellness: Policy for Low Risk Devices ("General Wellness Guidance").[3] In that guidance CDRH defines a general wellness product as products that (1) are intended for only general wellness use, as defined in that guidance, and (2) present a low risk to the safety of users and other persons. That guidance defines two categories of general wellness intended uses: (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

If the intended use of the software function is related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, then the product is not excluded from the definition of the term "device" under section 520(o)(1)(B) of the FD&C Act. Since the second category of a general wellness intended uses, as defined in the General Wellness Guidance, relates to the mitigation or prevention of a disease or condition, these products are not excluded from the definition of device as modified by this new provision of the FD&C Act. This second category of general wellness intended uses relates to sustaining or offering general improvement to functions associated with a general state of health while making reference to help reduce the risk of or help living well with certain chronic diseases or conditions. Although this type of general wellness product is not excluded from the definition of device, we intend to continue to not enforce the applicable requirements for this type of general wellness software function where it presents a low risk to the safety of users and other persons. As described in the General Wellness Guidance, FDA does not intend to examine whether low risk general wellness products in the second category are devices within the meaning of the FD&C Act, or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations, including, but not limited to: registration and listing and premarket notification requirements (21 CFR Part 807); labeling requirements (21 CFR Part 801 and 21 CFR 809.10); good manufacturing practice requirements as set forth in the Quality System regulation (21 CFR Part 820); and Medical Device Reporting (MDR) requirements (21 CFR Part 803).

According to section 520(o)(1)(B) of the FD&C Act, a software function with a healthy lifestyle claim (e.g., products that fall within the first category of general wellness intended uses as defined by the General Wellness Guidance) is not a device as long as its claims are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. For example, software with healthy lifestyle claims, such as weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function, are not devices when not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. Therefore, the following examples in Section V. of the General Wellness Guidance are not devices:

[3] Available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm429674.pdf .

- A mobile application that plays music to "soothe and relax" an individual and to "manage stress" (Illustrative Example 1)
- A mobile application that solely monitors and records daily energy expenditure and cardiovascular workout activities to "allow awareness of one's exercise activities to improve or maintain good cardiovascular health" (Illustrative Example 2)
- A mobile application that monitors and records food consumption to "manage dietary activity for weight management and alert the user, healthcare provider, or family member of unhealthy dietary activity" (Illustrative Example 3)

These examples will remain in the General Wellness Guidance, because they continue to meet the definition of general wellness products; however, the title of Section V. will be changed to "Examples of General Wellness Products that Are Not Medical Devices and Examples of General Wellness Products that Are Medical Devices for which FDA Does Not Intend to Enforce Requirements" to reflect that some of these examples are not medical devices under 201(h) of the FD&C Act.

For the MMA guidance, the following examples in Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) will be moved to Appendix A (Examples of mobile apps that are NOT medical devices) of the MMA Guidance, because they no longer meet the definition of the term "device" pursuant to section 520(o)(1)(B) of the FD&C Act:

- Mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness, such as those that:
  - Provide tools to promote or encourage healthy eating, exercise, weight loss or other activities generally related to a healthy lifestyle or wellness;
  - Provide dietary logs, calorie counters or make dietary suggestions;
  - Provide meal planners and recipes;
  - Track general daily activities or make exercise or posture suggestions;
  - Track a normal baby's sleeping and feeding habits;
  - Actively monitor and trend exercise activity;
  - Help healthy people track the quantity or quality of their normal sleep patterns;
  - Provide and track scores from mind-challenging games or generic "brain age" tests;
  - Provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
  - Use social gaming to encourage healthy lifestyle habits;
  - Calculate calories burned in a workout.

C. Software Function Intended to Serve as Electronic Patient Records

Under section 520(o)(1)(C) of the FD&C Act, the term device does not include certain software functions that are intended to serve as electronic patient records. Specifically, software functions that are intended to transfer, store, convert formats, or display electronic patient records that are

the equivalent of a paper medical chart are not devices, if the following three criteria outlined in 520(o)(1)(C)(i) – (iii) are met:

1. Such records were created, stored, transferred, or reviewed by health care professionals (HCPs), or by individuals working under supervision of such professionals, (Section 520(o)(1)(C)(i) of the FD&C Act);

2. Such records are part of information technology certified by the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program[4] (Section 520(o)(1)(C)(ii) of the FD&C Act); and

3. Such software functions are not intended for interpretation or analysis of patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition (Section 520(o)(1)(C)(iii) of the FD&C Act).

FDA does not intend to enforce the FDA requirements for software functions that are not certified by ONC, if they meet the other criteria in section 520(o)(1)(C)(i) and (iii) of the FD&C Act.

Software functions that enable patients or non-HCPs to create, store, or transfer health records for their own record-keeping purposes that are not intended to be created, stored, transferred or reviewed by a HCP are considered personal health records (PHRs). These software functions in PHR systems that are not intended for use in the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition are not devices under section 201(h) of the FD&C Act.

Software functions excluded from the device definition by section 520(o)(1)(C) of the FD&C Act may be contained in electronic health record (EHR) systems, PHR systems, and other health information technology. Such systems may also contain other software functions that could meet the definition of a device. FDA's approach to oversight of software functions that meet the definition of a device in a system with software functions that do not meet the definition of device (products with multiple functions) will be addressed in a separate guidance document.

Therefore, in the MMA Guidance, the following examples in Section V.B. (Mobile Apps for which FDA intends to exercise enforcement discretion) are not devices (pursuant to section 520(o)(1)(C) of the FD&C Act), and will be moved to Appendix A (Examples of mobile apps that are NOT medical devices) of that guidance:

- **Mobile apps that enable individuals to interact with ONC-certified EHR systems** -- These are apps that provide individuals with mobile access to health record systems or enable them to gain electronic access to health information stored within an EHR system. Applications that only allow individuals to view or download EHR data are also included

[4] "About the ONC Health IT Certification Program," available at https://www.healthit.gov/policy-researchers-implementers/about-onc-health-it-certification-program.

in this category. These mobile apps are generally meant to facilitate general patient health information management and health record-keeping activities.
    - Note: This example has been changed to clarify that only ONC-certified EHR functions are not devices according to the FD&C Act, as amended by 21st Century Cures.
    - For clarity, this example and other types of electronic patient record functions must meet the full description of section 520(o)(1)(C) in the FD&C Act, in that they are not devices only if they are reviewed by HCPs, certified by ONC, and are not intended for interpretation or analysis for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. However, FDA does not intend to enforce compliance with requirements that apply to these software functions if they are not certified by ONC.
- Provide patients with simple tools to organize and track their health information;
- Provide easy access to information related to patients' health conditions or treatments;
- Help patients document, show, or communicate potential medical conditions to health care providers

And in the MMA Guidance, the following examples will be moved from Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) to Appendix A (Examples of Mobile Apps that are Not Medical Devices) as long as the products are ONC-certified:

- Mobile apps that enable, during an encounter, a health care provider to access their patient's personal health record (health information) that is hosted on a web-based or other platform
- Mobile apps for HCPs that help track or manage patient immunizations by documenting the need for immunization, consent form, and immunization lot number.
    - This example has been changed from "assessing the need for immunization" to "documenting the need…" because the example is intended to serve as an example of an electronic patient record, and not clinical decision support software. FDA intends to provide clarification of section 520(o)(1)(E) of the FD&C Act and clinical decision support software in a separate guidance document.

D. Software Function Intended for Transferring, Storing, Converting Formats, Displaying Data and Results

Under section 520(o)(1)(D) of the FD&C Act, the term "device" does not include a software function that is intended "for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings" (section 520(o)(1)(D) of the FD&C Act).

The software functions that meet the definitions of Medical Device Data Systems (MDDS), medical image storage devices, or medical image communications devices provided in the Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices Guidance (or MDDS Guidance), and the Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, are, thus, now not devices under section 201(h) of the FD&C Act, pursuant to section 520(o)(1)(D) of the FD&C Act. As such, products that are solely intended to transfer, store, convert formats, and display medical device data and results, including medical images, waveforms, signals, or other clinical information are not devices and thus are not subject to FDA regulatory requirements. However, software functions that analyze or interpret medical device data in addition to transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results remain subject to FDA's regulatory oversight.

FDA does not consider the following functions to meet the definition of device under section 201(h) of the FD&C Act, as amended by the Cures Act:

1. Medical Device Data System (MDDS), defined as a software, electronic, or electrical hardware that is intended to provide one or more of the following uses, whether or not the use is for immediate clinical action, without controlling or altering the functions or parameters of any connected medical devices:
    a. The electronic transfer of medical device data;
    b. The electronic storage of medical device data;
    c. The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
    d. The electronic display of medical device data.

    Examples of MDDS include physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol.
2. Medical image storage device, defined as a device that provides electronic storage and retrieval functions for medical images. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.
3. Medical image communications device, defined as a device that provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, interfaces, and a communications protocol. [5]

Section 520(o)(1)(D) of the FD&C Act does not capture software functions intended to generate alarms or alerts or prioritize multi-patient displays, because these functions involve analysis or interpretation of laboratory test or other device data and results. For example, if a software function is intended to prioritize patients in an Intensive Care Unit based on their clinical status, then this function is intended to interpret or analyze device data, results, and findings and is, therefore, not excluded from the definition of device under section 520(o)(1)(D) of the FD&C Act. Similarly, software functions that analyze medical device data in order to provide a

[5] The identification statement of 21 CFR 892.2020 no longer meets the definition of a device as amended by the Cures Act. However, there are products regulated under § 892.2020 that continue to meet the definition of a device, according to the description in section 520(o)(1)(E) of the FD&C Act. FDA intends to issue separate guidance on section 520(o)(1)(E) of the FD&C Act.

notification or flag (e.g., that a parameter is out of range) are not excluded from the definition of device under subsection (D). However, FDA does not intend to enforce requirements under the FD&C Act and implementing regulations for these low risk software functions, such as the analysis of data to provide a notification, for which immediate clinical action is not needed. FDA intends to focus its regulatory oversight on software functions intended to generate alarms or alerts or prioritize multi-patient displays if they are intended to alert a caregiver to take an immediate clinical action.

The MDDS Guidance will be revised to clarify that products that are solely intended to transfer, store, convert formats, and display medical device data and results, including medical images, waveforms, signals, or other clinical information are not devices and thus are not subject to FDA regulatory requirements, whether or not the use is for immediate clinical action. Accordingly, the definition of MDDS will be revised in that guidance to the definition in item 1 above. The discussion and examples of devices that are used for immediate clinical action (active patient monitoring) will be revised:

- *Examples of devices that provide active patient monitoring* will be revised to *Examples of devices that analyze or interpret laboratory test or other device data that are the focus of FDA's regulatory oversight*
    - A nurse telemetry station that analyzes or interprets information from a bedside hospital monitor in an ICU in order to produce alarms or notifications.
    - A device that generates alarms or alerts from a monitoring device in a home setting and is intended to alert a caregiver to take an immediate clinical action.
- *Examples of devices that perform monitoring but are not considered to perform "active patient monitoring"* will be revised to *Examples of products that transfer, store, convert formats, or display medical device data and are not devices*

In the MMA Guidance, the following example will be revised and moved from Section V.A. (Subset of mobile apps that are the focus of FDA's regulatory oversight) to Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion):

- *Examples of displays of patient-specific medical device data include:* display of medical images directly from a Picture Archiving and Communication System (PACS) server and remote display of data from bedside monitors (note that software functions that analyze or interpret medical device data to generate alarms or alerts that are intended to be relied upon in deciding to take immediate clinical action, are subject to regulations associated with such devices)
    - The parenthetical note in this example has been changed from "note that mobile medical apps that display medical device data to generate alarms or alerts that are intended to be relied upon in deciding to take immediate clinical action, are subject to regulations associated with such devices" to the text above, because software functions that merely display medical device data are not medical devices. Software functions that analyze or interpret medical device data are medical devices and subject to FDA's regulatory oversight.

And the following example will be added to Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) of the MMA Guidance:

- Software tools that analyze stored clinical information to flag patient results based on specific clinical parameters (e.g., out of range results, potential drug interactions, opportunities for complementary tests, create disease registries, summarize patient-specific information in an integrated report, and/or track a patient's treatment or disease outcome) provided that the analysis performed by these software is not intended for immediate clinical action and does not represent a unique interpretation function but rather summarizes standard interpretation of individual variables that healthcare practitioners could do themselves.

In the MMA Guidance, the following examples will be moved from Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) to Appendix A (Examples of Mobile Apps that are Not Medical Devices):

- Mobile apps or software functions that are intended for transferring, storing, converting formats or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results and findings.
  - Mobile apps that transfer, store, convert formats, and display medical device data without modifying the data and do not control or alter the functions or parameters of any connected medical device (i.e., mobile apps that meet the definition of MDDS).
  - Mobile apps that meet the definition of MDDS and connect to a nursing central station and display medical device data to a physician's mobile platform for review.
  - Mobile apps that are not intended for diagnostic image review such as image display for multidisciplinary patient management meetings (e.g., rounds) or patient consultation (and include a persistent on-screen notice, such as "for informational purposes only and not intended for diagnostic use").

And the following example of a software function and its associated text in Section V.B. of the MMA Guidance is no a longer device pursuant to section 520(o)(1)(D) of the FD&C Act and will be moved to Appendix A (Examples of Mobile Apps that are Not Medical Devices) of that guidance:

- Mobile apps that meet the definition of Medical Device Data Systems

The Guidance for the Submission of Premarket Notifications for Medical Image Management Devices will be withdrawn, because some software functions described in that guidance no longer meet the definition of a device, as amended. For the limited subset of Medical Image Management Devices that continue to meet the definition of a device and continue to require a 510(k) submission, the information provided in that document, which was written in 2000, is out of date. CDRH encourages manufacturers to reference the most recent FDA-recognized versions of relevant voluntary consensus standards instead.

Public Law 114–255
114th Congress

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

Dec. 13, 2016
[H.R. 34]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

21st Century Cures Act.
42 USC 201 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

DIVISION A—21ST CENTURY CURES

21st Century Cures Act.

SEC. 1000. SHORT TITLE.

42 USC 201 note.

This Division may be cited as the "21st Century Cures Act".

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE

SEC. 1001. BEAU BIDEN CANCER MOONSHOT AND NIH INNOVATION PROJECTS.

(a) IN GENERAL.—The Director of the National Institutes of Health (referred to in this section as the "Director of NIH") shall use any funds appropriated pursuant to the authorization of appropriations in subsection (b)(3) to carry out the National Institutes of Health innovation projects described in subsection (b)(4) (referred to in this section as the "NIH Innovation Projects").

(b) NATIONAL INSTITUTES OF HEALTH INNOVATION ACCOUNT.—

(1) ESTABLISHMENT OF NIH INNOVATION ACCOUNT.—There is established in the Treasury an account, to be known as the "NIH Innovation Account" (referred to in this subsection as the "Account"), for purposes of carrying out the NIH Innovation Projects described in paragraph (4).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—

(A) IN GENERAL.—The following amounts shall be transferred to the Account from the general fund of the Treasury:

(i) For fiscal year 2017, $352,000,000.
(ii) For fiscal year 2018, $496,000,000.
(iii) For fiscal year 2019, $711,000,000.
(iv) For fiscal year 2020, $492,000,000.
(v) For fiscal year 2021, $404,000,000.
(vi) For fiscal year 2022, $496,000,000.
(vii) For fiscal year 2023, $1,085,000,000.
(viii) For fiscal year 2024, $407,000,000.
(ix) For fiscal year 2025, $127,000,000.
(x) For fiscal year 2026, $226,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2017 through 2026, there is authorized

to be appropriated from the Account to the Director of NIH, for the purpose of carrying out the NIH Innovation Projects, an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2017 through 2026, for any discretionary appropriation under the heading "NIH Innovation Account" provided to the Director of NIH pursuant to the authorization of appropriations under subparagraph (A) for the purpose of carrying out the NIH Innovation Projects, the total amount of such appropriations for the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(4) NIH INNOVATION PROJECTS.—NIH Innovation Projects authorized to be funded under this section shall consist of the following and, of the total amounts authorized to be appropriated under paragraph (3), there are authorized to be appropriated to each such project a total amount not to exceed the following, over the period of fiscal years 2017 through 2026:

(A) For the Precision Medicine Initiative, including for the advancement of a cohort of individuals to support the goals of the Precision Medicine Initiative, not to exceed a total of $1,455,000,000, as follows:

(i) For fiscal year 2017, $40,000,000.
(ii) For fiscal year 2018, $100,000,000.
(iii) For fiscal year 2019, $186,000,000.
(iv) For fiscal year 2020, $149,000,000.
(v) For fiscal year 2021, $109,000,000.
(vi) For fiscal year 2022, $150,000,000.
(vii) For fiscal year 2023, $419,000,000.
(viii) For fiscal year 2024, $235,000,000.
(ix) For fiscal year 2025, $36,000,000.
(x) For fiscal year 2026, $31,000,000.

(B) For the Brain Research through Advancing Innovative Neurotechnologies Initiative (known as the "BRAIN Initiative"), not to exceed a total of $1,511,000,000, as follows:

(i) For fiscal year 2017, $10,000,000.
(ii) For fiscal year 2018, $86,000,000.
(iii) For fiscal year 2019, $115,000,000.
(iv) For fiscal year 2020, $140,000,000.
(v) For fiscal year 2021, $100,000,000.
(vi) For fiscal year 2022, $152,000,000.
(vii) For fiscal year 2023, $450,000,000.
(viii) For fiscal year 2024, $172,000,000.
(ix) For fiscal year 2025, $91,000,000.
(x) For fiscal year 2026, $195,000,000.

(C) To support cancer research, such as the development of cancer vaccines, the development of more sensitive

diagnostic tests for cancer, immunotherapy and the development of combination therapies, and research that has the potential to transform the scientific field, that has inherently higher risk, and that seeks to address major challenges related to cancer, not to exceed a total of $1,800,000,000, as follows:

(i) For fiscal year 2017, $300,000,000.
(ii) For fiscal year 2018, $300,000,000.
(iii) For fiscal year 2019, $400,000,000.
(iv) For fiscal year 2020, $195,000,000.
(v) For fiscal year 2021, $195,000,000.
(vi) For fiscal year 2022, $194,000,000.
(vii) For fiscal year 2023, $216,000,000.

(D) For the National Institutes of Health, in coordination with the Food and Drug Administration, to award grants and contracts for clinical research to further the field of regenerative medicine using adult stem cells, including autologous stem cells, for which grants and contracts shall be contingent upon the recipient making available non-Federal contributions toward the costs of such research in an amount not less than $1 for each $1 of Federal funds provided in the award, not to exceed a total of $30,000,000, as follows:

(i) For fiscal year 2017, $2,000,000.
(ii) For each of fiscal years 2018 and 2019, $10,000,000.
(iii) For fiscal year 2020, $8,000,000.
(iv) For each of fiscal years 2021 through 2026, $0.

(c) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Director of NIH shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a work plan including the proposed allocation of funds authorized to be appropriated pursuant to subsection (b)(3) for each of fiscal years 2017 through 2026 for the NIH Innovation Projects and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

(i) recommendations from the Advisory Committee described in subparagraph (C);

(ii) the amount of money to be obligated or expended in each fiscal year for each NIH Innovation Project;

(iii) a description and justification of each such project; and

(iv) a description of how each such project supports the strategic research priorities identified in the NIH Strategic Plan under subsection (m) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by section 2031.

(C) RECOMMENDATIONS.—Prior to submitting the work plan under this paragraph, the Director of NIH shall seek recommendations from the Advisory Committee to the Director of NIH appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a) on—

(i) the allocations of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2026; and

(ii) on the contents of the proposed work plan.

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2018 through 2027, the Director of NIH shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report including—

(i) the amount of money obligated or expended in the prior fiscal year for each NIH Innovation Project;

(ii) a description of any such project using funds provided pursuant to the authorization of appropriations under subsection (b)(3); and

(iii) whether such projects are advancing the strategic research priorities identified in the NIH Strategic Plan under subsection (m) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by section 2031.

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Director of NIH shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the NIH Innovation Projects.

(d) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act, any funds made available pursuant to the authorization of appropriations under subsection (b)(3) may not be used for any purpose other than a NIH Innovation Project.

(e) SUNSET.—This section shall expire on September 30, 2026.

SEC. 1002. FDA INNOVATION PROJECTS.

(a) IN GENERAL.—The Commissioner of Food and Drugs (referred to in this section as the "Commissioner") shall use any funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) to carry out the activities described in subsection (b)(4).

(b) FDA INNOVATION ACCOUNT.—

(1) ESTABLISHMENT OF FDA INNOVATION ACCOUNT.—There is established in the Treasury an account, to be known as the "FDA Innovation Account" (referred to in this subsection as the "Account"), for purposes of carrying out the activities described in paragraph (4).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—

(A) IN GENERAL.—For each of fiscal years 2017 through 2025, the following amounts shall be transferred to the Account from the general fund of the Treasury:

(i) For fiscal year 2017, $20,000,000.
(ii) For fiscal year 2018, $60,000,000.
(iii) For fiscal year 2019, $70,000,000.
(iv) For fiscal year 2020, $75,000,000.
(v) For fiscal year 2021, $70,000,000.
(vi) For fiscal year 2022, $50,000,000.
(vii) For fiscal year 2023, $50,000,000.
(viii) For fiscal year 2024, $50,000,000.
(ix) For fiscal year 2025, $55,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2017 through 2025, there is authorized to be appropriated from the Account to the Commissioner, for the purpose of carrying out the activities described in paragraph (5), an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2017 through 2025, for any discretionary appropriation under the heading "FDA Innovation Account" provided to the Commissioner pursuant to the authorization of appropriations under subparagraph (A) for the purpose of carrying out the projects activities described in paragraph (4), the total amount of such appropriations in the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(4) FDA ACTIVITIES.—The activities authorized to be funded under this section are the activities under subtitles A through F (including the amendments made by such subtitles) of title III of this Act and section 1014 of the Federal Food, Drug, and Cosmetic Act, as added by section 3073 of this Act.

(c) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a work plan including the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2025 and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

(i) recommendations from the Advisory Committee described in subparagraph (C);

(ii) the amount of money to be obligated or expended in each fiscal year for each activity described in subsection (b)(4); and

(iii) a description and justification of each such project activity.

(C) RECOMMENDATIONS.—Prior to submitting the work plan under this paragraph, the Commissioner shall seek recommendations from the Science Board to the Food and Drug Administration, on the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2025 and on the contents of the proposed work plan.

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2018 through 2026, the Commissioner shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report including—

(i) the amount of money obligated or expended in the prior fiscal year for each activity described in subsection (b)(4);

(ii) a description of all such activities using funds provided pursuant to the authorization of appropriations under subsection (b)(3); and

(iii) how the activities are advancing public health.

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Commissioner shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the activities undertaken with such funding.

(d) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act, any funds made available pursuant to the authorization of appropriations in subsection (b)(3) shall not be used for any purpose other than an activity described in subsection (b)(4).

(e) SUNSET.—This section shall expire on September 30, 2025.

42 USC 290ee–3 note.

SEC. 1003. ACCOUNT FOR THE STATE RESPONSE TO THE OPIOID ABUSE CRISIS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall use any funds appropriated pursuant to the authorization of appropriations under subsection (b) to carry out the grant program described in subsection (c) for purposes of addressing the opioid abuse crisis within the States.

(b) ACCOUNT FOR THE STATE RESPONSE TO THE OPIOID ABUSE CRISIS.—

(1) ESTABLISHMENT.—There is established in the Treasury an account, to be known as the "Account For the State Response to the Opioid Abuse Crisis" (referred to in this subsection as the "Account"), to carry out the opioid grant program described in subsection (c).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—

(A) IN GENERAL.—The following amounts shall be transferred to the Account from the general fund of the Treasury:

(i) For fiscal year 2017, $500,000,000.

(ii) For fiscal year 2018, $500,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—In each of the fiscal years 2017 and 2018, there is authorized to be appropriated from the Account to the Secretary, for the grant program described in subsection (c), an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—In each of fiscal years 2017 and 2018, for any discretionary appropriation under the heading "Account For the State Response to the Opioid Abuse Crisis" for the grant program described in subsection (c), the total amount of such appropriations in the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(c) OPIOID GRANT PROGRAM.—

(1) STATE RESPONSE TO THE OPIOID ABUSE CRISIS.—Subject to the availability of appropriations, the Secretary shall award grants to States for the purpose of addressing the opioid abuse crisis within such States, in accordance with subparagraph (B). In awarding such grants, the Secretary shall give preference to States with an incidence or prevalence of opioid use disorders that is substantially higher relative to other States.

(2) OPIOID GRANTS.—Grants awarded to a State under this subsection shall be used for carrying out activities that supplement activities pertaining to opioids undertaken by the State agency responsible for administering the substance abuse prevention and treatment block grant under subpart II of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–21 et seq.), which may include public health-related activities such as the following:

(A) Improving State prescription drug monitoring programs.

(B) Implementing prevention activities, and evaluating such activities to identify effective strategies to prevent opioid abuse.

(C) Training for health care practitioners, such as best practices for prescribing opioids, pain management, recognizing potential cases of substance abuse, referral of patients to treatment programs, and overdose prevention.

(D) Supporting access to health care services, including those services provided by Federally certified opioid treatment programs or other appropriate health care providers to treat substance use disorders.

(E) Other public health-related activities, as the State determines appropriate, related to addressing the opioid abuse crisis within the State.

(d) ACCOUNTABILITY AND OVERSIGHT.—A State receiving a grant under subsection (c) shall include in a report related to substance abuse submitted to the Secretary pursuant to section 1942 of the Public Health Service Act (42 U.S.C. 300x–52), a description of—

(1) the purposes for which the grant funds received by the State under such subsection for the preceding fiscal year were expended and a description of the activities of the State under the program; and

(2) the ultimate recipients of amounts provided to the State in the grant.

(e) LIMITATIONS.—Any funds made available pursuant to the authorization of appropriations under subsection (b)—

(1) notwithstanding any transfer authority in any appropriations Act, shall not be used for any purpose other than the grant program in subsection (c); and

(2) shall be subject to the same requirements as substance abuse prevention and treatment programs under titles V and XIX of the Public Health Service Act (42 U.S.C. 290aa et seq., 300w et seq.).

(f) SUNSET.—This section shall expire on September 30, 2026.

SEC. 1004. BUDGETARY TREATMENT.

(a) STATUTORY PAYGO SCORECARDS.—The budgetary effects of division A of this Act shall not be entered on either PAYGO scorecard maintained pursuant to section 4(d) of the Statutory Pay-As-You-Go Act of 2010.

(b) SENATE PAYGO SCORECARDS.—The budgetary effects of division A of this Act shall not be entered on any PAYGO scorecard maintained for purposes of section 201 of S. Con. Res. 21 (110th Congress).

(c) RESERVATION OF SAVINGS.—None of the funds in the NIH Innovation Account, the FDA Innovation Account, or the Account For the State Response to the Opioid Abuse Crisis established by this title shall be made available except to the extent provided in advance in appropriations Acts, and legislation or an Act that rescinds or reduces amounts in such accounts shall not be estimated as a reduction in direct spending under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

SEC. 2001. NATIONAL INSTITUTES OF HEALTH REAUTHORIZATION.

Section 402A(a)(1) of the Public Health Service Act (42 U.S.C. 282a(a)(1)) is amended—

(1) in subparagraph (B), by striking "and" at the end;

(2) in subparagraph (C), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following new subparagraphs:

"(D) $34,851,000,000 for fiscal year 2018;

"(E) $35,585,871,000 for fiscal year 2019; and

"(F) $36,472,442,775 for fiscal year 2020.".

SEC. 2002. EUREKA PRIZE COMPETITIONS. 42 USC 283q.

(a) IN GENERAL.—Pursuant to the authorities and processes established under section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719), the Director of the National Institutes of Health shall support prize competitions for one or both of the following goals:

(1) Identifying and funding areas of biomedical science that could realize significant advancements through a prize competition.

(2) Improving health outcomes, particularly with respect to human diseases and conditions—

(A) for which public and private investment in research is disproportionately small relative to Federal Government expenditures on prevention and treatment activities with respect to such diseases and conditions, such that Federal expenditures on health programs would be reduced;

(B) that are serious and represent a significant disease burden in the United States; or

(C) for which there is potential for significant return on investment to the United States.

(b) TRACKING; REPORTING.—The Director of the National Institutes of Health shall—

(1) collect information on—

(A) the effect of innovations funded through the prize competitions under this section in advancing biomedical science or improving health outcomes pursuant to subsection (a); and

(B) the effect of the innovations on Federal expenditures; and

(2) include the information collected under paragraph (1) in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032).

Subtitle B—Advancing Precision Medicine

SEC. 2011. PRECISION MEDICINE INITIATIVE. 42 USC 289g–5.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by adding at the end the following:

"SEC. 498E. PRECISION MEDICINE INITIATIVE.

"(a) IN GENERAL.—The Secretary is encouraged to establish and carry out an initiative, to be known as the 'Precision Medicine Initiative' (in this section referred to as the 'Initiative'), to augment efforts to address disease prevention, diagnosis, and treatment.

"(b) COMPONENTS.—The Initiative described under subsection (a) may include—

"(1) developing a network of scientists to assist in carrying out the purposes of the Initiative;

"(2) developing new approaches for addressing scientific, medical, public health, and regulatory science issues;

"(3) applying genomic technologies, such as whole genomic sequencing, to provide data on the molecular basis of disease;

"(4) collecting information voluntarily provided by a diverse cohort of individuals that can be used to better understand health and disease; and

"(5) other activities to advance the goals of the Initiative, as the Secretary determines appropriate.

"(c) AUTHORITY OF THE SECRETARY.—In carrying out this section, the Secretary may—

"(1) coordinate with the Secretary of Energy, private industry, and others, as the Secretary determines appropriate, to identify and address the advanced supercomputing and other advanced technology needs for the Initiative;

"(2) develop and utilize public-private partnerships; and

"(3) leverage existing data sources.

"(d) REQUIREMENTS.—In the implementation of the Initiative under subsection (a), the Secretary shall—

"(1) ensure the collaboration of the National Institutes of Health, the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the Office for Civil Rights of the Department of Health and Human Services;

"(2) comply with existing laws and regulations for the protection of human subjects involved in research, including the protection of participant privacy;

"(3) implement policies and mechanisms for appropriate secure data sharing across systems that include protections for privacy and security of data;

"(4) consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities;

"(5) ensure that only authorized individuals may access controlled or sensitive, identifiable biological material and associated information collected or stored in connection with the Initiative; and

"(6) on the appropriate Internet website of the Department of Health and Human Services, identify any entities with access to such information and provide information with respect to the purpose of such access, a summary of the research project for which such access is granted, as applicable, and a description of the biological material and associated information to which the entity has access.

"(e) REPORT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report

on the relevant data access policies and procedures to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such report shall include steps the Secretary has taken to consult with experts or other heads of departments or agencies of the Federal Government in the development of such policies.".

SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH SUBJECTS.

(a) IN GENERAL.—Subsection (d) of section 301 of the Public Health Service Act (42 U.S.C. 241) is amended to read as follows:

"(d)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

"(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

"(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

"(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

"(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

"(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

"(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

"(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

"(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

"(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).

"(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used

for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

"(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

"(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

"(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.

"(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research.

"(4) For purposes of this subsection, the term 'identifiable, sensitive information' means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—

"(A) through which an individual is identified; or

"(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.".

42 USC 241 note.

(b) APPLICABILITY.—Beginning 180 days after the date of enactment of this Act, all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act).

SEC. 2013. PROTECTION OF IDENTIFIABLE AND SENSITIVE INFORMATION.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

"(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code, biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—

"(A) an individual is identified; or

"(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

"(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

"(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

"(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.".

SEC. 2014. DATA SHARING.

(a) IN GENERAL.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (23), by striking "and" at the end;

(2) in paragraph (24), by striking the period and inserting "; and"; and

(3) by inserting after paragraph (24) the following:

"(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

"(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

"(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient.".

(b) CONFIDENTIALITY.—Nothing in the amendments made by subsection (a) authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, or be construed to require recipients of grants or cooperative agreements through the National Institutes of Health to share such information. 42 USC 282 note.

Subtitle C—Supporting Young Emerging Scientists

SEC. 2021. INVESTING IN THE NEXT GENERATION OF RESEARCHERS.

(a) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

"SEC. 404M. NEXT GENERATION OF RESEARCHERS. 42 USC 283o.

"(a) NEXT GENERATION OF RESEARCHERS INITIATIVE.—There shall be established within the Office of the Director of the National Institutes of Health, the Next Generation of Researchers Initiative (referred to in this section as the 'Initiative'), through which the Director shall coordinate all policies and programs within the National Institutes of Health that are focused on promoting and providing opportunities for new researchers and earlier research independence.

"(b) ACTIVITIES.—The Director of the National Institutes of Health, through the Initiative shall—

"(1) promote policies and programs within the National Institutes of Health that are focused on improving opportunities for new researchers and promoting earlier research independence, including existing policies and programs, as appropriate;

"(2) develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity;

"(3) coordinate, as appropriate, with relevant agencies, professional and academic associations, academic institutions, and others, to improve and update existing information on the biomedical research workforce in order to inform programs related to the training, recruitment, and retention of biomedical researchers; and

"(4) carry out other activities, including evaluation and oversight of existing programs, as appropriate, to promote the development of the next generation of researchers and earlier research independence.".

(b) CONSIDERATION OF RECOMMENDATIONS.—In carrying out activities under section 404M(b) of the Public Health Service Act, the Director of the National Institutes of Health shall take into consideration the recommendations made by the National Academies of Sciences, Engineering, and Medicine as part of the comprehensive study on policies affecting the next generation of researchers under the Department of Health and Human Services Appropriations Act, 2016 (Public Law 114–113), and submit a report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, with respect to any actions taken by the National Institutes of Health based on the recommendations not later than 2 years after the completion of the study required pursuant to the Department of Health and Human Services Appropriations Act, 2016.

SEC. 2022. IMPROVEMENT OF LOAN REPAYMENT PROGRAM.

(a) INTRAMURAL LOAN REPAYMENT PROGRAM.—Section 487A of the Public Health Service Act (42 U.S.C. 288–1) is amended—

(1) by amending the section heading to read as follows: "**INTRAMURAL LOAN REPAYMENT PROGRAM**";

(2) in subsection (a)—

(A) by striking "The Secretary shall carry out a program" and inserting "The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2))";

(B) by striking "conduct" and inserting "conduct research";

(C) by striking "research with respect to acquired immune deficiency syndrome"; and

(D) by striking "$35,000" and inserting "$50,000";

(3) by redesignating subsection (b) as subsection (d);

(4) by inserting after subsection (a), the following:

"(b) SUBCATEGORIES OF RESEARCH.—

"(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

"(A) shall continue to focus on—

"(i) general research;

"(ii) research on acquired immune deficiency syndrome; and

"(iii) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

"(B) may focus on an area of emerging scientific or workforce need.

"(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

"(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director)."; and

(5) by adding at the end the following:

"(e) AVAILABILITY OF APPROPRIATIONS.—Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts are made available.".

(b) EXTRAMURAL LOAN REPAYMENT PROGRAM.—Section 487B of the Public Health Service Act (42 U.S.C. 288–2) is amended—

(1) by amending the section heading to read as follows: "**EXTRAMURAL LOAN REPAYMENT PROGRAM**";

(2) in subsection (a)—

(A) by striking "The Secretary, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, shall establish a program" and inserting "IN GENERAL.—The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2)),";

(B) by striking "(including graduate students)";

(C) by striking "with respect to contraception, or with respect to infertility,"; and

(D) by striking "service, not more than $35,000" and inserting "research, not more than $50,000";

(3) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively;

(4) by inserting after subsection (a), the following:

"(b) SUBCATEGORIES OF RESEARCH.—

"(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

"(A) shall continue to focus on—

"(i) contraception or infertility research;

"(ii) pediatric research, including pediatric pharmacological research;

"(iii) minority health disparities research;

"(iv) clinical research; and

"(v) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

"(B) may focus on an area of emerging scientific or workforce need.

"(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

"(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).";

(5) in subsection (d) (as so redesignated), by striking "The provisions" and inserting "APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—The provisions"; and

(6) in subsection (e) (as so redesignated), by striking "Amounts" and inserting "AVAILABILITY OF APPROPRIATIONS.—Amounts".

(c) TECHNICAL AND CONFORMING AMENDMENTS.—Title IV of the Public Health Service Act is amended—

(1) by striking section 464z–5 (42 U.S.C. 285t–2);

(2) by striking section 487C (42 U.S.C. 288–3);

(3) by striking section 487E (42 U.S.C. 288–5);

(4) by striking section 487F (42 U.S.C. 288–5a), as added by section 205 of Public Law 106–505, relating to loan repayment for clinical researchers; and

(5) by striking section 487F (42 U.S.C. 288–6), as added by section 1002(b) of Public Law 106–310 relating to pediatric research loan repayment.

(d) GAO REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the efforts of the National Institutes of Health to attract, retain, and develop emerging scientists, including underrepresented individuals in the sciences, such as women, racial and ethnic minorities, and other groups. Such report shall include an analysis of the impact of the additional authority provided to the Secretary of Health and Human Services under this Act to address workforce shortages and gaps in priority research areas, including which centers and research areas offered loan repayment program participants the increased award amount.

Subtitle D—National Institutes of Health Planning and Administration

SEC. 2031. NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.

(a) STRATEGIC PLAN.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) in subsection (b)(5), by inserting before the semicolon the following: ", and through the development, implementation,

and updating of the strategic plan developed under subsection (m)"; and

(2) by adding at the end the following:

"(m) NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, and at least every 6 years thereafter, the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the 'National Institutes of Health Strategic Plan') to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

"(2) REQUIREMENTS.—The strategy under paragraph (1) shall—

"(A) identify strategic research priorities and objectives across biomedical research, including—

"(i) an assessment of the state of biomedical and behavioral research, including areas of opportunity with respect to basic, clinical, and translational research;

"(ii) priorities and objectives to advance the treatment, cure, and prevention of health conditions;

"(iii) emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps; and

"(iv) the identification of near-, mid-, and long-term scientific needs;

"(B) consider, in carrying out subparagraph (A)—

"(i) disease burden in the United States and the potential for return on investment to the United States;

"(ii) rare diseases and conditions;

"(iii) biological, social, and other determinants of health that contribute to health disparities; and

"(iv) other factors the Director of National Institutes of Health determines appropriate;

"(C) include multi-institute priorities, including coordination of research among institutes and centers;

"(D) include strategic priorities for funding research through the Common Fund, in accordance with section 402A(c)(1)(C);

"(E) address the National Institutes of Health's proposed and ongoing activities related to training and the biomedical workforce; and

"(F) describe opportunities for collaboration with other agencies and departments, as appropriate.

"(3) USE OF PLANS.—Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.

"(4) CONSULTATION.—The Director of National Institutes of Health shall develop the strategic plan under paragraph (1) in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.".

(b) CONFORMING AMENDMENT.—Section 402A(c)(1)(C) of the Public Health Service Act (42 U.S.C. 282a(c)(1)(C)) is amended by striking "Not later than June 1, 2007, and every 2 years thereafter," and inserting "As part of the National Institutes of Health Strategic Plan required under section 402(m),".

(c) STRATEGIC PLAN.—Section 492B(a) of the Public Health Service Act (42 U.S.C. 289a–2(a)) is amended by adding at the end the following:

"(3) STRATEGIC PLANNING.—

"(A) IN GENERAL.—The directors of the national institutes and national centers shall consult at least once annually with the Director of the National Institute on Minority Health and Health Disparities and the Director of the Office of Research on Women's Health regarding objectives of the national institutes and national centers to ensure that future activities by such institutes and centers take into account women and minorities and are focused on reducing health disparities.

"(B) STRATEGIC PLANS.—Any strategic plan issued by a national institute or national center shall include details on the objectives described in subparagraph (A).".

SEC. 2032. TRIENNIAL REPORTS.

Section 403 of the Public Health Service Act (42 U.S.C. 283) is amended—

(1) in the section heading, by striking "**BIENNIAL**" and inserting "**TRIENNIAL**" ; and

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "biennial" and inserting "triennial";

(B) by amending paragraph (3) to read as follows:

"(3) A description of intra-National Institutes of Health activities, including—

"(A) identification of the percentage of funds made available by each national research institute and national center with respect to each applicable fiscal year for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

"(B) recommendations for promoting coordination of information among the centers of excellence.";

(C) in paragraph (4)—

(i) in subparagraph (B), by striking "demographic variables and other variables" and inserting "demographic variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health,"; and

(ii) in subparagraph (C)(v)—

(I) by striking "demographic variables and such" and inserting "demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each

national research institute and national center to the Director of National Institutes of Health under section 492B(f), and such"; and

(II) by striking "(regarding inclusion of women and minorities in clinical research)" and inserting "and other applicable requirements regarding inclusion of demographic groups"; and

(D) in paragraph (6)—

(i) in the matter preceding subparagraph (A), by striking "the following:" and inserting "the following—";

(ii) in subparagraph (A)—

(I) by striking "An evaluation" and inserting "an evaluation"; and

(II) by striking the period and inserting "; and";

(iii) by striking subparagraphs (B) and (D);

(iv) by redesignating subparagraph (C) as subparagraph (B); and

(v) in subparagraph (B), as redesignated by clause (iv), by striking "Recommendations" and inserting "recommendations".

SEC. 2033. INCREASING ACCOUNTABILITY AT THE NATIONAL INSTITUTES OF HEALTH.

(a) APPOINTMENT AND TERMS OF DIRECTORS OF NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.—Subsection (a) of section 405 of the Public Health Service Act (42 U.S.C. 284) is amended to read as follows:

"(a) APPOINTMENT.—

"(1) IN GENERAL.—The Director of the National Cancer Institute shall be appointed by the President, and the Directors of the other national research institutes and national centers shall be appointed by the Secretary, acting through the Director of National Institutes of Health. Each Director of a national research institute or national center shall report directly to the Director of National Institutes of Health.

"(2) APPOINTMENT.—

"(A) TERM.—A Director of a national research institute or national center who is appointed by the Secretary, acting through the Director of National Institutes of Health, shall be appointed for 5 years.

"(B) REAPPOINTMENT.—At the end of the term of a Director of a national research institute or national center, the Director may be reappointed in accordance with standards applicable to the relevant appointment mechanism. There shall be no limit on the number of terms that a Director may serve.

"(C) VACANCIES.—If the office of a Director of a national research institute or national center becomes vacant before the end of such Director's term, the Director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

"(D) CURRENT DIRECTORS.—Each Director of a national research institute or national center who is serving on the date of enactment of the 21st Century Cures Act shall

be deemed to be appointed for a 5-year term under this subsection beginning on such date of enactment.

"(E) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Secretary or the Director of National Institutes of Health to terminate the appointment of a director referred to in subparagraph (A) before the expiration of such director's 5-year term.

"(F) NATURE OF APPOINTMENT.—Appointments and reappointments under this subsection shall be made on the basis of ability and experience as it relates to the mission of the National Institutes of Health and its components, including compliance with any legal requirement that the Secretary or Director of National Institutes of Health determines relevant.

"(3) NONAPPLICATION OF CERTAIN PROVISION.—The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to Directors appointed under this subsection.".

(b) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—Section 405(b) of the Public Health Service Act (42 U.S.C. 284(b)) is amended by adding at the end the following:

"(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an 'R-series grant'), other than an award constituting a noncompetitive renewal of such a grant, or a noncompetitive administrative supplement to such a grant, the Director of such national research institute or national center shall, consistent with the peer review process—

"(A) review and make the final decision with respect to making the award; and

"(B) take into consideration, as appropriate—

"(i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 402(m);

"(ii) programs or projects funded by other agencies on similar research topics; and

"(iii) advice by staff and the advisory council or board of such national research institute or national center.".

(c) REPORT ON DUPLICATION IN FEDERAL BIOMEDICAL RESEARCH.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), shall, not later than 2 years after the date of enactment of this Act, submit a report to Congress on efforts to prevent and eliminate duplicative biomedical research that is not necessary for scientific purposes. Such report shall—

(1) describe the procedures in place to identify such duplicative research, including procedures for monitoring research applications and funded research awards to prevent unnecessary duplication;

(2) describe the steps taken to improve the procedures described in paragraph (1), in response to relevant recommendations made by the Comptroller General of the United States;

(3) describe how the Secretary operationally distinguishes necessary and appropriate scientific replication from unnecessary duplication; and

(4) provide examples of instances where the Secretary has identified unnecessarily duplicative research and the steps taken to eliminate the unnecessary duplication.

SEC. 2034. REDUCING ADMINISTRATIVE BURDEN FOR RESEARCHERS.

42 USC 3501 note.

(a) PLAN PREPARATION AND IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall—

(A) lead a review by research funding agencies of all regulations and policies related to the disclosure of financial conflicts of interest, including the minimum threshold for reporting financial conflicts of interest;

(B) make revisions, as appropriate, to harmonize existing policies and reduce administrative burden on researchers while maintaining the integrity and credibility of research findings and protections of human participants; and

(C) confer with the Office of the Inspector General about the activities of such office related to financial conflicts of interest involving research funding agencies.

(2) CONSIDERATIONS.—In updating policies under paragraph (1)(B), the Secretary shall consider—

(A) modifying the timelines for the reporting of financial conflicts of interest to just-in-time information by institutions receiving grant or cooperative agreement funding from the National Institutes of Health;

(B) ensuring that financial interest disclosure reporting requirements are appropriate for, and relevant to, awards that will directly fund research, which may include modification of the definition of the term "investigator" for purposes of the regulations and policies described in subparagraphs (A) and (B) of paragraph (1); and

(C) updating any applicable training modules of the National Institutes of Health related to Federal financial interest disclosure.

(b) MONITORING OF SUBRECIPIENTS OF FUNDING FROM THE NATIONAL INSTITUTES OF HEALTH.—The Director of the National Institutes of Health (referred to in this section as the "Director of National Institutes of Health") shall implement measures to reduce the administrative burdens related to monitoring of subrecipients of grants by primary awardees of funding from the National Institutes of Health, which may incorporate findings and recommendations from existing and ongoing activities. Such measures may include, as appropriate—

(1) an exemption from subrecipient monitoring requirements, upon request from the primary awardees, provided that—

(A) the subrecipient is subject to Federal audit requirements pursuant to the Uniform Guidance of the Office of Management and Budget;

(B) the primary awardee conducts, pursuant to guidance of the National Institutes of Health, a pre-award

evaluation of each subrecipient's risk of noncompliance with Federal statutes and regulations, the conditions of the subaward, and any recurring audit findings; and

(C) such exemption does not absolve the primary awardee of liability for misconduct by subrecipients; and

(2) the implementation of alternative grant structures that obviate the need for subrecipient monitoring, which may include collaborative grant models allowing for multiple primary awardees.

(c) REPORTING OF FINANCIAL EXPENDITURES.—The Secretary, in consultation with the Director of National Institutes of Health, shall evaluate financial expenditure reporting procedures and requirements for recipients of funding from the National Institutes of Health and take action, as appropriate, to avoid duplication between department and agency procedures and requirements and minimize burden to funding recipients.

(d) ANIMAL CARE AND USE IN RESEARCH.—Not later than 2 years after the date of enactment of this Act, the Director of National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, shall complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. In carrying out this effort, the Director of the National Institutes of Health shall seek the input of experts, as appropriate. The Director of the National Institutes of Health shall—

(1) identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative, including with respect to inspection and review requirements by Federal agencies and accrediting associations;

(2) take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and

(3) take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

(e) DOCUMENTATION OF PERSONNEL EXPENSES.—The Secretary shall clarify the applicability of the requirements under the Office of Management and Budget Uniform Guidance for management and certification systems adopted by entities receiving Federal research grants through the Department of Health and Human Services regarding documentation of personnel expenses, including clarification of the extent to which any flexibility to such requirements specified in such Uniform Guidance applies to entities receiving grants through the Department of Health and Human Services.

(f) RESEARCH POLICY BOARD.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Director of the Office of Management and Budget shall establish an advisory committee, to be known as the "Research Policy Board" (referred to in this subsection as the "Board"), to provide Federal Government officials with information on the effects of regulations related to Federal research requirements.

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Board shall include not more than 10 Federal members, including each of the following Federal members or their designees:

(i) The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget.

(ii) The Director of the Office of Science and Technology Policy.

(iii) The Secretary of Health and Human Services.

(iv) The Director of the National Science Foundation.

(v) The secretaries and directors of other departments and agencies that support or regulate scientific research, as determined by the Director of the Office of Management and Budget.

(B) NON-FEDERAL MEMBERS.—The Board shall be comprised of not less than 9 and not more than 12 representatives of academic research institutions, other private, nonprofit research institutions, or other nonprofit organizations with relevant expertise. Such members shall be appointed by a formal process, to be established by the Director of the Office of Management and Budget, in consultation with the Federal membership, and that incorporates—

(i) nomination by members of the nonprofit scientific research community, including academic research institutions; and

(ii) procedures to fill membership positions vacated before the end of a member's term.

(3) PURPOSE AND RESPONSIBILITIES.—The Board shall make recommendations regarding the modification and harmonization of regulations and policies having similar purposes across research funding agencies to ensure that the administrative burden of such research policy and regulation is minimized to the greatest extent possible and consistent with maintaining responsible oversight of federally funded research. Activities of the Board may include—

(A) providing thorough and informed analysis of regulations and policies;

(B) identifying negative or adverse consequences of existing policies and making actionable recommendations regarding possible improvement of such policies;

(C) making recommendations with respect to efforts within the Federal Government to improve coordination of regulation and policy related to research;

(D) creating a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices; and

(E) conducting ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes.

(4) EXPERT SUBCOMMITTEES.—The Board may form temporary expert subcommittees, as appropriate, to develop timely analysis on pressing issues and assist the Board in anticipating future regulatory challenges, including challenges emerging from new scientific advances.

(5) REPORTING REQUIREMENTS.—Not later than 2 years after the date of enactment of this Act, and once thereafter, the Board shall submit a report to the Director of the Office of Management and Budget, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, the heads of relevant Federal departments and agencies, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives containing formal recommendations on the conceptualization, development, harmonization, and reconsideration of scientific research policy, including the regulatory benefits and burdens.

(6) SUNSET.—The Board shall terminate on September 30, 2021.

(7) GAO REPORT.—Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out by the Board pursuant to this subsection and submit to the appropriate committees of Congress a report regarding the results of the independent evaluation. Such report shall review and assess the Board's activities with respect to the responsibilities described in paragraph (3).

SEC. 2035. EXEMPTION FOR THE NATIONAL INSTITUTES OF HEALTH FROM THE PAPERWORK REDUCTION ACT REQUIREMENTS.

Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended by section 2013, is further amended by adding at the end the following:

"(g) Subchapter I of chapter 35 of title 44, United States Code, shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.".

SEC. 2036. HIGH-RISK, HIGH-REWARD RESEARCH.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282), as amended by section 2031, is further amended by adding at the end the following:

"(n) UNIQUE RESEARCH INITIATIVES.—

"(1) IN GENERAL.—The Director of NIH may approve, after consideration of a proposal under paragraph (2)(A), requests by the national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out—

"(A) the Precision Medicine Initiative under section 498E; or

"(B) section 402(b)(7), except that not more than 50 percent of the funds available for a fiscal year through the Common Fund under section 402A(c)(1) for purposes of carrying out such section 402(b)(7) may be used to engage in such other transactions.

"(2) REQUIREMENTS.—The authority provided under this subsection may be used to conduct or support high impact cutting-edge research described in paragraph (1) using the other transactions authority described in such paragraph if the institute, center, or office—

"(A) submits a proposal to the Director of NIH for the use of such authority before conducting or supporting the research, including why the use of such authority is essential to promoting the success of the project;

"(B) receives approval for the use of such authority from the Director of NIH; and

"(C) for each year in which the institute, center, or office has used such authority in accordance with this subsection, submits a report to the Director of NIH on the activities of the institute, center, or office relating to such research.".

(b) REPORT TO CONGRESS.—Not later than September 30, 2020, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct an evaluation of the activities under subsection (n) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by subsection (a), and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the results of such evaluation.

(c) DUTIES OF DIRECTORS OF INSTITUTES.—Section 405(b)(1) of the Public Health Service Act (42 U.S.C. 284(b)(1)) is amended—

(1) by redesignating subparagraphs (C) through (L) as subparagraphs (D) through (M), respectively; and

(2) by inserting after subparagraph (B), the following:

"(C) shall, as appropriate, conduct and support research that has the potential to transform the scientific field, has inherently higher risk, and that seeks to address major current challenges;".

SEC. 2037. NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.

(a) IN GENERAL.—Section 479(b) of the Public Health Service Act (42 U.S.C. 287(b)) is amended—

(1) in paragraph (1), by striking "phase IIA" and inserting "phase IIB"; and

(2) in paragraph (2)—

(A) in the matter preceding subparagraph (A), by striking "phase IIB" and inserting "phase III";

(B) in subparagraph (A), by striking "phase IIB" and inserting "phase III";

(C) in subparagraph (B), by striking "phase IIA" and inserting "phase IIB"; and

(D) in subparagraph (C), by striking "phase IIB" and inserting "phase III".

(b) INCREASED TRANSPARENCY.—Section 479 of the Public Health Service Act (42 U.S.C. 287) is amended—

(1) in subsection (c)—

(A) in paragraph (4)(D), by striking "and" at the end;

(B) in paragraph (5), by striking the period and inserting a semicolon; and

(C) by adding at the end the following:

"(6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and

"(7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews."; and

(2) by adding at the end the following:

"(d) INCLUSION OF LIST.—The first biennial report submitted under this section after the date of enactment of the 21st Century Cures Act shall include a complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

"(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.".

SEC. 2038. COLLABORATION AND COORDINATION TO ENHANCE RESEARCH.

(a) RESEARCH PRIORITIES; COLLABORATIVE RESEARCH PROJECTS.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) by amending paragraph (4) to read as follows:

"(4) shall assemble accurate data to be used to assess research priorities, including—

"(A) information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities; and

"(B) data on study populations of clinical research, funded by or conducted at each national research institute and national center, which—

"(i) specifies the inclusion of—

"(I) women;

"(II) members of minority groups;

"(III) relevant age categories, including pediatric subgroups; and

"(IV) other demographic variables as the Director of the National Institutes of Health determines appropriate;

"(ii) is disaggregated by research area, condition, and disease categories; and

"(iii) is to be made publicly available on the Internet website of the National Institutes of Health;"; and

(2) in paragraph (8)—

(A) in subparagraph (A), by striking "and" at the end; and

(B) by adding at the end the following:

"(C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—

"(i) conduct research involving human subjects; and

"(ii) collect similar data; and

"(D) encourage the collaboration described in subparagraph (C) to—

"(i) allow for an increase in the number of subjects studied; and

"(ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;".

(b) REPORTING.—Section 492B(f) of the Public Health Service Act (42 U.S.C. 289a–2(f)) is amended—

(1) by striking "biennial" each place such term appears and inserting "triennial";

(2) by striking "The advisory council" and inserting the following:

"(1) IN GENERAL.—The advisory council"; and

(3) by adding at the end the following:

"(2) CONTENTS.—Each triennial report prepared by an advisory council of each national research institute as described in paragraph (1) shall include each of the following:

"(A) The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

"(B) The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.

"(C) For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—

"(i) have been completed during such reporting period; and

"(ii) are being carried out during such reporting period and have not been completed.

"(D) The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with subsection (c)(2)(A).".

(c) COORDINATION.—Section 486(c)(2) of the Public Health Service Act (42 U.S.C. 287d(c)(2)) is amended by striking "designees" and inserting "senior-level staff designees".

(d) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 2021, is further amended by adding at the end the following:

"SEC. 404N. POPULATION FOCUSED RESEARCH. 42 USC 283p.

"The Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations, including by—

"(1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable;

"(2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and

"(3) addressing methodological challenges.".

(e) REPORTING.— 42 USC 283p note.

(1) IN GENERAL.—The Secretary, in collaboration with the Director of the National Institutes of Health, shall as appropriate—

(A) continue to support research for the development of appropriate measures related to reporting health information about sexual and gender minority populations; and

(B) not later than 2 years after the date of enactment of this Act, disseminate and make public such measures.

(2) NATIONAL ACADEMY OF MEDICINE RECOMMENDATIONS.—In developing the measures described in paragraph (1)(A), the Secretary shall take into account recommendations made by the National Academy of Medicine.

(f) IMPROVING COORDINATION RELATED TO MINORITY HEALTH AND HEALTH DISPARITIES.—Section 464z–3 of the Public Health Service Act (42 U.S.C. 285t) is amended—

(1) by redesignating subsection (h), relating to interagency coordination, that follows subsection (j) as subsection (k); and

(2) in subsection (k) (as so redesignated)—

(A) in the subsection heading, by striking "INTER-AGENCY" and inserting "INTRA-NATIONAL INSTITUTES OF HEALTH";

(B) by striking "as the primary Federal officials" and inserting "as the primary Federal official";

(C) by inserting a comma after "review";

(D) by striking "Institutes and Centers of the National Institutes of Health" and inserting "national research institutes and national centers"; and

(E) by adding at the end the following: "The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities.".

42 USC 284r.

(g) BASIC RESEARCH.—

(1) DEVELOPING POLICIES.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health (referred to in this section as the "Director of the National Institutes of Health"), taking into consideration the recommendations developed under section 2039, shall develop policies for projects of basic research funded by National Institutes of Health to assess—

(A) relevant biological variables including sex, as appropriate; and

(B) how differences between male and female cells, tissues, or animals may be examined and analyzed.

(2) REVISING POLICIES.—The Director of the National Institutes of Health may update or revise the policies developed under paragraph (1) as appropriate.

(3) CONSULTATION AND OUTREACH.—In developing, updating, or revising the policies under this section, the Director of the National Institutes of Health shall—

(A) consult with—

(i) the Office of Research on Women's Health;

(ii) the Office of Laboratory Animal Welfare; and

(iii) appropriate members of the scientific and academic communities; and

(B) conduct outreach to solicit feedback from members of the scientific and academic communities on the influence of sex as a variable in basic research, including feedback

on when it is appropriate for projects of basic research involving cells, tissues, or animals to include both male and female cells, tissues, or animals.

(4) ADDITIONAL REQUIREMENTS.—The Director of the National Institutes of Health shall—

(A) ensure that projects of basic research funded by the National Institutes of Health are conducted in accordance with the policies developed, updated, or revised under this section, as applicable; and

(B) encourage that the results of such research, when published or reported, be disaggregated as appropriate with respect to the analysis of any sex differences.

(h) CLINICAL RESEARCH.— 42 USC 289a–2 note.

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Director of the National Institutes of Health, in consultation with the Director of the Office of Research on Women's Health and the Director of the National Institute on Minority Health and Health Disparities, shall update the guidelines established under section 492B(d) of Public Health Service Act (42 U.S.C. 289a–2(d)) in accordance with paragraph (2).

(2) REQUIREMENTS.—The updated guidelines described in paragraph (1) shall—

(A) reflect the science regarding sex differences;

(B) improve adherence to the requirements under section 492B of the Public Health Service Act (42 U.S.C. 289a–2), including the reporting requirements under subsection (f) of such section; and

(C) clarify the circumstances under which studies should be designed to support the conduct of analyses to detect significant differences in the intervention effect due to demographic factors related to section 492B of the Public Health Service Act, including in the absence of prior studies that demonstrate a difference in study outcomes on the basis of such factors and considering the effects of the absence of such analyses on the availability of data related to demographic differences.

(i) APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH.— 42 USC 282 note.

(1) INPUT FROM EXPERTS.—Not later than 180 days after the date of enactment of this Act, the Director of the National Institutes of Health shall convene a workshop of experts on pediatric and older populations to provide input on—

(A) appropriate age groups to be included in research studies involving human subjects; and

(B) acceptable justifications for excluding participants from a range of age groups from human subjects research studies.

(2) POLICY UPDATES.—Not later than 180 days after the conclusion of the workshop under paragraph (1), the Director of the National Institutes of Health shall make a determination with respect to whether the policies of the National Institutes of Health on the inclusion of relevant age groups in clinical studies need to be updated, and shall update such policies as appropriate. In making the determination, the Director of the National Institutes of Health shall take into consideration whether such policies—

(A) address the consideration of age as an inclusion variable in research involving human subjects; and

(B) identify the criteria for justification for any age-related exclusions in such research.

(3) PUBLIC AVAILABILITY OF FINDINGS AND CONCLUSIONS.—The Director of the National Institutes of Health shall—

(A) make the findings and conclusions resulting from the workshop under paragraph (1) and updates to policies in accordance with paragraph (2), as applicable, available to the public on the Internet website of the National Institutes of Health; and

(B) ensure that age-related data reported in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032) are made available to the public on the Internet website of the National Institutes of Health.

42 USC 282 note.

SEC. 2039. ENHANCING THE RIGOR AND REPRODUCIBILITY OF SCIENTIFIC RESEARCH.

(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene a working group under the Advisory Committee to the Director of the National Institutes of Health (referred to in this section as the "Advisory Committee"), appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a), to develop and issue recommendations through the Advisory Committee for a formal policy, which may incorporate or be informed by relevant existing and ongoing activities, to enhance rigor and reproducibility of scientific research funded by the National Institutes of Health.

(b) CONSIDERATIONS.—In developing and issuing recommendations through the Advisory Committee under subsection (a), the working group established under such subsection shall consider, as appropriate—

(1) preclinical experiment design, including analysis of sex as a biological variable;

(2) clinical experiment design, including—

(A) the diversity of populations studied for clinical research, with respect to biological, social, and other determinants of health that contribute to health disparities;

(B) the circumstances under which summary information regarding biological, social, and other factors that contribute to health disparities should be reported; and

(C) the circumstances under which clinical studies, including clinical trials, should conduct an analysis of the data collected during the study on the basis of biological, social, and other factors that contribute to health disparities;

(3) applicable levels of rigor in statistical methods, methodology, and analysis;

(4) data and information sharing in accordance with applicable privacy laws and regulations; and

(5) any other matter the working group determines relevant.

(c) POLICIES.—Not later than 18 months after the date of enactment of this Act, the Director of the National Institutes of Health shall consider the recommendations developed by the working group

and issued by the Advisory Committee under subsection (a) and develop or update policies as appropriate.

(d) REPORT.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health shall issue a report to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives regarding recommendations developed under subsection (a) and any subsequent policy changes implemented, to enhance rigor and reproducibility in scientific research funded by the National Institutes of Health.

(e) CONFIDENTIALITY.—Nothing in this section authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 2040. IMPROVING MEDICAL REHABILITATION RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH.

(a) IN GENERAL.—Section 452 of the Public Health Service Act (42 U.S.C. 285g–4) is amended—

(1) in subsection (b), by striking "conduct and support" and inserting "conduct, support, and coordination";

(2) in subsection (c)(1)(C), by striking "of the Center" and inserting "within the Center";

(3) in subsection (d)—

(A) by striking "(d)(1) In consultation" and all that follows through the end of paragraph (1) and inserting the following:

"(d)(1) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall develop a comprehensive plan (referred to in this section as the 'Research Plan') for the conduct, support, and coordination of medical rehabilitation research.";

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "; and" and inserting a semicolon;

(ii) in subparagraph (B), by striking the period and inserting "; and"; and

(iii) by adding at the end the following:

"(C) include goals and objectives for conducting, supporting, and coordinating medical rehabilitation research, consistent with the purpose described in subsection (b).";

(C) by striking paragraph (4) and inserting the following:

"(4) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall revise and update the Research Plan periodically, as appropriate, or not less than every 5 years. Not later than 30 days after the Research Plan is so revised and updated, the Director of the Center shall transmit the revised and updated Research Plan to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives."; and

(D) by adding at the end the following:

"(5) The Director of the Center, in consultation with the Director of the Institute, shall, prior to revising and updating the Research Plan, prepare a report for the coordinating committee established under subsection (e) and the advisory board established under subsection (f) that describes and analyzes the progress during the preceding fiscal year in achieving the goals and objectives described in paragraph (2)(C) and includes expenditures for rehabilitation research at the National Institutes of Health. The report shall include recommendations for revising and updating the Research Plan, and such initiatives as the Director of the Center and the Director of the Institute determine appropriate. In preparing the report, the Director of the Center and the Director of the Institute shall consult with the Director of the National Institutes of Health.";

(4) in subsection (e)—

(A) in paragraph (2), by inserting "periodically host a scientific conference or workshop on medical rehabilitation research and" after "The Coordinating Committee shall"; and

(B) in paragraph (3), by inserting "the Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health," after "shall be composed of";

(5) in subsection (f)(3)(B)—

(A) by redesignating clauses (ix) through (xi) as clauses (x) through (xii), respectively; and

(B) by inserting after clause (viii) the following:

"(ix) The Director of the Division of Program Coordination, Planning, and Strategic Initiatives."; and

(6) by adding at the end the following:

"(g)(1) The Secretary and the heads of other Federal agencies shall jointly review the programs carried out (or proposed to be carried out) by each such official with respect to medical rehabilitation research and, as appropriate, enter into agreements preventing duplication among such programs.

"(2) The Secretary shall, as appropriate, enter into interagency agreements relating to the coordination of medical rehabilitation research conducted by agencies of the National Institutes of Health and other agencies of the Federal Government.

"(h) For purposes of this section, the term 'medical rehabilitation research' means the science of mechanisms and interventions that prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function.".

(b) CONFORMING AMENDMENT.—Section 3 of the National Institutes of Health Amendments of 1990 (42 U.S.C. 285g–4 note) is amended—

(1) in subsection (a), by striking "IN GENERAL.—"; and

(2) by striking subsection (b).

42 USC 289a–2 note.

SEC. 2041. TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.

(a) TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a task force, in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), to be known as the "Task

Force on Research Specific to Pregnant Women and Lactating Women" (in this section referred to as the "Task Force").

(2) DUTIES.—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

(3) MEMBERSHIP.—

(A) FEDERAL MEMBERS.—The Task Force shall be composed of each of the following Federal members, or the designees of such members:

(i) The Director of the Centers for Disease Control and Prevention.

(ii) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the directors of such other appropriate national research institutes.

(iii) The Commissioner of Food and Drugs.

(iv) The Director of the Office on Women's Health.

(v) The Director of the National Vaccine Program Office.

(vi) The head of any other research-related agency or department not described in clauses (i) through (v) that the Secretary determines appropriate, which may include the Department of Veterans Affairs and the Department of Defense.

(B) NON-FEDERAL MEMBERS.—The Task Force shall be composed of each of the following non-Federal members, including—

(i) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

(ii) nonprofit organizations with expertise related to the health of women and children;

(iii) relevant industry representatives; and

(iv) other representatives, as appropriate.

(C) LIMITATIONS.—The non-Federal members described in subparagraph (B) shall—

(i) compose not more than one-half, and not less than one-third, of the total membership of the Task Force; and

(ii) be appointed by the Secretary.

(4) TERMINATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the Task Force shall terminate on the date that is 2 years after the date on which the Task Force is established under paragraph (1).

(B) EXTENSION.—The Secretary may extend the operation of the Task Force for one additional 2-year period following the 2-year period described in subparagraph (A), if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

(5) MEETINGS.—The Task Force shall meet not less than 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under paragraph (2).

(6) TASK FORCE REPORT TO CONGRESS.—Not later than 18 months after the date on which the Task Force is established under paragraph (1), the Task Force shall prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that includes each of the following:

(A) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies.

(B) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research.

(C) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women.

(D) Identification of Federal activities, including—

(i) the state of research on pregnancy and lactation;

(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

(iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities.

(E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

(b) CONFIDENTIALITY.—Nothing in this section shall authorize the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN AND LACTATING WOMEN IN RESEARCH.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary, considering any recommendations of the Task Force available at such time and in consultation with the heads of relevant agencies of the Department of Health and Human Services, shall, as appropriate, update regulations and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research.

(2) CRITERIA FOR EXCLUDING PREGNANT OR LACTATING WOMEN.—In updating any regulations or guidance described in paragraph (1), the Secretary shall consider any appropriate criteria to be used by institutional review boards and individuals reviewing grant proposals for excluding pregnant women or lactating women as a study population requiring additional protections from participating in human subject research.

SEC. 2042. STREAMLINING NATIONAL INSTITUTES OF HEALTH REPORTING REQUIREMENTS.

(a) TRANS-NATIONAL INSTITUTES OF HEALTH RESEARCH REPORTING.—Section 402A(c)(2) of the Public Health Service Act (42 U.S.C. 282a(c)(2)) is amended—

(1) by amending subparagraph (B) to read as follows:

"(B) REPORTING.—Not later than 2 years after the date of enactment of 21st Century Cures Act, the head of each national research institute or national center shall submit to the Director of the National Institutes of Health a report, to be included in the triennial report under section 403, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers."; and

(2) in subparagraphs (D) and (E) by striking "(B)(i)" each place it appears and inserting "(B)".

(b) FRAUD AND ABUSE REPORTING.—Section 403B of the Public Health Service Act (42 U.S.C. 283a–1) is amended—

(1) by striking subsection (b);

(2) by redesignating subsection (c) as subsection (b); and

(3) in subsection (b) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (a)".

(c) DOCTORAL DEGREES REPORTING.—Section 403C(a)(2) of the Public Health Service Act (42 U.S.C. 283a–2(a)(2)) is amended by striking "(not including any leaves of absence)".

(d) VACCINE REPORTING.—Section 404B of the Public Health Service Act (42 U.S.C. 283d) is amended—

(1) by striking subsection (b); and

(2) by striking "(a) DEVELOPMENT OF NEW VACCINES.—The Secretary" and inserting "The Secretary".

(e) NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.—Section 479(c) of the Public Health Service Act (42 U.S.C. 287(c)) is amended—

(1) in the subsection heading, by striking "ANNUAL" and inserting "BIENNIAL"; and

(2) in the matter preceding paragraph (1), by striking "an annual report" and inserting "a report on a biennial basis".

(f) REVIEW OF CENTERS OF EXCELLENCE.—

(1) REPEAL.—Section 404H of the Public Health Service Act (42 U.S.C. 283j) is repealed.

(2) CONFORMING AMENDMENT.—Section 399EE(c) of the Public Health Service Act (42 U.S.C. 280–4(c)) is amended by striking "399CC, 404H," and inserting "399CC".

(g) RAPID HIV TEST REPORT.—Section 502(a) of the Ryan White CARE Act Amendments of 2000 (42 U.S.C. 300cc note) is amended—

(1) by striking paragraph (2); and

(2) by redesignating paragraph (3) as paragraph (2).

(h) NATIONAL INSTITUTE OF NURSING RESEARCH.—

(1) REPEAL.—Section 464Y of the Public Health Service Act (42 U.S.C. 285q–3) is repealed.

(2) CONFORMING AMENDMENT.—Section 464X(g) of the Public Health Service Act (42 U.S.C. 285q–2(g)) is amended by striking "biennial report made under section 464Y," and inserting "triennial report made under section 403".

SEC. 2043. REIMBURSEMENT FOR RESEARCH SUBSTANCES AND LIVING ORGANISMS.

Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended by section 2035, is further amended—

(1) in the flush matter at the end of subsection (a)—

(A) by redesignating such matter as subsection (h)(1); and

(B) by moving such matter so as to appear at the end of such section; and

(2) in subsection (h) (as so redesignated), by adding at the end the following:

"(2) Where research substances and living organisms are made available under paragraph (1) through contractors, the Secretary may direct such contractors to collect payments on behalf of the Secretary for the costs incurred to make available such substances and organisms and to forward amounts so collected to the Secretary, in the time and manner specified by the Secretary.

"(3) Amounts collected under paragraph (2) shall be credited to the appropriations accounts that incurred the costs to make available the research substances and living organisms involved, and shall remain available until expended for carrying out activities under such accounts.".

SEC. 2044. SENSE OF CONGRESS ON INCREASED INCLUSION OF UNDERREPRESENTED POPULATIONS IN CLINICAL TRIALS.

It is the sense of Congress that the National Institute on Minority Health and Health Disparities should include within its strategic plan under section 402(m) of the Public Health Service Act (42 U.S.C. 282(m)) ways to increase representation of underrepresented populations in clinical trials.

Subtitle E—Advancement of the National Institutes of Health Research and Data Access

SEC. 2051. TECHNICAL UPDATES TO CLINICAL TRIALS DATABASE.

Section 402(j)(2)(D) of the Public Health Service Act (42 U.S.C. 282(j)(2)(D)) is amended—

(1) in clause (ii)(I), by inserting before the semicolon ", unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval"; and

(2) by adding at the end the following:

"(iii) OPTION TO MAKE CERTAIN CLINICAL TRIAL INFORMATION AVAILABLE EARLIER.—The Director of the National Institutes of Health shall inform responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

"(iv) COMBINATION PRODUCTS.—An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

"(I) an applicable drug clinical trial, if the Secretary determines under section 503(g) of the Federal Food, Drug, and Cosmetic Act that the primary mode of action of such product is that of a drug or biological product; or

"(II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.".

SEC. 2052. COMPLIANCE ACTIVITIES REPORTS.

(a) DEFINITIONS.—In this section:

(1) APPLICABLE CLINICAL TRIAL.—The term "applicable clinical trial" has the meaning given the term in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(2) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(b) REPORT ON ACTIVITIES TO ENCOURAGE COMPLIANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Director of the National Institutes of Health and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that describes education and outreach, guidance, enforcement, and other activities undertaken to encourage compliance with section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(c) REPORTS ON CLINICAL TRIALS.—

(1) IN GENERAL.—Not later than 2 years after the final compliance date under the final rule implementing section 402(j) of the Public Health Service Act, and every 2 years thereafter for the next 4 years, the Secretary, acting through the Director of the National Institutes of Health and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report describing—

(A) the total number of applicable clinical trials with complete data bank registration information registered during the period for which the report is being prepared (broken down by each year of such reporting period);

(B) the total number of applicable clinical trials registered during the period for which the report is being prepared for which results have been submitted to the data bank (broken down by each year of such reporting period);

(C) the activities undertaken by the Secretary to educate responsible persons about data bank registration and results submission requirements, including through issuance of guidance documents, informational meetings, and training sessions; and

(D) the activities described in the report submitted under subsection (b).

(2) ACTIONS TO ENFORCE COMPLIANCE.—After the Secretary has undertaken the educational activities described in paragraph (1)(C), the Secretary shall include in subsequent reports

submitted under paragraph (1) the number of actions taken by the Secretary during the period for which the report is being prepared to enforce compliance with data bank registration and results submission requirements.

SEC. 2053. UPDATES TO POLICIES TO IMPROVE DATA.

Section 492B(c) of the Public Health Service Act (42 U.S.C. 289a–2(c)) is amended—

(1) by striking "In the case" and inserting the following: "(1) IN GENERAL.—In the case"; and

(2) by adding at the end the following:

"(2) REPORTING REQUIREMENTS.—For any new and competing project of clinical research subject to the requirements under this section that receives a grant award 1 year after the date of enactment of the 21st Century Cures Act, or any date thereafter, for which a valid analysis is provided under paragraph (1)—

"(A) and which is an applicable clinical trial as defined in section 402(j), the entity conducting such clinical research shall submit the results of such valid analysis to the clinical trial registry data bank expanded under section 402(j)(3), and the Director of the National Institutes of Health shall, as appropriate, consider whether such entity has complied with the reporting requirement described in this subparagraph in awarding any future grant to such entity, including pursuant to section 402(j)(5)(A)(ii) when applicable; and

"(B) the Director of the National Institutes of Health shall encourage the reporting of the results of such valid analysis described in paragraph (1) through any additional means determined appropriate by the Director.".

SEC. 2054. CONSULTATION.

Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall consult with relevant Federal agencies, including the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the National Institutes of Health, as well as other stakeholders (including patients, researchers, physicians, industry representatives, and developers of health information technology) to receive recommendations with respect to enhancements to the clinical trial registry data bank under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)), including with respect to usability, functionality, and search capability.

Subtitle F—Facilitating Collaborative Research

SEC. 2061. NATIONAL NEUROLOGICAL CONDITIONS SURVEILLANCE SYSTEM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by inserting after section 399S the following:

"SEC. 399S–1. SURVEILLANCE OF NEUROLOGICAL DISEASES. 42 USC 280g–7a.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines, shall, as appropriate—

"(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases; and

"(2) incorporate information obtained through such activities into an integrated surveillance system, which may consist of or include a registry, to be known as the National Neurological Conditions Surveillance System.

"(b) RESEARCH.—The Secretary shall ensure that the National Neurological Conditions Surveillance System is designed in a manner that facilitates further research on neurological diseases.

"(c) CONTENT.—In carrying out subsection (a), the Secretary—

"(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

"(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, including information related to persons living with neurological diseases who choose to participate, such as—

"(A) demographics, such as age, race, ethnicity, sex, geographic location, family history, and other information, as appropriate;

"(B) risk factors that may be associated with neurological diseases, such as genetic and environmental risk factors and other information, as appropriate; and

"(C) diagnosis and progression markers;

"(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

"(A) the natural history of the diseases;

"(B) the prevention of the diseases;

"(C) the detection, management, and treatment approaches for the diseases; and

"(D) the development of outcomes measures;

"(4) may address issues identified during the consultation process under subsection (d); and

"(5) initially may address a limited number of neurological diseases.

"(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, which may include—

"(1) epidemiologists with experience in disease surveillance or registries;

"(2) representatives of national voluntary health associations that—

"(A) focus on neurological diseases; and

"(B) have demonstrated experience in research, care, or patient services;

"(3) health information technology experts or other information management specialists;

"(4) clinicians with expertise in neurological diseases; and

"(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

"(e) GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

"(f) COORDINATION WITH OTHER FEDERAL, STATE, AND LOCAL AGENCIES.—Subject to subsection (h), the Secretary shall—

"(1) make information and analysis in the National Neurological Conditions Surveillance System available, as appropriate—

"(A) to Federal departments and agencies, such as the National Institutes of Health and the Department of Veterans Affairs; and

"(B) to State and local agencies; and

"(2) identify, build upon, leverage, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health infrastructure, wherever practicable.

"(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are available, as appropriate, to the public, including researchers.

"(h) PRIVACY.—The Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

"(i) REPORTS.—

"(1) REPORT ON INFORMATION AND ANALYSES.—Not later than 1 year after the date on which any system is established under this section, the Secretary shall submit an interim report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding aggregate information collected pursuant to this section and epidemiological analyses, as appropriate. Such report shall be posted on the Internet website of the Department of Health and Human Services and shall be updated biennially.

"(2) IMPLEMENTATION REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

"(A) the development and maintenance of the National Neurological Conditions Surveillance System;

"(B) the type of information collected and stored in the surveillance system;

"(C) the use and availability of such information, including guidelines for such use; and

"(D) the use and coordination of databases that collect or maintain information on neurological diseases.

"(j) DEFINITION.—In this section, the term 'national voluntary health association' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States with experience serving the population of individuals with neurological disease and have demonstrated experience in neurological disease research, care, and patient services.

"(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.".

SEC. 2062. TICK-BORNE DISEASES. 42 USC 284s.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as "the Secretary") shall continue to conduct or support epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases.

(b) REPORTS.—The Secretary shall ensure that each triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032) includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to tick-borne diseases.

(c) TICK-BORNE DISEASES WORKING GROUP.—

(1) ESTABLISHMENT.—The Secretary shall establish a working group, to be known as the Tick-Borne Disease Working Group (referred to in this section as the "Working Group"), comprised of representatives of appropriate Federal agencies and other non-Federal entities, to provide expertise and to review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

(2) RESPONSIBILITIES.—The working group shall—

(A) not later than 2 years after the date of enactment of this Act, develop or update a summary of—

(i) ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases;

(ii) advances made pursuant to such research;

(iii) Federal activities related to tick-borne diseases, including—

(I) epidemiological activities related to tick-borne diseases; and

(II) basic, clinical, and translational tick-borne disease research related to the pathogenesis, prevention, diagnosis, and treatment of tick-borne diseases;

(iv) gaps in tick-borne disease research described in clause (iii)(II);

(v) the Working Group's meetings required under paragraph (4); and

(vi) the comments received by the Working Group;

(B) make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and

(C) solicit input from States, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

(3) MEMBERSHIP.—The members of the working group shall represent a diversity of scientific disciplines and views and shall be composed of the following members:

(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of the following:

(i) The Office of the Assistant Secretary for Health.

(ii) The Food and Drug Administration.

(iii) The Centers for Disease Control and Prevention.

(iv) The National Institutes of Health.

(v) Such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

(B) NON–FEDERAL PUBLIC MEMBERS.—Seven non–Federal public members, consisting of representatives of the following categories:

(i) Physicians and other medical providers with experience in diagnosing and treating tick-borne diseases.

(ii) Scientists or researchers with expertise.

(iii) Patients and their family members.

(iv) Nonprofit organizations that advocate for patients with respect to tick-borne diseases.

(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

(4) MEETINGS.—The Working Group shall meet not less than twice each year.

(5) REPORTING.—Not later than 2 years after the date of enactment of this Act, and every 2 years thereafter until termination of the Working Group pursuant to paragraph (7), the Working Group shall—

(A) submit a report on its activities under paragraph (2)(A) and any recommendations under paragraph (2)(B) to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(B) make such report publicly available on the Internet website of the Department of Health and Human Services.

(6) APPLICABILITY OF FACA.—The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(7) SUNSET.—The Working Group under this section shall terminate 6 years after the date of enactment of this Act.

42 USC 1320d–2 note.

SEC. 2063. ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES.

(a) GUIDANCE RELATED TO REMOTE ACCESS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue guidance clarifying that subparagraph (B) of section 164.512(i)(1)(ii) of part 164 of the Rule (prohibiting the removal of protected health information by a researcher) does not prohibit remote access to health information by a researcher for such purposes as described in section 164.512(i)(1)(ii) of part 164 of the Rule so long as—

(1) at a minimum, security and privacy safeguards, consistent with the requirements of the Rule, are maintained by the covered entity and the researcher; and

(2) the protected health information is not copied or otherwise retained by the researcher.

(b) GUIDANCE RELATED TO STREAMLINING AUTHORIZATION.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance on the following:

(1) AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION.—Clarification of the circumstances under which the authorization for the use or disclosure of protected health information, with respect to an individual, for future research purposes contains a sufficient description of the purpose of the use or disclosure, such as if the authorization—

(A) sufficiently describes the purposes such that it would be reasonable for the individual to expect that the protected health information could be used or disclosed for such future research;

(B) either—

(i) states that the authorization will expire on a particular date or on the occurrence of a particular event; or

(ii) states that the authorization will remain valid unless and until it is revoked by the individual; and

(C) provides instruction to the individual on how to revoke such authorization at any time.

(2) REMINDER OF THE RIGHT TO REVOKE.—Clarification of the circumstances under which it is appropriate to provide an individual with an annual notice or reminder that the individual has the right to revoke such authorization.

(3) REVOCATION OF AUTHORIZATION.—Clarification of appropriate mechanisms by which an individual may revoke an authorization for future research purposes, such as described in paragraph (1)(C).

(c) WORKING GROUP ON PROTECTED HEALTH INFORMATION FOR RESEARCH.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall convene a working group to study and report on the uses and disclosures of protected health information for research purposes, under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191).

(2) MEMBERS.—The working group shall include representatives of—

(A) relevant Federal agencies, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Office for Civil Rights;

(B) the research community;

(C) patients;

(D) experts in civil rights, such as privacy rights;

(E) developers of health information technology;

(F) experts in data privacy and security;

(G) health care providers;

(H) bioethicists; and

(I) other experts and entities, as the Secretary determines appropriate.

(3) REPORT.—Not later than 1 year after the date on which the working group is convened under paragraph (1), the working group shall conduct a review and submit a report to the Secretary containing recommendations on whether the uses and disclosures of protected health information for research purposes should be modified to allow protected health information to be available, as appropriate, for research purposes, including studies to obtain generalizable knowledge, while protecting individuals' privacy rights. In conducting the review and making recommendations, the working group shall—

(A) address, at a minimum—

(i) the appropriate manner and timing of authorization, including whether additional notification to the individual should be required when the individual's protected health information will be used or disclosed for such research;

(ii) opportunities for individuals to set preferences on the manner in which their protected health information is used in research;

(iii) opportunities for patients to revoke authorization;

(iv) notification to individuals of a breach in privacy;

(v) existing gaps in statute, regulation, or policy related to protecting the privacy of individuals, and

(vi) existing barriers to research related to the current restrictions on the uses and disclosures of protected health information; and

(B) consider, at a minimum—

(i) expectations and preferences on how an individual's protected health information is shared and used;

(ii) issues related to specific subgroups of people, such as children, incarcerated individuals, and individuals with a cognitive or intellectual disability impacting capacity to consent;

(iii) relevant Federal and State laws;

(iv) models of facilitating data access and levels of data access, including data segmentation, where applicable;

(v) potential impacts of disclosure and non-disclosure of protected health information on access to health care services; and

(vi) the potential uses of such data.

(4) REPORT SUBMISSION.—The Secretary shall submit the report under paragraph (3) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and shall post such report on the appropriate Internet website of the Department of Health and Human Services.

(5) TERMINATION.—The working group convened under paragraph (1) shall terminate the day after the report under paragraph (3) is submitted to Congress and made public in accordance with paragraph (4).

(d) DEFINITIONS.—In this section:

(1) THE RULE.—References to "the Rule" refer to part 160 or part 164, as appropriate, of title 45, Code of Federal Regulations (or any successor regulation).

(2) PART 164.—References to a specified section of "part 164", refer to such specified section of part 164 of title 45, Code of Federal Regulations (or any successor section).

Subtitle G—Promoting Pediatric Research

SEC. 2071. NATIONAL PEDIATRIC RESEARCH NETWORK.

Section 409D(d) of the Public Health Service Act (42 U.S.C. 284h(d)) is amended—

(1) in paragraph (1), by striking "in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research, may provide for the establishment of" and inserting "in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support"; and

(2) in paragraph (2)(A) and the first sentence of paragraph (2)(E), by striking "may" each place such term appears and inserting "shall".

SEC. 2072. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK.

It is the sense of Congress that—

(1) the National Institutes of Health should encourage a global pediatric clinical study network by providing grants, contracts, or cooperative agreements to support new and early stage investigators who participate in the global pediatric clinical study network;

(2) the Secretary of Health and Human Services (referred to in this section as the "Secretary") should engage with clinical investigators and appropriate authorities outside of the United States, including authorities in the European Union, during the formation of the global pediatric clinical study network to encourage the participation of such investigator and authorities; and

(3) once a global pediatric clinical study network is established and becomes operational, the Secretary should continue to encourage and facilitate the participation of clinical investigators and appropriate authorities outside of the United States, including in the European Union, to participate in the network with the goal of enhancing the global reach of the network.

TITLE III—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

SEC. 3001. PATIENT EXPERIENCE DATA.

Section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) is amended—

(1) in subsection (a)—

(A) in the subsection heading, by striking "IN GENERAL" and inserting "PATIENT ENGAGEMENT IN DRUGS AND DEVICES";

(B) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and moving such subparagraphs 2 ems to the right; and

(C) by striking "The Secretary" and inserting the following:

"(1) IN GENERAL.—The Secretary";

(2) by redesignating subsections (b) through (e) as paragraphs (2) through (5), respectively, and moving such paragraphs 2 ems to the right; and

(3) by adding at the end the following:

"(b) STATEMENT OF PATIENT EXPERIENCE.—

"(1) IN GENERAL.—Following the approval of an application that was submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act at least 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of such application.

"(2) DATA AND INFORMATION.—The data and information referred to in paragraph (1) are—

"(A) patient experience data;

"(B) information on patient-focused drug development tools; and

"(C) other relevant information, as determined by the Secretary.

"(c) PATIENT EXPERIENCE DATA.—For purposes of this section, the term 'patient experience data' includes data that—

"(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

"(2) are intended to provide information about patients' experiences with a disease or condition, including—

"(A) the impact of such disease or condition, or a related therapy, on patients' lives; and

"(B) patient preferences with respect to treatment of such disease or condition.".

21 USC 360bbb–8c note.

SEC. 3002. PATIENT-FOCUSED DRUG DEVELOPMENT GUIDANCE.

(a) PUBLICATION OF GUIDANCE DOCUMENTS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall develop a plan to issue draft and final versions of one or more guidance documents, over a period of 5 years, regarding the collection of patient experience data, and the use of such data and related information in drug development. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue a draft version of at least one such guidance document. Not later than 18 months after the public comment period on the draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(b) PATIENT EXPERIENCE DATA.—For purposes of this section, the term "patient experience data" has the meaning given such term in section 569C of the Federal Food, Drug, and Cosmetic Act (as added by section 3001).

(c) CONTENTS.—The guidance documents described in subsection (a) shall address—

(1) methodological approaches that a person seeking to collect patient experience data for submission to, and proposed use by, the Secretary in regulatory decisionmaking may use, that are relevant and objective and ensure that such data are accurate and representative of the intended population, including methods to collect meaningful patient input throughout the drug development process and methodological considerations for data collection, reporting, management, and analysis;

(2) methodological approaches that may be used to develop and identify what is most important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease;

(3) approaches to identifying and developing methods to measure impacts to patients that will help facilitate collection of patient experience data in clinical trials;

(4) methodologies, standards, and technologies to collect and analyze clinical outcome assessments for purposes of regulatory decisionmaking;

(5) how a person seeking to develop and submit proposed draft guidance relating to patient experience data for consideration by the Secretary may submit such proposed draft guidance to the Secretary;

(6) the format and content required for submissions under this section to the Secretary, including with respect to the information described in paragraph (1);

(7) how the Secretary intends to respond to submissions of information described in paragraph (1), if applicable, including any timeframe for response when such submission is not part of a regulatory application or other submission that has an associated timeframe for response; and

(8) how the Secretary, if appropriate, anticipates using relevant patient experience data and related information, including with respect to the structured risk-benefit assessment framework described in section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)), to inform regulatory decisionmaking.

SEC. 3003. STREAMLINING PATIENT INPUT.

21 USC 360bbb–8c note.

Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, that is initiated by the Secretary under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended by section 3001) or section 3002.

SEC. 3004. REPORT ON PATIENT EXPERIENCE DRUG DEVELOPMENT.

21 USC 355 note.

Not later than June 1 of 2021, 2026, and 2031, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall prepare and publish on the Internet website of the Food and Drug Administration a report assessing the use of patient experience data in regulatory decisionmaking, in particular with respect to the review of patient experience data and information on patient-focused drug development tools as part

of applications approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

Subtitle B—Advancing New Drug Therapies

SEC. 3011. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following new section:

21 USC 357.

"SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

"(a) PROCESS FOR QUALIFICATION.—

"(1) IN GENERAL.—The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use under which—

"(A)(i) a requestor initiates such process by submitting a letter of intent to the Secretary; and

"(ii) the Secretary accepts or declines to accept such letter of intent;

"(B)(i) if the Secretary accepts the letter of intent, a requestor submits a qualification plan to the Secretary; and

"(ii) the Secretary accepts or declines to accept the qualification plan; and

"(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

"(ii) the Secretary determines whether to accept such qualification package for review; and

"(iii) if the Secretary accepts such qualification package for review, the Secretary conducts such review in accordance with this section.

"(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—

"(A) IN GENERAL.—Subparagraphs (B), (C), and (D) shall apply with respect to the treatment of a letter of intent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as 'qualification submissions').

"(B) ACCEPTANCE FACTORS; NONACCEPTANCE.—The Secretary shall determine whether to accept a qualification submission based on factors which may include the scientific merit of the qualification submission. A determination not to accept a submission under paragraph (1) shall not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

"(C) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

"(i) as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug

development tool and the availability or lack of alternative treatments for such disease or condition; and

"(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of such a drug development tool and its proposed context of use as a public health priority.

"(D) ENGAGEMENT OF EXTERNAL EXPERTS.—The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of such consortia with respect to the review of any qualification plan submitted under paragraph (1) or the review of any full qualification package under paragraph (3).

"(3) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—

"(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

"(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

"(4) QUALIFICATION.—The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on the scientific merit of a full qualification package reviewed under paragraph (3).

"(b) EFFECT OF QUALIFICATION.—

"(1) IN GENERAL.—A drug development tool determined to be qualified under subsection (a)(4) for a proposed context of use specified by the requestor may be used by any person in such context of use for the purposes described in paragraph (2).

"(2) USE OF A DRUG DEVELOPMENT TOOL.—Subject to paragraph (3), a drug development tool qualified under this section may be used for—

"(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act; or

"(B) supporting the investigational use of a drug or biological product under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

"(3) RESCISSION OR MODIFICATION.—

"(A) IN GENERAL.—The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. Such a determination may be based on new information that calls into question the basis for such qualification.

"(B) MEETING FOR REVIEW.—If the Secretary rescinds or modifies under subparagraph (A) a determination to qualify a drug development tool, the requestor involved shall, on request, be granted a meeting with the Secretary to discuss the basis of the Secretary's decision to rescind or modify the determination before the effective date of the rescission or modification.

"(c) TRANSPARENCY.—

"(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a biannual basis, on the Internet website of the Food and Drug Administration the following:

"(A) Information with respect to each qualification submission under the qualification process under subsection (a), including—

"(i) the stage of the review process applicable to the submission;

"(ii) the date of the most recent change in stage status;

"(iii) whether external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package; and

"(iv) submissions from requestors under the qualification process under subsection (a), including any data and evidence contained in such submissions, and any updates to such submissions.

"(B) The Secretary's formal written determinations in response to such qualification submissions.

"(C) Any rescissions or modifications under subsection (b)(3) of a determination to qualify a drug development tool.

"(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (a).

"(E) A comprehensive list of—

"(i) all drug development tools qualified under subsection (a); and

"(ii) all surrogate endpoints which were the basis of approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act.

"(2) RELATION TO TRADE SECRETS ACT.—Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18, United States Code.

"(3) APPLICABILITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information contained in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act that is confidential commercial or trade secret information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) to alter the standards of evidence under subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d), or under section 351 of the Public Health Service Act (as applicable); or

"(2) to limit the authority of the Secretary to approve or license products under this Act or the Public Health Service Act, as applicable (as in effect before the date of the enactment of the 21st Century Cures Act).

"(e) DEFINITIONS.—In this section:

"(1) BIOMARKER.—The term 'biomarker'—

"(A) means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention; and

"(B) includes a surrogate endpoint.

"(2) BIOMEDICAL RESEARCH CONSORTIA.—The term 'biomedical research consortia' means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965), patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.

"(3) CLINICAL OUTCOME ASSESSMENT.—The term 'clinical outcome assessment' means—

"(A) a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and

"(B) includes a patient-reported outcome.

"(4) CONTEXT OF USE.—The term 'context of use' means, with respect to a drug development tool, the circumstances under which the drug development tool is to be used in drug development and regulatory review.

"(5) DRUG DEVELOPMENT TOOL.—The term 'drug development tool' includes—

"(A) a biomarker;

"(B) a clinical outcome assessment; and

"(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.

"(6) PATIENT-REPORTED OUTCOME.—The term 'patient-reported outcome' means a measurement based on a report from a patient regarding the status of the patient's health condition without amendment or interpretation of the patient's report by a clinician or any other person.

"(7) QUALIFICATION.—The terms 'qualification' and 'qualified' mean a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this Act.

"(8) REQUESTOR.—The term 'requestor' means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.

"(9) SURROGATE ENDPOINT.—The term 'surrogate endpoint' means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and—

"(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or

"(B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product in accordance with section 506(c).".

(b) GUIDANCE.— 21 USC 357 note.

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, in consultation with biomedical research consortia (as defined in subsection (e) of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and other interested parties through a collaborative public process, issue guidance to implement such section 507 that—

(A) provides a conceptual framework describing appropriate standards and scientific approaches to support the development of biomarkers delineated under the taxonomy established under paragraph (3);

(B) with respect to the qualification process under such section 507—

(i) describes the requirements that entities seeking to qualify a drug development tool under such section shall observe when engaging in such process;

(ii) outlines reasonable timeframes for the Secretary's review of letters, qualification plans, or full qualification packages submitted under such process; and

(iii) establishes a process by which such entities or the Secretary may consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the Secretary in the review of qualification plans and full qualification submissions under such section; and

(C) includes such other information as the Secretary determines appropriate.

(2) TIMING.—Not later than 3 years after the date of the enactment of this Act, the Secretary shall issue draft guidance under paragraph (1) on the implementation of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)). The Secretary shall issue final guidance on the implementation of such section not later than 6 months after the date on which the comment period for the draft guidance closes.

(3) TAXONOMY.—

(A) IN GENERAL.—For purposes of informing guidance under this subsection, the Secretary shall, in consultation with biomedical research consortia and other interested parties through a collaborative public process, establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.

(B) PUBLIC AVAILABILITY.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall make such taxonomy publicly available in draft form for public comment. The Secretary shall finalize the taxonomy not later than 1 year after the close of the public comment period.

(c) MEETING AND REPORT.—

(1) MEETING.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall convene a public meeting to describe and solicit public input regarding the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Secretary shall make publicly available on the Internet website of the Food and Drug Administration a report. Such report shall include, with respect to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), information on—

(A) the number of requests submitted, as a letter of intent, for qualification of a drug development tool (as defined in subsection (e) of such section 507);

(B) the number of such requests accepted and determined to be eligible for submission of a qualification plan or full qualification package (as such terms are defined in subsection (e) of such section 507), respectively;

(C) the number of such requests for which external scientific experts were utilized in the development of a qualification plan or review of a full qualification package;

(D) the number of qualification plans and full qualification packages, respectively, submitted to the Secretary; and

(E) the drug development tools qualified through such qualification process, specified by type of tool, such as a biomarker or clinical outcome assessment (as such terms are defined in subsection (e) of such section 507).

SEC. 3012. TARGETED DRUGS FOR RARE DISEASES.

Subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is amended by inserting after section 529 the following:

"SEC. 529A. TARGETED DRUGS FOR RARE DISEASES. 21 USC 360ff–1.

"(a) PURPOSE.—The purpose of this section, through the approach provided for in subsection (b), is to—

"(1) facilitate the development, review, and approval of genetically targeted drugs and variant protein targeted drugs to address an unmet medical need in one or more patient subgroups, including subgroups of patients with different mutations of a gene, with respect to rare diseases or conditions that are serious or life-threatening; and

"(2) maximize the use of scientific tools or methods, including surrogate endpoints and other biomarkers, for such purposes.

"(b) LEVERAGING OF DATA FROM PREVIOUSLY APPROVED DRUG APPLICATION OR APPLICATIONS.—The Secretary may, consistent with applicable standards for approval under this Act or section 351(a) of the Public Health Service Act, allow the sponsor of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for a genetically targeted drug or a variant protein targeted drug to rely upon data and information—

"(1) previously developed by the same sponsor (or another sponsor that has provided the sponsor with a contractual right of reference to such data and information); and

"(2) submitted by a sponsor described in paragraph (1) in support of one or more previously approved applications that were submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act,

for a drug that incorporates or utilizes the same or similar genetically targeted technology as the drug or drugs that are the subject

of an application or applications described in paragraph (2) or for a variant protein targeted drug that is the same or incorporates or utilizes the same variant protein targeted drug, as the drug or drugs that are the subject of an application or applications described in paragraph (2).

"(c) DEFINITIONS.—For purposes of this section—

"(1) the term 'genetically targeted drug' means a drug that—

"(A) is the subject of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening;

"(B) may result in the modulation (including suppression, up-regulation, or activation) of the function of a gene or its associated gene product; and

"(C) incorporates or utilizes a genetically targeted technology;

"(2) the term 'genetically targeted technology' means a technology comprising non-replicating nucleic acid or analogous compounds with a common or similar chemistry that is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition, including a disease or condition due to other variants in the same gene; and

"(3) the term 'variant protein targeted drug' means a drug that—

"(A) is the subject of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening;

"(B) modulates the function of a product of a mutated gene where such mutation is responsible in whole or in part for a given disease or condition; and

"(C) is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(1) alter the authority of the Secretary to approve drugs pursuant to this Act or section 351 of the Public Health Service Act (as authorized prior to the date of enactment of the 21st Century Cures Act), including the standards of evidence, and applicable conditions, for approval under such applicable Act; or

"(2) confer any new rights, beyond those authorized under this Act or the Public Health Service Act prior to enactment of this section, with respect to the permissibility of a sponsor referencing information contained in another application submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.".

SEC. 3013. REAUTHORIZATION OF PROGRAM TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) IN GENERAL.—Section 529(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)) is amended by striking paragraph (5) and inserting the following:

"(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after September 30, 2020, unless the rare pediatric disease product application—

"(A) is for a drug that, not later than September 30, 2020, is designated under subsection (d) as a drug for a rare pediatric disease; and

"(B) is, not later than September 30, 2022, approved under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.".

(b) REPORT.—The Advancing Hope Act of 2016 (Public Law 114–229) is amended by striking section 3.

SEC. 3014. GAO STUDY OF PRIORITY REVIEW VOUCHER PROGRAMS.

(a) STUDY.—The Comptroller General of the United States (referred to in this section as the "Comptroller General") shall conduct a study addressing the effectiveness and overall impact of the following priority review voucher programs, including any such programs amended or established by this Act:

(1) The neglected tropical disease priority review voucher program under section 524 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n).

(2) The rare pediatric disease priority review voucher program under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff).

(3) The medical countermeasure priority review voucher program under section 565A of the Federal Food, Drug, and Cosmetic Act, as added by section 3086.

(b) ISSUANCE OF REPORT.—Not later than January 31, 2020, the Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study under subsection (a).

(c) CONTENTS OF REPORTS.—The report submitted under subsection (b) shall address—

(1) for each drug for which a priority review voucher has been awarded as of initiation of the study—

(A) the indications for which the drug is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), pursuant to an application under section 505(b)(1) of such Act, or licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a));

(B) whether, and to what extent, the voucher impacted the sponsor's decision to develop the drug; and

(C) whether, and to what extent, the approval or licensure of the drug, as applicable and appropriate—

(i) addressed a global unmet need related to the treatment or prevention of a neglected tropical disease, including whether the sponsor of a drug coordinated with international development organizations;

(ii) addressed an unmet need related to the treatment of a rare pediatric disease; or

(iii) affected the Nation's preparedness against a chemical, biological, radiological, or nuclear threat, including naturally occurring threats;

(2) for each drug for which a priority review voucher has been used—

(A) the indications for which such drug is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), pursuant to an application under section 505(b)(1) of such Act, or licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262);

(B) the value of the voucher, if transferred; and

(C) the length of time between the date on which the voucher was awarded and the date on which the voucher was used; and

(3) an analysis of the priority review voucher programs described in subsection (a), including—

(A) the resources used by the Food and Drug Administration in reviewing drugs for which vouchers were used, including the effect of the programs on the Food and Drug Administration's review of drugs for which priority review vouchers were not awarded or used;

(B) whether any improvements to such programs are necessary to appropriately target incentives for the development of drugs that would likely not otherwise be developed, or developed in as timely a manner, and, as applicable and appropriate—

(i) address global unmet needs related to the treatment or prevention of neglected tropical diseases, including in countries in which neglected tropical diseases are endemic; or

(ii) address unmet needs related to the treatment of rare pediatric diseases; and

(C) whether the sunset of the rare pediatric disease program and medical countermeasure program has had an impact on the program, including any potential unintended consequences.

(d) PROTECTION OF NATIONAL SECURITY.—The Comptroller General shall conduct the study and issue reports under this section in a manner that does not compromise national security.

SEC. 3015. AMENDMENTS TO THE ORPHAN DRUG GRANTS.

Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) is amended—

(1) in subsection (a), by striking paragraph (1) and inserting the following: "(1) defraying the costs of developing drugs for rare diseases or conditions, including qualified testing expenses,"; and

(2) in subsection (b)(1)—

(A) in subparagraph (A)(ii), by striking "and" after the semicolon;

(B) in subparagraph (B), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(C) prospectively planned and designed observational studies and other analyses conducted to assist in the understanding of the natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to—

"(i) develop or validate a drug development tool related to a rare disease or condition; or

"(ii) understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct subpopulations affected by a rare disease or condition.".

SEC. 3016. GRANTS FOR STUDYING CONTINUOUS DRUG MANUFACTURING. 21 USC 399h.

(a) IN GENERAL.—The Secretary of Health and Human Services may award grants to institutions of higher education and nonprofit organizations for the purpose of studying and recommending improvements to the process of continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques.

(b) DEFINITIONS.—In this section—

(1) the term "drug" has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(2) the term "biological product" has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)); and

(3) the term "institution of higher education" has the meaning given such term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

Subtitle C—Modern Trial Design and Evidence Development

SEC. 3021. NOVEL CLINICAL TRIAL DESIGNS. 21 USC 355 note.

(a) PROPOSALS FOR USE OF NOVEL CLINICAL TRIAL DESIGNS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For purposes of assisting sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall conduct a public meeting and issue guidance in accordance with subsection (b).

(b) GUIDANCE ADDRESSING USE OF NOVEL CLINICAL TRIAL DESIGNS.—

(1) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall update or issue guidance addressing the use of complex adaptive and other novel trial design in the development and regulatory review and approval or licensure for drugs and biological products.

(2) CONTENTS.—The guidance under paragraph (1) shall address—

(A) the use of complex adaptive and other novel trial designs, including how such clinical trials proposed or submitted help to satisfy the substantial evidence standard under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d));

(B) how sponsors may obtain feedback from the Secretary on technical issues related to modeling and simulations prior to—

(i) completion of such modeling or simulations; or

(ii) the submission of resulting information to the Secretary;

(C) the types of quantitative and qualitative information that should be submitted for review; and

(D) recommended analysis methodologies.

(3) PUBLIC MEETING.—Prior to updating or issuing the guidance required by paragraph (1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patient advocacy organizations, consumer groups, and disease research foundations, through a public meeting to be held not later than 18 months after the date of enactment of this Act.

(4) TIMING.—The Secretary shall update or issue a draft version of the guidance required by paragraph (1) not later than 18 months after the date of the public meeting required by paragraph (3) and finalize such guidance not later than 1 year after the date on which the public comment period for the draft guidance closes.

SEC. 3022. REAL WORLD EVIDENCE.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505E (21 U.S.C. 355f) the following:

21 USC 355g.

"SEC. 505F. UTILIZING REAL WORLD EVIDENCE.

"(a) IN GENERAL.—The Secretary shall establish a program to evaluate the potential use of real world evidence—

"(1) to help to support the approval of a new indication for a drug approved under section 505(c); and

"(2) to help to support or satisfy postapproval study requirements.

"(b) REAL WORLD EVIDENCE DEFINED.—In this section, the term 'real world evidence' means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials.

"(c) PROGRAM FRAMEWORK.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary shall establish a draft framework for implementation of the program under this section.

"(2) CONTENTS OF FRAMEWORK.—The framework shall include information describing—

"(A) the sources of real world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities;

"(B) the gaps in data collection activities;

"(C) the standards and methodologies for collection and analysis of real world evidence; and

"(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

"(3) CONSULTATION.—

"(A) IN GENERAL.—In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and other interested parties.

"(B) PROCESS.—The consultation under subparagraph (A) may be carried out through approaches such as—

"(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate;

"(ii) a contract, grant, or other arrangement, as the Secretary determines appropriate, with such a partnership or an independent research organization; or

"(iii) public workshops with the entities described in such subparagraph.

"(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than 2 years after the date of enactment of the 21st Century Cures Act and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of real world evidence.

"(e) GUIDANCE FOR INDUSTRY.—The Secretary shall—

"(1) utilize the program established under subsection (a), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

"(A) the circumstances under which sponsors of drugs and the Secretary may rely on real world evidence for the purposes described in paragraphs (1) and (2) of subsection (a); and

"(B) the appropriate standards and methodologies for collection and analysis of real world evidence submitted for such purposes;

"(2) not later than 5 years after the date of enactment of the 21st Century Cures Act, issue draft guidance for industry as described in paragraph (1); and

"(3) not later than 18 months after the close of the public comment period for the draft guidance described in paragraph (2), issue revised draft guidance or final guidance.

"(f) RULE OF CONSTRUCTION.—

"(1) IN GENERAL.—Subject to paragraph (2), nothing in this section prohibits the Secretary from using real world evidence for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such nonspecified use.

"(2) STANDARDS OF EVIDENCE AND SECRETARY'S AUTHORITY.—This section shall not be construed to alter—

"(A) the standards of evidence under—

"(i) subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d); or

"(ii) section 351(a) of the Public Health Service Act; or

"(B) the Secretary's authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.".

42 USC 289 note.

SEC. 3023. PROTECTION OF HUMAN RESEARCH SUBJECTS.

(a) IN GENERAL.—In order to simplify and facilitate compliance by researchers with applicable regulations for the protection of human subjects in research, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, to the extent practicable and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b).

(b) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—The Secretary shall, as appropriate—

(1) make such modifications to the provisions of the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules as may be necessary—

(A) to reduce regulatory duplication and unnecessary delays;

(B) to modernize such provisions in the context of multisite and cooperative research projects; and

(C) to protect vulnerable populations, incorporate local considerations, and support community engagement through mechanisms such as consultation with local researchers and human research protection programs, in a manner consistent with subparagraph (B); and

(2) ensure that human subject research that is subject to the HHS Human Subject Regulations and to the FDA Human Subject Regulations may—

(A) use joint or shared review;

(B) rely upon the review of—

(i) an independent institutional review board; or

(ii) an institutional review board of an entity other than the sponsor of the research; or

(C) use similar arrangements to avoid duplication of effort.

(c) CONSULTATION.—In harmonizing or modifying regulations or guidance under this section, the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology, and medical device developers, clinical research organizations, patient groups, and others).

(d) TIMING.—The Secretary shall complete the harmonization described in subsection (a) not later than 3 years after the date of enactment of this Act.

(e) PROGRESS REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization.

(f) DEFINITIONS.—

(1) HUMAN SUBJECT REGULATIONS.—In this section:

(A) FDA HUMAN SUBJECT REGULATIONS.—The term "FDA Human Subject Regulations" means the provisions

of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).

(B) HHS HUMAN SUBJECT REGULATIONS.—The term "HHS Human Subject Regulations" means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

(C) VULNERABLE POPULATION RULES.—The term "vulnerable population rules" means—

(i) except in the case of research described in clause (ii), the provisions of subparts B through D of part 46, Code of Federal Regulations (or any successor regulations); and

(ii) in the case of research that is subject to FDA Human Subject Regulations, the provisions applicable to vulnerable populations under part 56 of title 21, Code of Federal Regulations (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

(2) INSTITUTIONAL REVIEW BOARD DEFINED.—In this section, the term "institutional review board" has the meaning that applies to the term "institutional review board" under the HHS Human Subject Regulations.

SEC. 3024. INFORMED CONSENT WAIVER OR ALTERATION FOR CLINICAL INVESTIGATIONS.

(a) DEVICES.—Section 520(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is amended—

(1) in subparagraph (D), by striking "except where subject to such conditions as the Secretary may prescribe, the investigator" and inserting the following: "except where, subject to such conditions as the Secretary may prescribe—

"(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

"(ii) the investigator"; and

(2) in the matter following subparagraph (D), by striking "subparagraph (D)" and inserting "subparagraph (D)(ii)".

(b) DRUGS.—Section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended by striking "except where it is not feasible or it is contrary to the best interests of such human beings" and inserting "except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings".

Subtitle D—Patient Access to Therapies and Information

SEC. 3031. SUMMARY LEVEL REVIEW.

(a) FFDCA.—Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended by adding at the end the following:

"(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect

to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

"(B) A supplemental application is eligible for review as described in subparagraph (A) only if—

"(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

"(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

"(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually—

"(i) the number of applications reviewed solely under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

"(ii) the average time for completion of review under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

"(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act; and

"(iv) the number of applications reviewed under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act for which the Secretary made use of full data sets in addition to the qualified data summary.

"(D) In this paragraph—

"(i) the term 'qualified indication' means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

"(ii) the term 'qualified data summary' means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.".

(b) PHSA.—Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended by adding at the end the following:

"(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

"(ii) In this subparagraph, the terms 'qualified indication' and 'qualified data summary' have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.".

SEC. 3032. EXPANDED ACCESS POLICY.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561 (21 U.S.C. 360bbb) the following:

21 USC 360bbb–0.

"SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.

"(a) IN GENERAL.—The manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 561(b) for provision of such a drug.

"(b) PUBLIC AVAILABILITY OF EXPANDED ACCESS POLICY.—The policies under subsection (a) shall be made public and readily available, such as by posting such policies on a publicly available Internet website. Such policies may be generally applicable to all investigational drugs of such manufacturer or distributor.

"(c) CONTENT OF POLICY.—A policy described in subsection (a) shall include—

"(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

"(2) procedures for making such requests;

"(3) the general criteria the manufacturer or distributor will use to evaluate such requests for individual patients, and for responses to such requests;

"(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and

"(5) a hyperlink or other reference to the clinical trial record containing information about the expanded access for such drug that is required under section 402(j)(2)(A)(ii)(II)(gg) of the Public Health Service Act.

"(d) NO GUARANTEE OF ACCESS.—The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

"(e) REVISED POLICY.—Nothing in this section shall prevent a manufacturer or distributor from revising a policy required under this section at any time.

"(f) APPLICATION.—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the later of—

"(1) the date that is 60 calendar days after the date of enactment of the 21st Century Cures Act; or

"(2) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational drug.".

SEC. 3033. ACCELERATED APPROVAL FOR REGENERATIVE ADVANCED THERAPIES.

(a) IN GENERAL.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) by transferring subsection (e) (relating to construction) so that it appears before subsection (f) (relating to awareness efforts); and

(2) by adding at the end the following:

"(g) REGENERATIVE ADVANCED THERAPY.—

"(1) IN GENERAL.—The Secretary, at the request of the sponsor of a drug, shall facilitate an efficient development program for, and expedite review of, such drug if the drug qualifies as a regenerative advanced therapy under the criteria described in paragraph (2).

"(2) CRITERIA.—A drug is eligible for designation as a regenerative advanced therapy under this subsection if—

"(A) the drug is a regenerative medicine therapy (as defined in paragraph (8));

"(B) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and

"(C) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition.

"(3) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a regenerative advanced therapy concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

"(4) DESIGNATION.—Not later than 60 calendar days after the receipt of a request under paragraph (3), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (2). If the Secretary determines that the drug meets the criteria, the Secretary shall designate the drug as a regenerative advanced therapy and shall take such actions as are appropriate under paragraph (1). If the Secretary determines that a drug does not meet the criteria for such designation, the Secretary shall include with the determination a written description of the rationale for such determination.

"(5) ACTIONS.—The sponsor of a regenerative advanced therapy shall be eligible for the actions to expedite development and review of such therapy under subsection (a)(3)(B), including early interactions to discuss any potential surrogate or intermediate endpoint to be used to support the accelerated approval of an application for the product under subsection (c).

"(6) ACCESS TO EXPEDITED APPROVAL PATHWAYS.—An application for a regenerative advanced therapy under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act may be—

"(A) eligible for priority review, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012; and

"(B) eligible for accelerated approval under subsection (c), as agreed upon pursuant to subsection (a)(3)(B), through, as appropriate—

"(i) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit; or

"(ii) reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate.

"(7) POSTAPPROVAL REQUIREMENTS.—The sponsor of a regenerative advanced therapy that is granted accelerated approval and is subject to the postapproval requirements under subsection (c) may, as appropriate, fulfill such requirements, as the Secretary may require, through—

"(A) the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records;

"(B) the collection of larger confirmatory data sets, as agreed upon pursuant to subsection (a)(3)(B); or

"(C) postapproval monitoring of all patients treated with such therapy prior to approval of the therapy.

"(8) DEFINITION.—For purposes of this section, the term 'regenerative medicine therapy' includes cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act and part 1271 of title 21, Code of Federal Regulations.".

(b) RULE OF CONSTRUCTION.—Nothing in this section and the amendments made by this section shall be construed to alter the authority of the Secretary of Health and Human Services— 21 USC 356 note.

(1) to approve drugs pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and section 351 of the Public Health Service Act (42 U.S.C. 262) as authorized prior to the date of enactment of the 21st Century Cures Act, including the standards of evidence, and applicable conditions, for approval under such Acts; or

(2) to alter the authority of the Secretary to require postapproval studies pursuant to such Acts, as authorized prior to the date of enactment of the 21st Century Cures Act.

(c) CONFORMING AMENDMENT.—Section 506(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(e)(1)) is amended by inserting "and the 21st Century Cures Act" after "Food and Drug Administration Safety and Innovation Act".

SEC. 3034. GUIDANCE REGARDING DEVICES USED IN THE RECOVERY, ISOLATION, OR DELIVERY OF REGENERATIVE ADVANCED THERAPIES. 21 USC 356g note.

(a) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance clarifying how, in the context of regenerative advanced therapies, the Secretary will evaluate devices used in the recovery, isolation, or delivery of regenerative advanced therapies. In doing so, the Secretary shall specifically address—

(1) how the Food and Drug Administration intends to simplify and streamline regulatory requirements for combination device and cell or tissue products;

(2) what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device;

(3) when the Food and Drug Administration considers it is necessary, if ever, for the intended use of a device to be limited to a specific intended use with only one particular type of cell; and

(4) application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.

(b) FINAL GUIDANCE.—Not later than 12 months after the close of the period for public comment on the draft guidance under subsection (a), the Secretary of Health and Human Services shall finalize such guidance.

SEC. 3035. REPORT ON REGENERATIVE ADVANCED THERAPIES. 21 USC 356 note.

(a) REPORT TO CONGRESS.—Before March 1 of each calendar year, the Secretary of Health and Human Services shall, with

respect to the previous calendar year, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(1) the number and type of applications for approval of regenerative advanced therapies filed, approved or licensed as applicable, withdrawn, or denied; and

(2) how many of such applications or therapies, as applicable, were granted accelerated approval or priority review.

(b) REGENERATIVE ADVANCED THERAPY.—In this section, the term "regenerative advanced therapy" has the meaning given such term in section 506(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 3033 of this Act.

SEC. 3036. STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following:

21 USC 356g.

"SEC. 506G. STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES.

"(a) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordinate and prioritize the development of standards and consensus definition of terms, through a public process, to support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies, including with respect to the manufacturing processes and controls of such products.

"(b) ACTIVITIES.—

"(1) IN GENERAL.—In carrying out this section, the Secretary shall continue to—

"(A) identity opportunities to help advance the development of regenerative medicine therapies and regenerative advanced therapies;

"(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies through regulatory predictability; and

"(C) work with stakeholders, such as those described in subsection (a), as appropriate, in the development of such standards.

"(2) REGULATIONS AND GUIDANCE.—Not later than 1 year after the development of standards as described in subsection (a), the Secretary shall review relevant regulations and guidance and, through a public process, update such regulations and guidance as the Secretary determines appropriate.

"(c) DEFINITIONS.—For purposes of this section, the terms 'regenerative medicine therapy' and 'regenerative advanced therapy' have the meanings given such terms in section 506(g).".

SEC. 3037. HEALTH CARE ECONOMIC INFORMATION.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)) is amended—

(1) by striking "(a) If its" and inserting "(a)(1) If its";

(2) by striking "a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations" and inserting "a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement";

(3) by striking "directly relates" and inserting "relates";

(4) by striking "and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph" and inserting ", is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph"; and

(5) by striking "In this paragraph, the term" and all that follows and inserting the following:

"(2)(A) For purposes of this paragraph, the term 'health care economic information' means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.

"(B) Such term does not include any analysis that relates only to an indication that is not approved under section 505 or under section 351 of the Public Health Service Act for such drug.".

SEC. 3038. COMBINATION PRODUCT INNOVATION.

(a) IN GENERAL.—Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

(1) by striking paragraph (3);

(2) by redesignating paragraph (2) as paragraph (7);

(3) by redesignating paragraphs (4) and (5) as paragraphs (8) and (9), respectively;

(4) by striking "(g)(1)" and all that follows through the end of paragraph (1) and inserting the following:

"(g)(1)(A) The Secretary shall, in accordance with this subsection, assign a primary agency center to regulate products that constitute a combination of a drug, device, or biological product.

"(B) The Secretary shall conduct the premarket review of any combination product under a single application, whenever appropriate.

"(C) For purposes of this subsection, the term 'primary mode of action' means the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

"(D) The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

"(i) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction;

"(ii) a device, the agency center charged with premarket review of devices shall have primary jurisdiction; or

"(iii) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

"(E) In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the combination product has any chemical action within or on the human body.

"(F) If a sponsor of a combination product disagrees with the determination under subparagraph (D)—

"(i) such sponsor may request, and the Secretary shall provide, a substantive rationale to such sponsor that references scientific evidence provided by the sponsor and any other scientific evidence relied upon by the Secretary to support such determination; and

"(ii)(I) the sponsor of the combination product may propose one or more studies (which may be nonclinical, clinical, or both) to establish the relevance, if any, of the chemical action in achieving the primary mode of action of such product;

"(II) if the sponsor proposes any such studies, the Secretary and the sponsor of such product shall collaborate and seek to reach agreement, within a reasonable time of such proposal, not to exceed 90 calendar days, on the design of such studies; and

"(III) if an agreement is reached under subclause (II) and the sponsor conducts one or more of such studies, the Secretary shall consider the data resulting from any such study when reevaluating the determination of the primary mode of action of such product, and unless and until such reevaluation has occurred and the Secretary issues a new determination, the determination of the Secretary under subparagraph (D) shall remain in effect.

"(2)(A)(i) To establish clarity and certainty for the sponsor, the sponsor of a combination product may request a meeting on such combination product. If the Secretary concludes that a determination of the primary mode of action pursuant to paragraph (1)(D) is necessary, the sponsor may request such meeting only after the Secretary makes such determination. If the sponsor submits a written meeting request, the Secretary shall, not later than

75 calendar days after receiving such request, meet with the sponsor of such combination product.

"(ii) A meeting under clause (i) may—

"(I) address the standards and requirements for market approval or clearance of the combination product;

"(II) address other issues relevant to such combination product, such as requirements related to postmarket modification of such combination product and good manufacturing practices applicable to such combination product; and

"(III) identify elements under subclauses (I) and (II) that may be more appropriate for discussion and agreement with the Secretary at a later date given that scientific or other information is not available, or agreement is otherwise not feasible regarding such elements, at the time a request for such meeting is made.

"(iii) Any agreement under this subparagraph shall be in writing and made part of the administrative record by the Secretary.

"(iv) Any such agreement shall remain in effect, except—

"(I) upon the written agreement of the Secretary and the sponsor or applicant; or

"(II) pursuant to a decision by the director of the reviewing division of the primary agency center, or a person more senior than such director, in consultation with consulting centers and the Office, as appropriate, that an issue essential to determining whether the standard for market clearance or other applicable standard under this Act or the Public Health Service Act applicable to the combination product has been identified since the agreement was reached, or that deviating from the agreement is otherwise justifiable based on scientific evidence, for public health reasons.

"(3) For purposes of conducting the premarket review of a combination product that contains an approved constituent part described in paragraph (4), the Secretary may require that the sponsor of such combination product submit to the Secretary only data or information that the Secretary determines is necessary to meet the standard for clearance or approval, as applicable, under this Act or the Public Health Service Act, including any incremental risks and benefits posed by such combination product, using a risk-based approach and taking into account any prior finding of safety and effectiveness or substantial equivalence for the approved constituent part relied upon by the applicant in accordance with paragraph (5).

"(4) For purposes of paragraph (3), an approved constituent part is—

"(A) a drug constituent part of a combination product being reviewed in a single application or request under section 515, 510(k), or 513(f)(2) (submitted in accordance with paragraph (5)), that is an approved drug, provided such application or request complies with paragraph (5);

"(B) a device constituent part approved under section 515 that is referenced by the sponsor and that is available for use by the Secretary under section 520(h)(4); or

"(C) any constituent part that was previously approved, cleared, or classified under section 505, 510(k), 513(f)(2), or 515 of this Act for which the sponsor has a right of reference or any constituent part that is a nonprescription drug, as defined in section 760(a)(2).

"(5)(A) If an application is submitted under section 515 or 510(k) or a request is submitted under section 513(f)(2), consistent with any determination made under paragraph (1)(D), for a combination product containing as a constituent part an approved drug—

"(i) the application or request shall include the certification or statement described in section 505(b)(2); and

"(ii) the applicant or requester shall provide notice as described in section 505(b)(3).

"(B) For purposes of this paragraph and paragraph (4), the term 'approved drug' means an active ingredient—

"(i) that was in an application previously approved under section 505(c);

"(ii) where such application is relied upon by the applicant submitting the application or request described in subparagraph (A);

"(iii) for which full reports of investigations that have been made to show whether such drug is safe for use and whether such drug is effective in use were not conducted by or for the applicant submitting the application or request described in subparagraph (A); and

"(iv) for which the applicant submitting the application or request described in subparagraph (A) has not obtained a right of reference or use from the person by or for whom the investigations described in clause (iii) were conducted.

"(C) The following provisions shall apply with respect to an application or request described in subparagraph (A) to the same extent and in the same manner as if such application or request were an application described in section 505(b)(2) that referenced the approved drug:

"(i) Subparagraphs (A), (B), (C), and (D) of section 505(c)(3).

"(ii) Clauses (ii), (iii), and (iv) of section 505(c)(3)(E).

"(iii) Subsections (b) and (c) of section 505A.

"(iv) Section 505E(a).

"(v) Section 527(a).

"(D) Notwithstanding any other provision of this subsection, an application or request for classification for a combination product described in subparagraph (A) shall be considered an application submitted under section 505(b)(2) for purposes of section 271(e)(2)(A) of title 35, United States Code.

"(6) Nothing in this subsection shall be construed as prohibiting a sponsor from submitting separate applications for the constituent parts of a combination product, unless the Secretary determines that a single application is necessary.";

(5) in paragraph (8) (as redesignated by paragraph (3))—

(A) in subparagraph (C)—

(i) by amending clause (i) to read as follows:

"(i) In carrying out this subsection, the Office shall help to ensure timely and effective premarket review that involves more than one agency center by coordinating such reviews, overseeing the timeliness of such reviews, and overseeing the alignment of feedback regarding such reviews.";

(ii) in clause (ii), by inserting "and alignment" after "the timeliness" each place it appears; and

(iii) by adding at the end the following new clauses:

"(iii) The Office shall ensure that, with respect to a combination product, a designated person or persons in the primary agency

center is the primary point or points of contact for the sponsor of such combination product. The Office shall also coordinate communications to and from any consulting center involved in such premarket review, if requested by such primary agency center or any such consulting center. Agency communications and commitments, to the extent consistent with other provisions of law and the requirements of all affected agency centers, from the primary agency center shall be considered as communication from the Secretary on behalf of all agency centers involved in the review.

"(iv) The Office shall, with respect to the premarket review of a combination product—

"(I) ensure that any meeting between the Secretary and the sponsor of such product is attended by each agency center involved in the review, as appropriate;

"(II) ensure that each consulting agency center has completed its premarket review and provided the results of such review to the primary agency center in a timely manner; and

"(III) ensure that each consulting center follows the guidance described in clause (vi) and advises, as appropriate, on other relevant regulations, guidances, and policies.

"(v) In seeking agency action with respect to a combination product, the sponsor of such product—

"(I) shall identify the product as a combination product; and

"(II) may request in writing the participation of representatives of the Office in meetings related to such combination product, or to have the Office otherwise engage on such regulatory matters concerning the combination product.

"(vi) Not later than 4 years after the date of enactment of the 21st Century Cures Act, and after a public comment period of not less than 60 calendar days, the Secretary shall issue a final guidance that describes—

"(I) the structured process for managing pre-submission interactions with sponsors developing combination products;

"(II) the best practices for ensuring that the feedback in such pre-submission interactions represents the Agency's best advice based on the information provided during such pre-submission interactions;

"(III) the information that is required to be submitted with a meeting request under paragraph (2), how such meetings relate to other types of meetings in the Food and Drug Administration, and the form and content of any agreement reached through a meeting under such paragraph (2);"; and

(B) in subparagraph (G)—

(i) in the matter preceding clause (i), by inserting "(except with respect to clause (iv), beginning not later than one year after the date of the enactment of the 21st Century Cures Act)" after "enactment of this paragraph";

(ii) in clause (ii), by striking "and" at the end;

(iii) in clause (iii), by striking the period at the end and inserting "; and"; and

(iv) by adding at the end the following new clause:

"(iv) identifying the percentage of combination products for which a dispute resolution, with respect to premarket review, was requested by the combination product's sponsor."; and

(6) in paragraph (9) (as redesignated by paragraph (3))—

(A) in subparagraph (C)—

(i) in clause (i), by striking the comma at the end and inserting a semicolon;

(ii) in clause (ii), by striking ", and" at the end and inserting a semicolon;

(iii) in clause (iii), by striking the period at the end and inserting "; and"; and

(iv) by adding at the end the following:

"(iv) de novo classification under section 513(a)(1)."; and

(B) by adding at the end the following:

"(D) The terms 'premarket review' and 'reviews' include all activities of the Food and Drug Administration conducted prior to approval or clearance of an application, notification, or request for classification submitted under section 505, 510(k), 513(f)(2), 515, or 520 of this Act or under section 351 of the Public Health Service Act, including with respect to investigational use of the product.".

(b) INFORMATION FOR APPROVAL OF COMBINATION PRODUCTS.—Section 520(h)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(h)(4)) is amended—

(1) in subparagraph (A), by striking "Any information" and inserting "Subject to subparagraph (C), any information"; and

(2) by adding at the end the following new subparagraph:

"(C) No information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) may be used to approve or clear any application submitted under section 515 or 510(k) or to classify a product under section 513(f)(2) for a combination product containing as a constituent part an approved drug (as defined in section 503(g)(5)(B)) unless—

"(i) the application includes the certification or statement referenced in section 503(g)(5)(A);

"(ii) the applicant provides notice as described in section 503(g)(5)(A); and

"(iii) the Secretary's approval of such application is subject to the provisions in section 503(g)(5)(C).".

21 USC 355 note.

(c) VARIATIONS FROM CGMP STREAMLINED APPROACH.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall identify types of combination products and manufacturing processes with respect to which the Secretary proposes that good manufacturing processes may be adopted that vary from the requirements set forth in section 4.4 of title 21, Code of Federal Regulations (or any successor regulations) or that the Secretary proposes can satisfy the requirements in section 4.4 through alternative or streamlined mechanisms. The Secretary shall identify such types, variations from such requirements, and such mechanisms, in a proposed list published in the Federal Register. After a public comment period regarding the appropriate good manufacturing practices for such types, the Secretary shall publish a final list in the Federal Register, notwithstanding section 553 of title 5, United States Code. The Secretary shall evaluate such types, variations, and mechanisms using a risk-based approach. The Secretary shall periodically review such final list.

Subtitle E—Antimicrobial Innovation and Stewardship

SEC. 3041. ANTIMICROBIAL RESISTANCE MONITORING.

(a) IN GENERAL.—Section 319E of the Public Health Service Act (42 U.S.C. 247d–5) is amended—

(1) by redesignating subsections (f) and (g) as subsections (l) and (m), respectively; and

(2) by inserting after subsection (e), the following:

"(f) MONITORING AT FEDERAL HEALTH CARE FACILITIES.—The Secretary shall encourage reporting on aggregate antimicrobial drug use and antimicrobial resistance to antimicrobial drugs and the implementation of antimicrobial stewardship programs by health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service and shall provide technical assistance to the Secretary of Defense and the Secretary of Veterans Affairs, as appropriate and upon request.

"(g) REPORT ON ANTIMICROBIAL RESISTANCE IN HUMANS AND USE OF ANTIMICROBIAL DRUGS.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, and annually thereafter, the Secretary shall prepare and make publicly available data and information concerning—

"(1) aggregate national and regional trends of antimicrobial resistance in humans to antimicrobial drugs, including such drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act;

"(2) antimicrobial stewardship, which may include summaries of State efforts to address antimicrobial resistance in humans to antimicrobial drugs and antimicrobial stewardship; and

"(3) coordination between the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs with respect to the monitoring of—

"(A) any applicable resistance under paragraph (1); and

"(B) drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act.

"(h) INFORMATION RELATED TO ANTIMICROBIAL STEWARDSHIP PROGRAMS.—The Secretary shall, as appropriate, disseminate guidance, educational materials, or other appropriate materials related to the development and implementation of evidence-based antimicrobial stewardship programs or practices at health care facilities, such as nursing homes and other long-term care facilities, ambulatory surgical centers, dialysis centers, outpatient clinics, and hospitals, including community and rural hospitals.

"(i) SUPPORTING STATE-BASED ACTIVITIES TO COMBAT ANTIMICROBIAL RESISTANCE.—The Secretary shall continue to work with State and local public health departments on statewide or regional programs related to antimicrobial resistance. Such efforts may include activities to related to—

"(1) identifying patterns of bacterial and fungal resistance in humans to antimicrobial drugs;

"(2) preventing the spread of bacterial and fungal infections that are resistant to antimicrobial drugs; and

"(3) promoting antimicrobial stewardship.

"(j) ANTIMICROBIAL RESISTANCE AND STEWARDSHIP ACTIVITIES.—

"(1) IN GENERAL.—For the purposes of supporting stewardship activities, examining changes in antimicrobial resistance, and evaluating the effectiveness of section 506(h) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall—

"(A) provide a mechanism for facilities to report data related to their antimicrobial stewardship activities (including analyzing the outcomes of such activities); and

"(B) evaluate—

"(i) antimicrobial resistance data using a standardized approach; and

"(ii) trends in the utilization of drugs approved under such section 506(h) with respect to patient populations.

"(2) USE OF SYSTEMS.—The Secretary shall use available systems, including the National Healthcare Safety Network or other systems identified by the Secretary, to fulfill the requirements or conduct activities under this section.

"(k) ANTIMICROBIAL.—For purposes of subsections (f) through (j), the term 'antimicrobial' includes any antibacterial or antifungal drugs, and may include drugs that eliminate or inhibit the growth of other microorganisms, as appropriate.".

42 USC 247d–5 note.

(b) AVAILABILITY OF DATA.—The Secretary shall make the data collected pursuant to this subsection public. Nothing in this subsection shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 3042. LIMITED POPULATION PATHWAY.

Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by section 3033, is further amended by adding at the end the following:

"(h) LIMITED POPULATION PATHWAY FOR ANTIBACTERIAL AND ANTIFUNGAL DRUGS.—

"(1) IN GENERAL.—The Secretary may approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, as a limited population drug pursuant to this subsection only if—

"(A) the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs;

"(B) the standards for approval under section 505(c) and (d), or the standards for licensure under section 351 of the Public Health Service Act, as applicable, are met; and

"(C) the Secretary receives a written request from the sponsor to approve the drug as a limited population drug pursuant to this subsection.

"(2) BENEFIT-RISK CONSIDERATION.—The Secretary's determination of safety and effectiveness of an antibacterial or antifungal drug shall reflect the benefit-risk profile of such drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such limited population. Such drug may be

approved under this subsection notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population.

"(3) ADDITIONAL REQUIREMENTS.—A drug approved under this subsection shall be subject to the following requirements, in addition to any other applicable requirements of this Act:

"(A) LABELING.—To indicate that the safety and effectiveness of a drug approved under this subsection has been demonstrated only with respect to a limited population—

"(i) all labeling and advertising of an antibacterial or antifungal drug approved under this subsection shall contain the statement 'Limited Population' in a prominent manner and adjacent to, and not more prominent than—

"(I) the proprietary name of such drug, if any; or

"(II) if there is no proprietary name, the established name of the drug, if any, as defined in section 503(e)(3), or, in the case of a drug that is a biological product, the proper name, as defined by regulation; and

"(ii) the prescribing information for the drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: 'This drug is indicated for use in a limited and specific population of patients.'.

"(B) PROMOTIONAL MATERIAL.—The sponsor of an antibacterial or antifungal drug subject to this subsection shall submit to the Secretary copies of all promotional materials related to such drug at least 30 calendar days prior to dissemination of the materials.

"(4) OTHER PROGRAMS.—A sponsor of a drug that seeks approval of a drug under this subsection may also seek designation or approval, as applicable, of such drug under other applicable sections or subsections of this Act or the Public Health Service Act.

"(5) GUIDANCE.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs. The Secretary shall publish final guidance within 18 months of the close of the public comment period on such draft guidance. The Secretary may approve antibacterial and antifungal drugs under this subsection prior to issuing guidance under this paragraph.

"(6) ADVICE.—The Secretary shall provide prompt advice to the sponsor of a drug for which the sponsor seeks approval under this subsection to enable the sponsor to plan a development program to obtain the necessary data for such approval, and to conduct any additional studies that would be required to gain approval of such drug for use in a broader population.

"(7) TERMINATION OF LIMITATIONS.—If, after approval of a drug under this subsection, the Secretary approves a broader indication for such drug under section 505(b) or section 351(a) of the Public Health Service Act, the Secretary may remove

any postmarketing conditions, including requirements with respect to labeling and review of promotional materials under paragraph (3), applicable to the approval of the drug under this subsection.

"(8) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter the authority of the Secretary to approve drugs pursuant to this Act or section 351 of the Public Health Service Act, including the standards of evidence and applicable conditions for approval under such Acts, the standards of approval of a drug under such Acts, or to alter the authority of the Secretary to monitor drugs pursuant to such Acts.

"(9) REPORTING AND ACCOUNTABILITY.—

"(A) BIENNIAL REPORTING.—The Secretary shall report to Congress not less often than once every 2 years on the number of requests for approval, and the number of approvals, of an antibacterial or antifungal drug under this subsection.

"(B) GAO REPORT.—Not later than December 2021, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the coordination of activities required under section 319E of the Public Health Service Act. Such report shall include a review of such activities, and the extent to which the use of the pathway established under this subsection has streamlined premarket approval for antibacterial or antifungal drugs for limited populations, if such pathway has functioned as intended, if such pathway has helped provide for safe and effective treatment for patients, if such premarket approval would be appropriate for other categories of drugs, and if the authorities under this subsection have affected antibacterial or antifungal resistance.".

21 USC 356 note.

SEC. 3043. PRESCRIBING AUTHORITY.

Nothing in this subtitle, or an amendment made by this subtitle, shall be construed to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under subsection (h) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as added by section 3042), by health care professionals, or to limit the practice of health care.

SEC. 3044. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS; ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 511 the following:

21 USC 360a–2.

"SEC. 511A. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

"(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

"(1) PURPOSE.—The purpose of this section is to clarify the Secretary's authority to—

"(A) efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public

health, due to, among other things, the constant evolution of microorganisms that leads to the development of resistance to drugs that have been effective in decreasing morbidity and mortality for patients, which warrants unique management of antimicrobial drugs that is inappropriate for most other drugs in order to delay or prevent the development of further resistance to existing therapies;

"(B) provide for public notice of the availability of recognized interpretive criteria and interpretive criteria standards; and

"(C) clear under section 510(k), classify under section 513(f)(2), or approve under section 515, antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms, as applicable, to antimicrobial drugs.

"(2) IDENTIFICATION OF CRITERIA.—The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

"(A) if such criteria are available on the date of approval of the drug under section 505 of this Act or licensure of the drug under section 351 of the Public Health Service Act (as applicable), upon such approval or licensure; or

"(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

"(3) BASES FOR INITIAL IDENTIFICATION.—The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (2), based on the Secretary's review of, to the extent available and relevant—

"(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

"(B) the relationship of susceptibility test interpretive criteria to morbidity and mortality associated with the disease or condition for which such drug is used; and

"(C) such other evidence and information as the Secretary considers appropriate.

"(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.—

"(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the 21st Century Cures Act, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards and interpretive criteria in accordance with paragraph (2) (referred to in this section as the 'Interpretive Criteria Website').

"(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS AND INTERPRETIVE CRITERIA.—

"(A) IN GENERAL.—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

"(i) established by a nationally or internationally recognized standard development organization that—

"(I) establishes and maintains procedures to address potential conflicts of interest and ensure transparent decisionmaking;

"(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decision-making; and

"(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

"(ii) recognized in whole, or in part, by the Secretary under subsection (c).

"(B) OTHER LIST.—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include a list of interpretive criteria, if any, that the Secretary has determined to be appropriate with respect to legally marketed antimicrobial drugs, where—

"(i) the Secretary does not recognize, in whole or in part, an interpretive criteria standard described under subparagraph (A) otherwise applicable to such a drug;

"(ii) the Secretary withdraws under subsection (c)(1)(A) recognition of a standard, in whole or in part, otherwise applicable to such a drug;

"(iii) the Secretary approves an application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, with respect to marketing of such a drug for which there are no relevant interpretive criteria included in a standard recognized by the Secretary under subsection (c); or

"(iv) because the characteristics of such a drug differ from other drugs with the same active ingredient, the interpretive criteria with respect to such drug—

"(I) differ from otherwise applicable interpretive criteria included in a standard listed under subparagraph (A) or interpretive criteria otherwise listed under this subparagraph; and

"(II) are determined by the Secretary to be appropriate for the drug.

"(C) REQUIRED STATEMENTS.—The Interpretive Criteria Website shall include statements conveying—

"(i) that the website provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to a certain drug (or drugs);

"(ii) that—

"(I) the safety and efficacy of such drugs in treating clinical infections due to such bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the susceptibility information described in clause (i) to be included on the website; and

"(II) the clinical significance of such susceptibility information in such instances is unknown;

"(iii) that the approved product labeling for specific drugs provides the uses for which the Secretary has approved the product; and

"(iv) any other information that the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria included on the website.

"(3) NOTICE.—Not later than the date on which the Interpretive Criteria Website is established, the Secretary shall publish a notice of that establishment in the Federal Register.

"(4) INAPPLICABILITY OF MISBRANDING PROVISION.—The inclusion in the approved labeling of an antimicrobial drug of a reference or hyperlink to the Interpretive Criteria Website, in and of itself, shall not cause the drug to be misbranded in violation of section 502.

"(5) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

"(c) RECOGNITION OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA.—

"(1) EVALUATION AND PUBLICATION.—

"(A) IN GENERAL.—Beginning on the date of the establishment of the Interpretive Criteria Website, and at least every 6 months thereafter, the Secretary shall—

"(i) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (b)(2)(A)(i); and

"(ii) publish on the public website of the Food and Drug Administration a notice—

"(I) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

"(II) recognizing the new or updated standards;

"(III) recognizing one or more parts of the new or updated interpretive criteria specified in such a standard and declining to recognize the remainder of such standard; and

"(IV) making any necessary updates to the lists under subsection (b)(2).

"(B) UPON APPROVAL OF A DRUG.—Upon the approval of an initial or supplemental application for an antimicrobial drug under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, where such approval is based on susceptibility test interpretive criteria which differ from those contained in a standard recognized, or from those otherwise listed, by the Secretary pursuant to this subsection, or for which there are no relevant interpretive criteria standards recognized, or interpretive criteria otherwise listed, by the Secretary pursuant to this subsection, the Secretary shall update the lists under subparagraphs (A) and (B) of subsection (b)(2) to include the susceptibility test interpretive criteria upon which such approval was based.

"(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards under paragraph (1)(A), the Secretary may consider—

"(A) the Secretary's determination that such a standard is not applicable to a particular drug because the characteristics of the drug differ from other drugs with the same active ingredient;

"(B) information provided by interested third parties, including public comment on the annual compilation of notices published under paragraph (3);

"(C) any bases used to identify susceptibility test interpretive criteria under subsection (a)(2); and

"(D) such other information or factors as the Secretary determines appropriate.

"(3) ANNUAL COMPILATION OF NOTICES.—Each year, the Secretary shall compile the notices published under paragraph (1)(A) and publish such compilation in the Federal Register and provide for public comment. If the Secretary receives comments, the Secretary shall review such comments and, if the Secretary determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards or criteria—

"(A) recognized by the Secretary under this subsection; or

"(B) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(4) RELATION TO SECTION 514(c).—Any susceptibility test interpretive standard recognized under this subsection or any criteria otherwise listed under subsection (b)(2)(B) shall be deemed to be recognized as a standard by the Secretary under section 514(c)(1).

"(5) VOLUNTARY USE OF INTERPRETIVE CRITERIA.—Nothing in this section prohibits a person from seeking approval or clearance of a drug or device, or changes to the drug or the device, on the basis of susceptibility test interpretive criteria which differ from those contained in a standard recognized, or from those otherwise listed, by the Secretary pursuant to subsection (b)(2).

"(d) ANTIMICROBIAL DRUG LABELING.—

"(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—

"(A) IN GENERAL.—With respect to an antimicrobial drug lawfully introduced or delivered for introduction into interstate commerce for commercial distribution before the establishment of the Interpretive Criteria Website, a holder of an approved application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, for each such drug, not later than 1 year after establishment of the Interpretive Criteria Website described in subsection (b)(1), shall remove susceptibility test interpretive criteria, if any, and related information from the approved drug labeling and replace it with a reference to the Interpretive Criteria Website.

"(B) LABELING CHANGES.—The labeling changes required by this section shall be considered a minor change

under section 314.70 of title 21, Code of Federal Regulations (or any successor regulations) that may be implemented through documentation in the next applicable annual report.

"(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs approved on or after the date of the establishment of the Interpretive Criteria Website described in subsection (b)(1), the labeling for such a drug shall include, in lieu of susceptibility test interpretive criteria and related information, a reference to such Website.

"(e) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

"(1) IN GENERAL.—Notwithstanding sections 501, 502, 505, 510, 513, and 515, if the conditions specified in paragraph (2) are met (in addition to other applicable provisions under this chapter) with respect to an antimicrobial susceptibility testing device described in subsection (f)(1), the Secretary may authorize the marketing of such device for a use described in such subsection.

"(2) CONDITIONS APPLICABLE TO ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The conditions specified in this paragraph are the following:

"(A) The device is used to make a determination of susceptibility using susceptibility test interpretive criteria that are—

"(i) included in a standard recognized by the Secretary under subsection (c); or

"(ii) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(B) The labeling of such device includes statements conveying—

"(i) that the device provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to antimicrobial drugs;

"(ii) that—

"(I) the safety and efficacy of such drugs in treating clinical infections due to such bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the device to report the susceptibility of such bacteria, fungi, or other microorganisms, as applicable, to such drugs; and

"(II) the clinical significance of such susceptibility information in those instances is unknown;

"(iii) that the approved labeling for drugs tested using such a device provides the uses for which the Secretary has approved such drugs; and

"(iv) any other information the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria described in subparagraph (A).

"(C) The antimicrobial susceptibility testing device meets all other requirements to be cleared under section

510(k), classified under section 513(f)(2), or approved under section 515.

"(f) DEFINITIONS.—In this section:

"(1) The term 'antimicrobial susceptibility testing device' means a device that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).

"(2) The term 'qualified infectious disease product' means a qualified infectious disease product designated under section 505E(d).

"(3) The term 'susceptibility test interpretive criteria' means—

"(A) one or more specific numerical values which characterize the susceptibility of bacteria or other microorganisms to the drug tested; and

"(B) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

"(4)(A) The term 'antimicrobial drug' means, subject to subparagraph (B), a systemic antibacterial or antifungal drug that—

"(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus;

"(ii) may include a qualified infectious disease product designated under section 505E(d); and

"(iii) is subject to section 503(b)(1).

"(B) If provided by the Secretary through regulations, such term may include—

"(i) drugs other than systemic antibacterial and antifungal drugs; and

"(ii) biological products (as such term is defined in section 351 of the Public Health Service Act) to the extent such products exhibit antimicrobial activity.

"(5) The term 'interpretive criteria standard' means a compilation of susceptibility test interpretive criteria developed by a standard development organization that meets the criteria set forth in subsection (b)(2)(A)(i).

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(1) alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard under section 505(d)) or under section 351 of the Public Health Service Act (as applicable); or

"(2) with respect to clearing devices under section 510(k), classifying devices under section 513(f)(2), or approving devices under section 515—

"(A) apply with respect to any drug, device, or biological product, in any context other than an antimicrobial drug and an antimicrobial susceptibility testing device that uses susceptibility test interpretive criteria to characterize and report the susceptibility of certain bacteria, fungi, or other microorganisms, as applicable, to such drug to reflect patient morbidity and mortality in accordance with this section; or

"(B) unless specifically stated, have any effect on authorities provided under other sections of this Act, including any regulations issued under such sections.".

(b) CONFORMING AMENDMENTS.—

(1) REPEAL OF PRIOR RELATED AUTHORITY.—Section 1111 of the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 247d–5a), relating to identification of clinically susceptible concentrations of antimicrobials, is repealed.

(2) ADDITION TO CATEGORIES OF MISBRANDED DRUGS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following: "(dd) If it is an antimicrobial drug, as defined in section 511A(f), and its labeling fails to conform with the requirements under section 511A(d).".

(3) RECOGNITION OF INTERPRETIVE CRITERIA STANDARD AS DEVICE STANDARD.—Section 514(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)(1)(A)) is amended by inserting after "the Secretary shall, by publication in the Federal Register" the following: "(or, with respect to a susceptibility test interpretive criteria standard under section 511A, by posting on the Interpretive Criteria Website in accordance with such section)".

(c) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the progress made in implementing section 511A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as added by subsection (a).

(d) REQUESTS FOR UPDATES TO INTERPRETIVE CRITERIA WEBSITE.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information from interested parties regarding updating the lists established under section 511A(b) of the Federal Food, Drug, and Cosmetic Act and posted on the Interpretive Criteria Website established under section 511A(c) of such Act. 21 USC 360a–2 note.

Subtitle F—Medical Device Innovations

SEC. 3051. BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515B, as added by section 3034(b), the following:

"SEC. 515C. BREAKTHROUGH DEVICES. 21 USC 360e–3.

"(a) PURPOSE.—The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies.

"(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

"(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

"(2)(A) that represent breakthrough technologies;

"(B) for which no approved or cleared alternatives exist;

"(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

"(D) the availability of which is in the best interest of patients.

"(c) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate such device for expedited development and priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a notification under section 510(k), or a petition for classification under section 513(f)(2).

"(d) DESIGNATION PROCESS.—

"(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for expedited development and priority review.

"(2) REVIEW.—Review of a request under subsection (c) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

"(3) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

"(A) was designated under this section; or

"(B) was given priority review under section 515(d)(5), as in effect prior to the date of enactment of the 21st Century Cures Act.

"(e) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.—

"(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (d) the Secretary shall—

"(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (c);

"(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (c) for the device;

"(C) adopt an efficient process for timely dispute resolution;

"(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

"(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

"(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend such external experts;

"(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor) for applications submitted under section 515(c); and

"(H) assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

"(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (d), the Secretary, in collaboration with the device sponsor, may, as appropriate—

"(A) coordinate with the sponsor regarding early agreement on a data development plan;

"(B) take steps to ensure that the design of clinical trials is as efficient and flexible as practicable, when scientifically appropriate;

"(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to application for approval under section 515(c); and

"(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

"(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

"(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

"(f) PRIORITY REVIEW GUIDANCE.—

"(1) CONTENT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

"(A) set forth the process by which a person may seek a designation under subsection (d);

"(B) provide a template for requests under subsection (c);

"(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

"(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

"(1) the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B) and consideration and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

"(2) the authority of the Secretary with respect to clinical holds under section 520(g)(8)(A);

"(3) the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary determines appropriate; or

"(4) the authority of the Secretary with respect to postmarket surveillance under sections 519(h) and 522.".

(b) DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is amended by inserting "a request for designation under section 515C," after "application under section 515,".

(c) TERMINATION OF PREVIOUS PROGRAM.—

(1) IN GENERAL.—Section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is amended—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5).

(2) CONFORMING AMENDMENT.—Section 737(5) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 379i(5)) is amended by striking "515(d)(6)" and inserting "515(d)(5)".

(d) REPORT.—On January 1, 2019, the Secretary of Health and Human Services shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) on the program under section 515C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in bringing safe and effective devices included in such program to patients as soon as possible; and

(2) that includes recommendations, if any, to strengthen the program to better meet patient device needs in a manner as timely as possible.

SEC. 3052. HUMANITARIAN DEVICE EXEMPTION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in paragraph (1) by striking "fewer than 4,000" and inserting "not more than 8,000";

(2) in paragraph (2)(A) by striking "fewer than 4,000" and inserting "not more than 8,000"; and

(3) in paragraph (6)(A)(ii), by striking "4,000" and inserting "8,000".

(b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that defines the criteria for establishing "probable benefit" as that term is used in section 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)). 21 USC 360j note.

SEC. 3053. RECOGNITION OF STANDARDS.

(a) IN GENERAL.—Section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (B) the following new subparagraphs:

"(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

"(ii) Not later than 60 calendar days after the Secretary receives such a request, the Secretary shall—

"(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

"(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

"(iii) The Secretary shall make a response issued under clause (ii)(II) publicly available, in such a manner as the Secretary determines appropriate.

"(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (ii)(I), in accordance with subparagraph (A).

"(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition."; and

(2) by adding at the end the following:

"(4) The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.".

(b) GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and update, if necessary, previously published guidance and standard operating procedures identifying the principles for recognizing standards, and for withdrawing the recognition of standards, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), taking into account the experience with and reliance on a standard by foreign regulatory authorities and the 21 USC 360d note.

device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

SEC. 3054. CERTAIN CLASS I AND CLASS II DEVICES.

(a) CLASS I DEVICES.—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended—

(1) by striking "A report under subsection (k)" and inserting "(1) A report under subsection (k)"; and

(2) by adding at the end the following new paragraph:

"(2) Not later than 120 calendar days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

"(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

"(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.".

(b) CLASS II DEVICES.—Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—

(1) by striking "(m)(1)" and all that follows through "by the Secretary." and inserting the following:

"(m)(1) The Secretary shall—

"(A) not later than 90 days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate—

"(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

"(ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice; and

"(B) not later than 210 calendar days after the date of enactment of the 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).";

(2) in paragraph (2)—

(A) by striking "1 day after the date of publication of a list under this subsection," and inserting "1 calendar day after the date of publication of the final list under paragraph (1)(B),"; and

(B) by striking "30-day period" and inserting "60-calendar-day period"; and

(C) by adding at the end the following new paragraph:

"(3) Upon the publication of the final list under paragraph (1)(B)—

"(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

"(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.".

SEC. 3055. CLASSIFICATION PANELS.

(a) CLASSIFICATION PANELS.—Paragraph (5) of section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended—

(1) by striking "(5)" and inserting "(5)(A)"; and

(2) by adding at the end the following:

"(B) When a device is specifically the subject of review by a classification panel, the Secretary shall—

"(i) ensure that adequate expertise is represented on the classification panel to assess—

"(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

"(II) the technology of the device; and

"(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

"(C) For purposes of subparagraph (B)(i), the term 'adequate expertise' means that the membership of the classification panel includes—

"(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

"(ii) at least one voting member who is knowledgeable about the technology of the device.

"(D) The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of medical device submissions to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.".

(b) PANEL REVIEW PROCESS.—Section 513(b)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(6)) is amended—

(1) in subparagraph (A)(iii), by inserting before the period at the end ", including, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person's organization to address such specific issues in the time provided"; and

(2) by striking subparagraph (B) and inserting the following new subparagraph:

"(B)(i) Any meeting of a classification panel with respect to the review of a device shall—

"(I) provide adequate time for initial presentations by the person whose device is specifically the subject of such review and by the Secretary; and

"(II) encourage free and open participation by all interested persons.

"(ii) Following the initial presentations described in clause (i), the panel may—

"(I) pose questions to a designated representative described in subparagraph (A)(iii); and

"(II) consider the responses to such questions in the panel's review of the device.".

SEC. 3056. INSTITUTIONAL REVIEW BOARD FLEXIBILITY.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in subsection (g)(3)—

(A) in subparagraph (A)(i)—

(i) by striking "local"; and

(ii) by striking "which has been"; and

(B) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(2) in subsection (m)(4)—

(A) by striking subparagraph (A) and inserting the following:

"(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary; and";

(B) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(C) in the matter following subparagraph (B), by striking "local".

42 USC 263a note.

SEC. 3057. CLIA WAIVER IMPROVEMENTS.

(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that—

(1) revises "Section V. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy" of the guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" and dated January 30, 2008; and

(2) includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.

SEC. 3058. LEAST BURDENSOME DEVICE REVIEW.

(a) IN GENERAL.—Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following:

"(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

"(1) The Secretary shall—

"(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section and section 515(c)(5); and

"(B) periodically assess the implementation of the least burdensome requirements, including the employee training

under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

"(2) Not later than 18 months after the date of enactment of the 21st Century Cures Act, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

"(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;

"(B) include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decisionmaking;

"(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

"(D) summarize the findings of such audit in a final audit report; and

"(E) within 30 calendar days of completion of such final audit report, make such final audit report available—

"(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

"(ii) on the Internet website of the Food and Drug Administration.".

(b) PREMARKET APPLICATIONS.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended by adding at the end the following:

"(5)(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

"(B) For purposes of subparagraph (A), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

"(C) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

"(D) Nothing in this paragraph alters the standards for premarket approval of a device.".

(c) RATIONALE FOR SIGNIFICANT DECISIONS REGARDING DEVICES.—Section 517A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)) is amended by adding at the end the following:

"(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 513(i)(1)(D), section 513(a)(3)(D), and section 515(c)(5), as applicable.".

SEC. 3059. CLEANING INSTRUCTIONS AND VALIDATION DATA REQUIREMENT.

(a) IN GENERAL.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

"(q) REUSABLE MEDICAL DEVICES.—

"(1) IN GENERAL.—Not later than 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall identify and publish a list of reusable device types for which reports under subsection (k) are required to include—

"(A) instructions for use, which have been validated in a manner specified by the Secretary; and

"(B) validation data, the types of which shall be specified by the Secretary;

regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

"(2) REVISION OF LIST.—The Secretary shall revise the list under paragraph (2), as the Secretary determines appropriate, with notice in the Federal Register.

"(3) CONTENT OF REPORTS.—Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on such list, shall include such instructions for use and validation data.".

21 USC 360 note.

(b) DEVICE MODIFICATIONS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue final guidance regarding when a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is required to be submitted for a modification or change to a legally marketed device. Such final guidance shall be issued not later than 1 year after the date on which the comment period closes for the draft guidance on such subject.

SEC. 3060. CLARIFYING MEDICAL SOFTWARE REGULATION.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

"(o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—

"(1) The term device, as defined in section 201(h), shall not include a software function that is intended—

"(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

"(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

"(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats,

or display the equivalent of a paper medical chart, so long as—

"(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

"(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

"(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

"(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

"(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

"(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

"(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

"(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

"(2) In the case of a product with multiple functions that contains—

"(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and

"(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),

the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

"(3)(A) Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1)

shall not be excluded from the definition of device under section 201(h) if—

"(i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

"(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

"(B) Subparagraph (A) shall apply only if the Secretary—

"(i) publishes a notification and proposed order in the Federal Register;

"(ii) includes in such notification the Secretary's finding, including the rationale and identification of the evidence on which such finding was based, as described in subparagraph (A)(i); and

"(iii) provides for a period of not less than 30 calendar days for public comment before issuing a final order or withdrawing such proposed order.

"(C) In making a finding under subparagraph (A)(i) with respect to a software function, the Secretary shall consider—

"(i) the likelihood and severity of patient harm if the software function were to not perform as intended;

"(ii) the extent to which the software function is intended to support the clinical judgment of a health care professional;

"(iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and

"(iv) the intended user and user environment, such as whether a health care professional will use a software function of a type described in subparagraph (E) of paragraph (1).

"(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

"(A) exercise enforcement discretion as to any device subject to regulation under this Act;

"(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

"(C) regulate software as a device under this Act if such software meets the criteria under section 513(a)(1)(C).".

21 USC 360j note.

(b) REPORTS.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, not later than 2 years after the date of enactment of this Act and every 2 years thereafter, that—

(1) includes input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary;

(2) examines information available to the Secretary on any risks and benefits to health associated with software functions described in section 520(o)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as amended by subsection (a)); and

(3) summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.

(c) CLASSIFICATION OF ACCESSORIES.—Section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended by adding at the end the following:

"(9) The Secretary shall classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.".

(d) CONFORMING AMENDMENT.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by adding at the end the following: "The term 'device' does not include software functions excluded pursuant to section 520(o).".

Subtitle G—Improving Scientific Expertise and Outreach at FDA

SEC. 3071. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH AND BIOMEDICAL PRODUCT ASSESSMENT SERVICE.

(a) HIRING AND RETENTION AUTHORITY.—Section 228 of the Public Health Service Act (42 U.S.C. 237) is amended—

(1) in the section heading, by inserting "**AND BIOMEDICAL PRODUCT ASSESSMENT**" after "**RESEARCH**";

(2) in subsection (a)—

(A) in paragraph (1), by striking "Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members" and inserting "Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the 'Service'), not to exceed 2,000 members, the purpose of which is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment";

(B) by amending paragraph (2) to read as follows:

"(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service."; and

(C) by adding at the end the following:

"(3) The Secretary shall assign experts under this section to agencies within the Department of Health and Human Services taking into account the need for the expertise of such expert.";

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "or clinical research evaluation" and inserting ", clinical research evaluation, or biomedical product assessment"; and

(B) in paragraph (1), by inserting "or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field," after the comma;

(4) in subsection (d)(2), by striking "and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5, United States Code" and inserting "and shall not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code";

(5) by striking subsection (e); and

(6) by redesignating subsections (f) and (g) as subsections (e) and (f), respectively.

(b) GAO STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the effectiveness of the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a) and the impact of such amendments, if any, on all agencies or departments of the Department of Health and Human Services, and, not later than 4 years after the date of enactment of this Act, shall submit a report based on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) CONTENT OF STUDY AND REPORT.—The study and report under paragraph (1) shall include an examination of the extent to which recruitment and retention of outstanding and qualified scientific, medical, or technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment have improved or otherwise have been affected by the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a), including by determining, during the period between the date of enactment of this Act and the completion of the study—

(A) the total number of members recruited and retained under the Senior Biomedical Research and Biomedical Product Assessment Service under such section 228, and the effect of increasing the number of members eligible for such Service;

(B) the number of members of such Senior Biomedical Research and Biomedical Product Assessment Service hired with a doctoral level degree in biomedicine or a related field, and the number of such members hired with a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field; and

(C) the number of Senior Biomedical Research and Biomedical Product Assessment Service members that have been hired by each agency or department of the Department of Health and Human Services, and how such Department assigns such members to each agency or department.

SEC. 3072. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 714 (21 U.S.C. 379d–3) the following:

"SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL. 21 USC 379d–3a.

"(a) IN GENERAL.—The Secretary may, notwithstanding title 5, United States Code, governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Such positions shall be within the competitive service.

"(b) COMPENSATION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Commissioner of Food and Drugs may determine and set—

"(A) the annual rate of pay of any individual appointed under subsection (a); and

"(B) for purposes of retaining qualified employees, the annual rate of pay for any qualified scientific, technical, or professional personnel appointed to a position described in subsection (a) before the date of enactment of the 21st Century Cures Act.

"(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code.

"(3) PUBLIC AVAILABILITY.—The annual rate of pay provided to an individual in accordance with this section shall be publicly available information.

"(c) RULE OF CONSTRUCTION.—The authorities under this section shall not be construed to affect the authority provided under section 714.

"(d) REPORT ON WORKFORCE PLANNING.—

"(1) IN GENERAL.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report on workforce planning to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines the extent to which the Food and Drug Administration has a critical need for qualified individuals for scientific, technical, or professional positions, including—

"(A) an analysis of the workforce needs at the Food and Drug Administration and the Secretary's strategic plan for addressing such needs, including through use of the authority under this section; and

"(B) a recruitment and retention plan for hiring qualified scientific, technical, and professional candidates, which may include the use of—

"(i) recruitment through nongovernmental recruitment or placement agencies;

"(ii) recruitment through academic institutions;

"(iii) recruitment or hiring bonuses, if applicable;

"(iv) recruitment using targeted direct hiring authorities; and

"(v) retention of qualified scientific, technical, and professional employees using the authority under this section, or other applicable authorities of the Secretary.

"(2) RECOMMENDATIONS.—The report under paragraph (1) may include the recommendations of the Commissioner of Food and Drugs that would help the Food and Drug Administration to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.".

(b) GAO STUDY AND REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the ability of the Food and Drug Administration to hire, train, and retain qualified scientific, technical, and professional staff, not including contractors, necessary to fulfill the mission of the Food and Drug Administration to protect and promote public health. Not later than January 1, 2022, the Comptroller General shall submit a report on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) CONTENTS OF STUDY.—The Comptroller General shall include in the study and report under paragraph (1)—

(A) information about the progress of the Food and Drug Administration in recruiting and retaining qualified scientific, technical, and professional staff outstanding in the field of biomedical research, clinical research evaluation, and biomedical product assessment;

(B) the extent to which critical staffing needs exist at the Food and Drug Administration, and barriers to hiring, training, and retaining qualified staff, if any;

(C) an examination of the recruitment and retention strategies of the Food and Drug Administration, including examining any strategic workforce plan, focused on improving scientific, technical, and professional staff recruitment and retention; and

(D) recommendations for potential improvements that would address staffing needs of the Food and Drug Administration.

SEC. 3073. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

(a) IN GENERAL.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

21 USC 399g.

"SEC. 1014. FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

"(a) IN GENERAL.—The Secretary shall establish one or more Intercenter Institutes within the Food and Drug Administration (referred to in this section as an 'Institute') for a major disease area or areas. With respect to the major disease area of focus of an Institute, such Institute shall develop and implement processes for coordination of activities, as applicable to such major disease area or areas, among the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health (for the purposes of this section, referred to as the 'Centers'). Such activities may include—

"(1) coordination of staff from the Centers with diverse product expertise in the diagnosis, cure, mitigation, treatment, or prevention of the specific diseases relevant to the major disease area of focus of the Institute;

"(2) streamlining, where appropriate, the review of medical products to diagnose, cure, mitigate, treat, or prevent the specific diseases relevant to the major disease area of focus of the Institute, applying relevant standards under sections 505, 510(k), 513(f)(2), and 515 of this Act and section 351 of the Public Health Service Act, and other applicable authorities;

"(3) promotion of scientific programs within the Centers related to the major disease area of focus of the Institute;

"(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;

"(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and

"(6) facilitation of the collaborative relationships of the Centers with other agencies within the Department of Health and Human Services regarding the major disease area of focus of the Institute.

"(b) PUBLIC PROCESS.—The Secretary shall provide a period for public comment during the time that each Institute is being implemented.

"(c) TIMING.—The Secretary shall establish at least one Institute under subsection (a) before the date that is 1 year after the date of enactment of the 21st Century Cures Act.

"(d) TERMINATION OF INSTITUTES.—The Secretary may terminate any Institute established pursuant to this section if the Secretary determines such Institute is no longer benefitting the public health. Not less than 60 days prior to so terminating an Institute, the Secretary shall provide public notice, including the rationale for such termination.".

(b) TECHNICAL AMENDMENTS.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended—

(1) by redesignating section 1012 as section 1013; and

(2) by redesignating the second section 1011 (with respect to improving the training of State, local, territorial, and tribal food safety officials), as added by section 209(a) of the FDA Food Safety Modernization Act (Public Law 111–353), as section 1012.

SEC. 3074. SCIENTIFIC ENGAGEMENT. 42 USC 3506a.

(a) IN GENERAL.—Scientific meetings that are attended by scientific or medical personnel, or other professionals, of the Department of Health and Human Services for whom attendance at such meeting is directly related to their professional duties and the mission of the Department—

(1) shall not be considered conferences for the purposes of complying with Federal reporting requirements contained in annual appropriations Acts or in this section; and

(2) shall not be considered conferences for purposes of a restriction contained in an annual appropriations Act, based on Office of Management and Budget Memorandum M-12-12 or any other regulation restricting travel to such meeting.

(b) LIMITATION.—Nothing in this section shall be construed to exempt travel for scientific meetings from Federal regulations relating to travel.

(c) REPORTS.—Not later than 90 days after the end of the fiscal year, each operating division of the Department of Health and Human Services shall prepare, and post on an Internet website of the operating division, an annual report on scientific meeting attendance and related travel spending for each fiscal year. Such report shall include—

(1) general information concerning the scientific meeting activities involved;

(2) information concerning the total amount expended for such meetings;

(3) a description of all such meetings that were attended by scientific or medical personnel, or other professionals, of each such operating division where the total amount expended by the operating division associated with each such meeting were in excess of $30,000, including—

(A) the total amount of meeting expenses incurred by the operating division for such meeting;

(B) the location of such meeting;

(C) the date of such meeting;

(D) a brief explanation on how such meeting advanced the mission of the operating division; and

(E) the total number of individuals whose travel expenses or other scientific meeting expenses were paid by the operating division; and

(4) with respect to any such meeting where the total expenses to the operating division exceeded $150,000, a description of the exceptional circumstances that necessitated the expenditure of such amounts.

SEC. 3075. DRUG SURVEILLANCE.

(a) NEW DRUGS.—Section 505(k)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)(5)), as amended by section 2074, is further amended—

(1) in subparagraph (A), by striking ", bi-weekly screening" and inserting "screenings";

(2) in subparagraph (B), as redesignated by section 2074(1)(C), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(C) make available on the Internet website of the Food and Drug Administration—

"(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

"(ii) criteria for public posting of adverse event signals.".

(b) FAERS REVISION.—Section 505(r)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(r)(2)(D)) is amended by striking ", by 18 months" and all that follows through the semicolon at the end of the subparagraph and inserting "and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 351 of the Public Health Service Act;".

(c) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505–1(f)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)(5)) is amended—

(1) in the matter preceding subparagraph (A), by inserting "or other advisory committee" after "(or successor committee)"; and

(2) in subparagraph (B), by striking "at least annually," and inserting "periodically".

SEC. 3076. REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) BOARD OF DIRECTORS.—

(1) COMPOSITION AND SIZE.—Section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

(A) by redesignating clause (ii) as clause (iii);

(B) by inserting after clause (i) the following:

"(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries."; and

(C) in clause (iii)(I), as redesignated by subparagraph (A), by striking "The ex officio members shall ensure" and inserting "The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure".

(2) FEDERAL EMPLOYEES ALLOWED TO SERVE ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)), as redesignated by paragraph (1)(A), is amended by adding at the end the following: "For purposes of this section, the term 'employee of the Federal Government' does not include a special Government employee, as that term is defined in section 202(a) of title 18, United States Code.".

(3) STAGGERED TERMS.—Subparagraph (A) of section 770(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended to read as follows:

"(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

"(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i)

shall expire on a staggered basis as determined by the ex officio members; and

"(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.".

(b) EXECUTIVE DIRECTOR COMPENSATION.—Section 770(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(g)(2)) is amended by striking "but shall not be greater than the compensation of the Commissioner".

(c) SEPARATION OF FUNDS.—Section 770(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(m)) is amended by striking "are held in separate accounts from funds received from entities under subsection (i)" and inserting "are managed as individual programmatic funds under subsection (i), according to best accounting practices".

Subtitle H—Medical Countermeasures Innovation

SEC. 3081. MEDICAL COUNTERMEASURE GUIDELINES.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in subsection (a), by adding at the end the following:

"(3) UTILIZATION GUIDELINES.—The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 319F–1), qualified pandemic and epidemic products (as defined in section 319F–3), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile."; and

(2) in subsection (g)—

(A) by amending paragraph (4) to read as follows:

"(4) REPORT ON SECURITY COUNTERMEASURE PROCUREMENT.—Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

"(A) in meeting the security countermeasure needs identified under this section; and

"(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d)).".

SEC. 3082. CLARIFYING BARDA CONTRACTING AUTHORITY.

(a) IN GENERAL.—Section 319F–2(g) of the Public Health Service Act (42 U.S.C. 247d–6b(g)) is amended by adding at the end the following:

"(5) CLARIFICATION ON CONTRACTING AUTHORITY.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 319L), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 319L.".

(b) BARDA CONTRACTING AUTHORITY.—Section 319L(c)(3) of the Public Health Service Act (42 U.S.C. 247d–7c) is amended by inserting ", including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section" before the period.

SEC. 3083. COUNTERMEASURE BUDGET PLAN.

Section 2811(b)(7) of the Public Health Service Act (42 U.S.C. 300hh–10(b)(7)) is amended—

(1) in the matter preceding subparagraph (A), by striking the first sentence and inserting "Develop, and update not later than March 1 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, and the corresponding efforts to develop qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), and qualified pandemic or epidemic products (as defined in section 319F–3) for each such threat.";

(2) in subparagraph (C), by striking "; and" and inserting a semicolon;

(3) in subparagraph (D), by striking "to the appropriate committees of Congress upon request." and inserting ", not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and"; and

(4) by adding at the end the following:

"(E) not later than March 15 of each year, be made publicly available in a manner that does not compromise national security.".

SEC. 3084. MEDICAL COUNTERMEASURES INNOVATION.

Section 319L(c)(4) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(4)) is amended by adding at the end the following:

"(E) MEDICAL COUNTERMEASURES INNOVATION PARTNER.—

"(i) IN GENERAL.—To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts, cooperative agreements, or other transactions as described in paragraph (5)) with an independent, nonprofit entity to—

"(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and

the development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;

"(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

"(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

"(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

"(ii) ELIGIBILITY.—

"(I) IN GENERAL.—To be eligible to enter into an agreement under clause (i) an entity shall—

"(aa) be an independent, nonprofit entity;

"(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

"(cc) have experience in promoting novel technology innovation;

"(dd) be problem-driven and solution-focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

"(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products;

"(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures; and

"(gg) not be within the Department of Health and Human Services.

"(II) PARTNERING EXPERIENCE.—In selecting an entity with which to enter into an agreement under clause (i), the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs.

"(iii) NOT AGENCY.—An entity that enters into an agreement under clause (i) shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5, United States Code.

"(iv) DIRECTION.—Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agreement under clause (i). As part of this agreement the Director of BARDA shall—

"(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

"(II) develop a description of work to be performed by the entity under the agreement;

"(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent development and partnerships consistent with the needs and requirements set forth in this subparagraph;

"(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

"(V) ensure, as a condition of the agreement that the entity—

"(aa) has in place a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

"(bb) protects against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

"(cc) provides monthly accounting on the use of funds provided under such agreement; and

"(dd) provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

"(v) SUPPLEMENT NOT SUPPLANT.—Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

"(vi) NO ESTABLISHMENT OF ENTITY.—To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services an entity for the purposes of carrying out this subparagraph.

"(vii) TRANSPARENCY AND OVERSIGHT.—Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

"(viii) INDEPENDENT EVALUATION.—Not later than 4 years after the date of enactment of the 21st Century Cures Act, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities

conducted under this subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

"(ix) SUNSET.—This subparagraph shall have no force or effect after September 30, 2022.".

SEC. 3085. STREAMLINING PROJECT BIOSHIELD PROCUREMENT.

Section 319F–2(c) of the Public Health Service Act (42 U.S.C. 247d–6b(c)) is amended—

(1) in paragraph (4)(A)(ii), by striking "make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure" and inserting "and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable";

(2) in paragraph (6)—

(A) by striking subparagraphs (A), (B), and (E);

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (A) and (B), respectively;

(C) by amending subparagraph (A), as so redesignated, to read as follows:

"(A) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary shall notify the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons for each such rejection."; and

(D) in the heading, by striking "RECOMMENDATION FOR PRESIDENT'S APPROVAL" and inserting "RECOMMENDATIONS FOR PROCUREMENT"; and

(3) in paragraph (7)—

(A) by striking subparagraphs (A) and (B) and inserting the following:

"(A) PAYMENTS FROM SPECIAL RESERVE FUND.—The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph."; and

(B) by redesignating subparagraph (C) as subparagraph (B).

SEC. 3086. ENCOURAGING TREATMENTS FOR AGENTS THAT PRESENT A NATIONAL SECURITY THREAT.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by inserting after section 565 the following:

"SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS. 21 USC 360bbb–4a.

"(a) DEFINITIONS.—In this section:

"(1) HUMAN DRUG APPLICATION.—The term 'human drug application' has the meaning given such term in section 735(1).

"(2) PRIORITY REVIEW.—The term 'priority review', with respect to a human drug application, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

"(3) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the material threat medical countermeasure application.

"(4) MATERIAL THREAT MEDICAL COUNTERMEASURE APPLICATION.—The term 'material threat medical countermeasure application' means an application that—

"(A) is a human drug application for a drug intended for use—

"(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act; or

"(ii) to mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, or biological product against such agent; and

"(B) the Secretary determines eligible for priority review;

"(C) is approved after the date of enactment of the 21st Century Cures Act; and

"(D) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351(a) of the Public Health Service Act.

"(b) PRIORITY REVIEW VOUCHER.—

"(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

"(2) TRANSFERABILITY.—The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351(a) of the Public Health Service Act will be submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times

a priority review voucher may be transferred before such voucher is used.

"(3) NOTIFICATION.—

"(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

"(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

"(c) PRIORITY REVIEW USER FEE.—

"(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

"(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

"(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2016, for that fiscal year, the amount of the priority review user fee.

"(4) PAYMENT.—

"(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used.

"(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

"(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

"(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

"(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

"(6) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

"(d) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Internet website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

"(1) The Secretary issues a priority review voucher under this section.

"(2) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher issued under this section.

"(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher issued under any section of this Act with respect to such drug.

"(f) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of medical countermeasures.

"(g) SUNSET.—The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2023.".

SEC. 3087. PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.

Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

"(f) DETERMINATION WITH RESPECT TO PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.—

"(1) DETERMINATION.—If the Secretary determines, after consultation with such public health officials as may be necessary, that—

"(A)(i) the criteria set forth for a public health emergency under paragraph (1) or (2) of subsection (a) has been met; or

"(ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and

"(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44, United States Code (commonly referred to as the Paperwork Reduction Act),

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public

health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate postresponse review regarding such public health emergency if such immediate postresponse review does not exceed a reasonable length of time.

"(2) TRANSPARENCY.—If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet website of the Department of Health and Human Services a brief justification for such waiver, the anticipated period of time such waiver will be in effect, and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

"(3) EFFECTIVENESS OF WAIVER.—Any waiver under this subsection shall take effect on the date on which the Secretary posts information on the Internet website as provided for in this subsection.

"(4) TERMINATION OF WAIVER.—Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

"(5) LIMITATIONS.—

"(A) PERIOD OF WAIVER.—The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate postresponse review regarding the public health emergency consistent with the requirements of this subsection.

"(B) SUBSEQUENT COMPLIANCE.—An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44, United States Code, and the Secretary shall ensure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.".

SEC. 3088. CLARIFYING FOOD AND DRUG ADMINISTRATION EMERGENCY USE AUTHORIZATION.

(a) AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended—

(1) in subsection (a)(2)—

(A) in subparagraph (A)—

(i) by striking "or 515" and inserting "512, or 515"; and

(ii) by inserting "or conditionally approved under section 571 of this Act" after "Public Health Service Act"; and

(B) in subparagraph (B), by inserting "conditionally approved under section 571," after "approved," each place the term appears;

(2) in subsection (b)(4), by striking the second comma after "determination";

(3) in subsection (e)(3)(B), by striking "section 503(b)" and inserting "subsection (b) or (f) of section 503 or under section 504";

(4) in subsection (f)(2)—

(A) by inserting ", or an animal to which," after "to a patient to whom"; and

(B) by inserting "or by the veterinarian caring for such animal, as applicable" after "attending physician";

(5) in subsection (g)(1), by inserting "conditional approval under section 571," after "approval,";

(6) in subsection (h)(1), by striking "or section 520(g)"and inserting "512(j), or 520(g)"; and

(7) in subsection (k), by striking "section 520(g),"and inserting "512(j), or 520(g)".

(b) NEW ANIMAL DRUGS.—Section 512(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)(1)) is amended—

(1) in subparagraph (B), by striking "or" at the end;

(2) in subparagraph (C), by striking the period and inserting "; or"; and

(3) by inserting after subparagraph (C) the following:

"(D) there is in effect an authorization pursuant to section 564 with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to any conditions of such authorization.".

(c) EMERGENCY USE OF MEDICAL PRODUCTS.—Section 564A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a) is amended—

(1) in subsection (a)(1)(A), by inserting ", conditionally approved under section 571," after "chapter"; and

(2) in subsection (d), by striking "sections 503(b) and 520(e)" and inserting "subsections (b) and (f) of section 503, section 504, and section 520(e)".

(d) PRODUCTS HELD FOR EMERGENCY USE.—Section 564B(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3b(2)) is amended—

(1) in subparagraph (A)—

(A) by inserting "or conditionally approved under section 571 of this Act" after "Public Health Service Act"; and

(B) by striking "or 515" and inserting "512, or 515"; and

(2) in subparagraph (B), by striking "or 520" and inserting "512, or 520".

Subtitle I—Vaccine Access, Certainty, and Innovation

SEC. 3091. PREDICTABLE REVIEW TIMELINES OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

21 USC 360bbb–4 note.

(a) CONSIDERATION OF NEW VACCINES.—Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory

Committee on Immunization Practices (in this section referred to as the "Advisory Committee") shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.

(b) ADDITIONAL INFORMATION.—If the Advisory Committee does not make a recommendation with respect to the use of a vaccine at the Advisory Committee's first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee shall provide an update on the status of such committee's review.

(c) CONSIDERATION FOR BREAKTHROUGH THERAPIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH EMERGENCY.—The Advisory Committee shall make recommendations with respect to the use of certain vaccines in a timely manner, as appropriate, including vaccines that—

(1) are designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) and licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(2) could be used in a public health emergency.

(d) DEFINITION.—In this section, the terms "Advisory Committee on Immunization Practices" and "Advisory Committee" mean the Advisory Committee on Immunization Practices established by the Secretary pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.".

SEC. 3092. REVIEW OF PROCESSES AND CONSISTENCY OF ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES RECOMMENDATIONS.

(a) REVIEW.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the processes used by the Advisory Committee on Immunization Practices in formulating and issuing recommendations pertaining to vaccines, including with respect to consistency.

(b) CONSIDERATIONS.—The review under subsection (a) shall include an assessment of—

(1) the criteria used to evaluate new and existing vaccines, including the identification of any areas for which flexibility in evaluating such criteria is necessary and the reason for such flexibility;

(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and

(3) the extent to which the processes used by the work groups of the Advisory Committee on Immunization Practices are consistent among such groups, including the identification of reasons for any variation.

(c) STAKEHOLDERS.—In carrying out the review under subsection (a), the Director of the Centers for Disease Control and Prevention shall solicit input from vaccine stakeholders.

(d) REPORT.—Not later than 18 months after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress, and make publicly available, a report on the results of the review under subsection (a), including any recommendations

on improving the consistency of the processes described in such subsection.

(e) DEFINITION.—In this section, the term "Advisory Committee on Immunization Practices" means the Advisory Committee on Immunization Practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.

SEC. 3093. ENCOURAGING VACCINE INNOVATION.

42 USC 300aa–2 note.

(a) VACCINE MEETINGS.—The Director of the Centers for Disease Control and Prevention shall ensure that appropriate staff within the relevant centers and divisions of the Office of Infectious Diseases, and others, as appropriate, coordinate with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization, including with regard to meetings with stakeholders related to such topics.

(b) REPORT ON VACCINE INNOVATION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), in collaboration with appropriate agencies or offices within the Department of Health and Human Services, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and post publicly on the Internet website of the Department of Health and Human Services, a report on ways to promote innovation in the development of vaccines that minimize the burden of infectious disease.

(2) CONTENTS.—The report described in paragraph (1) shall review the current status of vaccine development and, as appropriate—

(A) consider the optimal process to determine which vaccines would be beneficial to public health and how information on such vaccines is disseminated to key stakeholders;

(B) examine and identify whether obstacles exist that inhibit the development of beneficial vaccines; and

(C) make recommendations about how best to remove any obstacles identified under subparagraph (B) in order to promote and incentivize vaccine innovation and development.

(3) CONSULTATION.—In preparing the report under this subsection, the Secretary may consult with—

(A) representatives of relevant Federal agencies and departments, including the Department of Defense and the Department of Veterans Affairs;

(B) academic researchers;

(C) developers and manufacturers of vaccines;

(D) medical and public health practitioners;

(E) representatives of patient, policy, and advocacy organizations; and

(F) representatives of other entities, as the Secretary determines appropriate.

(c) UPDATES RELATED TO MATERNAL IMMUNIZATION.—

(1) ADDITIONAL VACCINES.—Section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) is amended by adding at the end the following:

"(3) VACCINES RECOMMENDED FOR USE IN PREGNANT WOMEN.—The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.".

(2) PETITION CONTENT.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) is amended by adding at the end the following:

"(f) MATERNAL IMMUNIZATION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this subtitle, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

"(2) DEFINITION.—As used in this subsection, the term 'child' shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1, United States Code, except that, for purposes of this subsection, such section 8 shall be applied as if the term 'include' in subsection (a) of such section were replaced with the term 'mean'.".

(3) PETITIONERS.—Section 2111(b)(2) of the Public Health Service Act (42 U.S.C. 300aa–11(b)(2)) is amended by adding "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine." at the end.

Subtitle J—Technical Corrections

SEC. 3101. TECHNICAL CORRECTIONS.

(a) FFDCA.—

(1) REFERENCES.—Except as otherwise expressly provided, whenever in this subsection an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(2) AMENDMENTS.—

(A) PROHIBITED ACTS.—Section 301(r) (21 U.S.C. 331(r)) is amended by inserting ", drug," after "device" each place the term appears.

(B) NEW DRUGS.—Section 505 (21 U.S.C. 355) is amended—

(i) in subsection (d), in the last sentence, by striking "premarket approval" and inserting "marketing approval"; and

(ii) in subsection (q)(5)(A), by striking "subsection (b)(2) or (j) of the Act or 351(k)" and inserting "subsection (b)(2) or (j) of this section or section 351(k)".

(C) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505–1(h)(21 U.S.C. 355–1(h)) is amended—

(i) in paragraph (2)(A)(iii)—

(I) in the clause heading, by striking "LABEL" and inserting "LABELING";

(II) by striking "label" each place the term appears and inserting "labeling"; and

(III) by striking "sponsor" and inserting "responsible person"; and

(ii) in paragraph (8), by striking "and (7)." and inserting "and (7)".

(D) PEDIATRIC STUDY PLANS.—Section 505B (21 U.S.C. 355c) is amended—

(i) in subsection (e)—

(I) in paragraph (2)—

(aa) in subparagraph (A), by inserting "study" after "initial pediatric" each place the term appears; and

(bb) in subparagraph (B), in the subparagraph heading, by striking "INITIAL PLAN" and inserting "INITIAL PEDIATRIC STUDY PLAN";

(II) in paragraph (5), in the paragraph heading, by inserting "AGREED INITIAL PEDIATRIC STUDY" before "PLAN"; and

(III) in paragraph (6), by striking "agreed initial pediatric plan" and inserting "agreed initial pediatric study plan"; and

(ii) in subsection (f)(1), by inserting "and any significant amendments to such plans," after "agreed initial pediatric study plans,".

(E) DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIVE-SAVING DRUGS.—Section 506C (21 U.S.C. 356c) is amended—

(i) in subsection (c), by striking "discontinuation" and inserting "discontinuance"; and

(ii) in subsection (g)(1), by striking "section 505(j) that could help" and inserting "section 505(j), that could help".

(F) ANNUAL REPORTING ON DRUG SHORTAGES.—Section 506C–1(a) (21 U.S.C. 331(a)) is amended, in the matter before paragraph (1)—

(i) by striking "Not later than the end of calendar year 2013, and not later than the end of each calendar year thereafter," and inserting "Not later than March 31 of each calendar year,"; and

(ii) by inserting ", with respect to the preceding calendar year," after "a report".

(G) DRUG SHORTAGE LIST.—Section 506E(b)(3)(E) (21 U.S.C. 356e(b)(3)(E)) is amended by striking "discontinuation" and inserting "discontinuance".

(H) INSPECTIONS OF ESTABLISHMENTS.—Section 510(h) (21 U.S.C. 360(h)) is amended—

(i) in paragraph (4), in the matter preceding subparagraph (A), by striking "establishing the risk-based scheduled" and inserting "establishing a risk-based schedule"; and

(ii) in paragraph (6)—

(I) in subparagraph (A), by striking "fiscal" and inserting "calendar" each place the term appears; and

(II) in subparagraph (B), by striking "an active ingredient of a drug, a finished drug product, or an excipient of a drug" and inserting "an active ingredient of a drug or a finished drug product".

(I) CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE.—Section 513(f)(2)(A) (21 U.S.C. 360c(f)(2)(A)) is amended—

(i) in clause (i), by striking "within 30 days"; and

(ii) in clause (iv), by striking "low-moderate" and inserting "low to moderate".

(J) PREMARKET APPROVAL.—Section 515(a)(1) (21 U.S.C. 360e(a)(1)) is amended by striking "subject to a an order" and inserting "subject to an order".

(K) PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.—Section 518A (21 U.S.C. 360h–1) is amended—

(i) by striking subsection (c); and

(ii) by redesignating subsection (d) as subsection (c).

(L) UNIQUE DEVICE IDENTIFIER.—Section 519(f) (21 U.S.C. 360i(f)) is amended by striking "and life sustaining" and inserting "or life sustaining".

(M) PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.—Section 524(c)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(c)(4)(A)) is amended by striking "Services Act" and inserting "Service Act".

(N) PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.—Section 524A (21 U.S.C. 360n–1) is amended—

(i) by striking "If the Secretary" and inserting the following:

"(a) IN GENERAL.—If the Secretary";

(ii) by striking "any" and inserting "the first"; and

(iii) by adding at the end the following:

"(b) CONSTRUCTION.—Nothing in this section shall prohibit the Secretary from giving priority review to a human drug application or efficacy supplement submitted for approval under section 505(b) that otherwise meets the criteria for the Secretary to grant priority review.".

(O) CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.—Section 569(a)(2)(A) (21 U.S.C. 360bbb–8(a)(2)(A)) is amended, in the first sentence, by striking "subsection (c)" and inserting "subsection (b)".

(P) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section 569A(c) (21 U.S.C. 360bbb–8a(c)) is amended by inserting "or under the Public Health Service Act" after "this Act".

(Q) USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.—Section 569B (21 U.S.C. 360bbb–8b) is amended by striking "drug or device" and inserting "drug, biological product, or device" each place the term appears.

(R) MEDICAL GASES DEFINITIONS.—Section 575(1)(H) (21 U.S.C. 360ddd(1)(H)) is amended—

(i) by inserting "for a new drug" after "any period of exclusivity"; and

(ii) by inserting "or any period of exclusivity for a new animal drug under section 512(c)(2)(F)," after "section 505A,".

(S) REGULATION OF MEDICAL GASES.—Section 576(a) (21 U.S.C. 360ddd–1(a)) is amended—

(i) in the matter preceding subparagraph (A) of paragraph (1), by inserting "who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce" after "any person"; and

(ii) in paragraph (3)—

(I) in subparagraph (A)—

(aa) in clause (i)(VIII), by inserting "for a new drug" after "any period of exclusivity"; and

(bb) in clause (ii), in the matter preceding subclause (I), by inserting "the" before "final use"; and

(II) in subparagraph (B)—

(aa) in clause (i), by inserting "for a new drug" after "any period of exclusivity"; and

(bb) in clause (ii), by inserting a comma after "drug product".

(T) INAPPLICABILITY OF DRUG FEES TO DESIGNATED MEDICAL GASES.—Section 577 (21 U.S.C. 360ddd–2) is amended by inserting "or 740(a)" after "section 736(a)".

(U) CONFLICTS OF INTEREST.—Section 712(e)(1)(B) (21 U.S.C. 379d–1(e)(1)(B)) is amended by striking "services" and inserting "service".

(V) AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.—Section 744H(a) (21 U.S.C. 379j–52(a)) is amended—

(i) in paragraph (1)(A)(v), by striking "Biosimilars User Fee Act of 2012" and inserting "Biosimilar User Fee Act of 2012"; and

(ii) in paragraph (2)(B), by striking "Biosimilars User Fee Act of 2012" and inserting "Biosimilar User Fee Act of 2012".

(W) REGISTRATION OF COMMERCIAL IMPORTERS.—

(i) AMENDMENT.—Section 801(s)(2) (21 U.S.C. 381(s)(2)) is amended by adding at the end the following:

"(D) EFFECTIVE DATE.—In establishing the effective date of the regulations under subparagraph (A), the Secretary shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good

importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.".

(ii) CONFORMING AMENDMENT.—Section 714 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1074) is amended by striking subsection (d).

(X) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809(a)(2) (21 U.S.C. 384e(a)(2)) is amended by striking "conduction" and inserting "conducting".

(b) FDASIA.—

(1) FINDINGS RELATING TO DRUG APPROVAL.—Section 901(a)(1)(A) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 21 U.S.C. 356 note) is amended by striking "serious and life-threatening diseases" and inserting "serious or life-threatening diseases".

(2) REPORTING OF INCLUSION OF DEMOGRAPHIC SUBGROUPS.—Section 907 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1092, 1093) is amended—

(A) in the section heading, by striking "**BIOLOGICS**" in the heading and inserting "**BIOLOGICAL PRODUCTS**"; and

(B) in subsection (a)(2)(B), by striking "applications for new drug applications" and inserting "new drug applications".

(3) COMBATING PRESCRIPTION DRUG ABUSE.—Section 1122 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1112, 1113) is amended—

(A) in subsection (a)(2), by striking "dependance" and inserting "dependence"; and

(B) in subsection (c), by striking "promulgate" and inserting "issue".

SEC. 3102. COMPLETED STUDIES.

The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505(k)(5) (21 U.S.C. 355(k)(5))—

(A) in subparagraph (A), by inserting "and" after the semicolon;

(B) by striking subparagraph (B); and

(C) by redesignating subparagraph (C) as subparagraph (B);

(2) in section 505A (21 U.S.C. 355a), by striking subsection (p);

(3) in section 505B (21 U.S.C. 355c)—

(A) by striking subsection (l); and

(B) by redesignating subsection (m) as subsection (l); and

(4) in section 523 (21 U.S.C. 360m), by striking subsection (d).

TITLE IV—DELIVERY

SEC. 4001. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

(a) IN GENERAL.—The Health Information Technology for Economic and Clinical Health Act (title XIII of division A of Public Law 111–5) is amended—

(1) by adding at the end of part 1 of subtitle A the following:

"SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

42 USC 300jj–11 note.

"(a) REDUCTION IN BURDENS GOAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with providers of health services, health care suppliers of services, health care payers, health professional societies, health information technology developers, health care quality organizations, health care accreditation organizations, public health entities, States, and other appropriate entities, shall, in accordance with subsection (b)—

"(1) establish a goal with respect to the reduction of regulatory or administrative burdens (such as documentation requirements) relating to the use of electronic health records;

"(2) develop a strategy for meeting the goal established under paragraph (1); and

"(3) develop recommendations for meeting the goal established under paragraph (1).

"(b) STRATEGY AND RECOMMENDATIONS.—

"(1) IN GENERAL.—To achieve the goal established under subsection (a)(1), the Secretary, in consultation with the entities described in such subsection, shall, not later than 1 year after the date of enactment of the 21st Century Cures Act, develop a strategy and recommendations to meet the goal in accordance with this subsection.

"(2) STRATEGY.—The strategy developed under paragraph (1) shall address the regulatory and administrative burdens (such as documentation requirements) relating to the use of electronic health records. Such strategy shall include broad public comment and shall prioritize—

"(A)(i) incentives for meaningful use of certified EHR technology for eligible professionals and hospitals under sections 1848(a)(7) and 1886(b)(3)(B)(ix), respectively, of the Social Security Act (42 U.S.C. 1395w–4(a)(7), 1395ww(b)(3)(B)(ix));

"(ii) the program for making payments under section 1903(a)(3)(F) of the Social Security Act (42 U.S.C. 1396b(a)(3)(F)) to encourage the adoption and use of certified EHR technology by Medicaid providers;

"(iii) the Merit-based Incentive Payment System under section 1848(q) of the Social Security Act (42 U.S.C. 1395w–4(q));

"(iv) alternative payment models (as defined in section 1833(z)(3)(C) of the Social Security Act (42 U.S.C. 1395l(z)(3)(C));

"(v) the Hospital Value-Based Purchasing Program under section 1886(o) of the Social Security Act (42 U.S.C. 1395ww(o)); and

"(vi) other value-based payment programs, as the Secretary determines appropriate;

"(B) health information technology certification;

"(C) standards and implementation specifications, as appropriate;

"(D) activities that provide individuals access to their electronic health information;

"(E) activities related to protecting the privacy of electronic health information;

"(F) activities related to protecting the security of electronic health information;

"(G) activities related to facilitating health and clinical research;

"(H) activities related to public health;

"(I) activities related to aligning and simplifying quality measures across Federal programs and other payers;

"(J) activities related to reporting clinical data for administrative purposes; and

"(K) other areas, as the Secretary determines appropriate.

"(3) RECOMMENDATIONS.—The recommendations developed under paragraph (1) shall address—

"(A) actions that improve the clinical documentation experience;

"(B) actions that improve patient care;

"(C) actions to be taken by the Secretary and by other entities; and

"(D) other areas, as the Secretary determines appropriate, to reduce the reporting burden required of health care providers.

"(4) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the development of the goal, strategies, or recommendations described in this section.

"(c) APPLICATION OF CERTAIN REGULATORY REQUIREMENTS.—A physician (as defined in section 1861(r)(1) of the Social Security Act), to the extent consistent with applicable State law, may delegate electronic medical record documentation requirements specified in regulations promulgated by the Centers for Medicare & Medicaid Services to a person performing a scribe function who is not such physician if such physician has signed and verified the documentation."; and

(2) in the table of contents in section 13001(b), by inserting after the item relating to section 13102 the following:

"13103. Assisting doctors and hospitals in improving the quality and care for patients.".

(b) CERTIFICATION OF HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERVICE.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)) is amended by adding at the end the following:

"(C) HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERVICE.—

"(i) IN GENERAL.—The National Coordinator shall encourage, keep, or recognize, through existing authorities, the voluntary certification of health information technology under the program developed under

subparagraph (A) for use in medical specialties and sites of service for which no such technology is available or where more technological advancement or integration is needed.

"(ii) SPECIFIC MEDICAL SPECIALTIES.—The Secretary shall accept public comment on specific medical specialties and sites of service, in addition to those described in clause (i), for the purpose of selecting additional specialties and sites of service as necessary.

"(iii) HEALTH INFORMATION TECHNOLOGY FOR PEDIATRICS.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary, in consultation with relevant stakeholders, shall make recommendations for the voluntary certification of health information technology for use by pediatric health providers to support the health care of children. Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary shall adopt certification criteria under section 3004 to support the voluntary certification of health information technology for use by pediatric health providers to support the health care of children.".

(c) MEANINGFUL USE STATISTICS.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the HIT Advisory Committee of the Office of the National Coordinator for Health Information Technology, a report concerning attestation statistics for the Medicare and Medicaid EHR Meaningful Use Incentive programs to assist in informing standards adoption and related practices. Such statistics shall include attestation information delineated by State, including, to the extent practicable, the number of providers who did not meet the minimum criteria necessary to attest for the Medicare and Medicaid EHR Meaningful Use Incentive programs for a calendar year, and shall be made publicly available on the Internet website of the Secretary on at least a quarterly basis.

(2) AUTHORITY TO ALTER FORMAT.—The Secretary of Health and Human Services may alter the format of the reports on the attestation of eligible health care professionals following the first performance year of the Merit-based Incentive Payment System to account for changes arising from the implementation of such payment system.

SEC. 4002. TRANSPARENT REPORTING ON USABILITY, SECURITY, AND FUNCTIONALITY.

(a) ENHANCEMENTS TO CERTIFICATION.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11), as amended by section 4001(b), is further amended by adding at the end the following:

"(D) CONDITIONS OF CERTIFICATION.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other

conditions and requirements under this title, that the health information technology developer or entity—

"(i) does not take any action that constitutes information blocking as defined in section 3022(a);

"(ii) provides assurances satisfactory to the Secretary that such developer or entity, unless for legitimate purposes specified by the Secretary, will not take any action described in clause (i) or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

"(iii) does not prohibit or restrict communication regarding—

"(I) the usability of the health information technology;

"(II) the interoperability of the health information technology;

"(III) the security of the health information technology;

"(IV) relevant information regarding users' experiences when using the health information technology;

"(V) the business practices of developers of health information technology related to exchanging electronic health information; and

"(VI) the manner in which a user of the health information technology has used such technology;

"(iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws;

"(v) has successfully tested the real world use of the technology for interoperability (as defined in section 3000) in the type of setting in which such technology would be marketed;

"(vi) provides to the Secretary an attestation that the developer or entity—

"(I) has not engaged in any of the conduct described in clause (i);

"(II) has provided assurances satisfactory to the Secretary in accordance with clause (ii);

"(III) does not prohibit or restrict communication as described in clause (iii);

"(IV) has published information in accordance with clause (iv);

"(V) ensures that its technology allows for health information to be exchanged, accessed, and used, in the manner described in clause (iv); and

"(VI) has undertaken real world testing as described in clause (v); and

"(vii) submits reporting criteria in accordance with section 3009A(b).".

"(E) COMPLIANCE WITH CONDITIONS OF CERTIFICATION.—The Secretary may encourage compliance with the conditions of certification described in subparagraph (D) and take action to discourage noncompliance, as appropriate.".

(b) EHR SIGNIFICANT HARDSHIP EXCEPTION.—

(1) APPLICATION TO ELIGIBLE PROFESSIONALS.—

(A) IN CASE OF DECERTIFICATION.—Section 1848(a)(7)(B) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)(B)) is amended by inserting after the first sentence the following new sentence: "The Secretary shall exempt an eligible professional from the application of the payment adjustment under subparagraph (A) with respect to a year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such professional has been decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act.".

(B) CONTINUED APPLICATION UNDER MIPS.—Section 1848(o)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)(D)) is amended by adding at the end the following new sentence: "The provisions of subparagraphs (B) and (D) of subsection (a)(7), shall apply to assessments of MIPS eligible professionals under subsection (q) with respect to the performance category described in subsection (q)(2)(A)(iv) in an appropriate manner which may be similar to the manner in which such provisions apply with respect to payment adjustments made under subsection (a)(7)(A).".

(2) APPLICATION TO ELIGIBLE HOSPITALS.—Section 1886(b)(3)(B)(ix)(II) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ix)(II)) is amended by inserting after the first sentence the following new sentence: "The Secretary shall exempt an eligible hospital from the application of the payment adjustment under subclause (I) with respect to a fiscal year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such hospital is decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act.".

(c) ELECTRONIC HEALTH RECORD REPORTING PROGRAM.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.) is amended by adding at the end the following:

"SEC. 3009A. ELECTRONIC HEALTH RECORD REPORTING PROGRAM. 42 USC 300jj–19a.

"(a) REPORTING CRITERIA.—

"(1) CONVENING OF STAKEHOLDERS.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall convene stakeholders, as described in paragraph (2), for the purpose of developing the reporting criteria in accordance with paragraph (3).

"(2) DEVELOPMENT OF REPORTING CRITERIA.—The reporting criteria under this subsection shall be developed through a public, transparent process that reflects input from relevant stakeholders, including—

"(A) health care providers, including primary care and specialty care health care professionals;

"(B) hospitals and hospital systems;

"(C) health information technology developers;

"(D) patients, consumers, and their advocates;

"(E) data sharing networks, such as health information exchanges;

"(F) authorized certification bodies and testing laboratories;

"(G) security experts;

"(H) relevant manufacturers of medical devices;

"(I) experts in health information technology market economics;

"(J) public and private entities engaged in the evaluation of health information technology performance;

"(K) quality organizations, including the consensus based entity described in section 1890 of the Social Security Act;

"(L) experts in human factors engineering and the measurement of user-centered design; and

"(M) other entities or individuals, as the Secretary determines appropriate.

"(3) CONSIDERATIONS FOR REPORTING CRITERIA.—The reporting criteria developed under this subsection—

"(A) shall include measures that reflect categories including—

"(i) security;

"(ii) usability and user-centered design;

"(iii) interoperability;

"(iv) conformance to certification testing; and

"(v) other categories, as appropriate to measure the performance of electronic health record technology;

"(B) may include categories such as—

"(i) enabling the user to order and view the results of laboratory tests, imaging tests, and other diagnostic tests;

"(ii) submitting, editing, and retrieving data from registries such as clinician-led clinical data registries;

"(iii) accessing and exchanging information and data from and through health information exchanges;

"(iv) accessing and exchanging information and data from medical devices;

"(v) accessing and exchanging information and data held by Federal, State, and local agencies and other applicable entities useful to a health care provider or other applicable user in the furtherance of patient care;

"(vi) accessing and exchanging information from other health care providers or applicable users;

"(vii) accessing and exchanging patient generated information;

"(viii) providing the patient or an authorized designee with a complete copy of their health information from an electronic record in a computable format;

"(ix) providing accurate patient information for the correct patient, including exchanging such information, and avoiding the duplication of patients records; and

"(x) other categories regarding performance, accessibility, as the Secretary determines appropriate; and

"(C) shall be designed to ensure that small and startup health information technology developers are not unduly disadvantaged by the reporting criteria.

"(4) MODIFICATIONS.—After the reporting criteria have been developed under paragraph (3), the Secretary may convene stakeholders and conduct a public comment period for the purpose of modifying the reporting criteria developed under such paragraph.

"(b) PARTICIPATION.—As a condition of maintaining certification under section 3001(c)(5)(D), a developer of certified electronic health records shall submit to an appropriate recipient of a grant, contract, or agreement under subsection (c)(1) responses to the criteria developed under subsection (a), with respect to all certified technology offered by such developer.

"(c) REPORTING PROGRAM.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall award grants, contracts, or agreements to independent entities on a competitive basis to support the convening of stakeholders as described in subsection (a)(2), collect the information required to be reported in accordance with the criteria established as described subsection (a)(3), and develop and implement a process in accordance with paragraph (5) and report such information to the Secretary.

"(2) APPLICATIONS.—An independent entity that seeks a grant, contract, or agreement under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a description of—

"(A) the proposed method for reviewing and summarizing information gathered based on reporting criteria established under subsection (a);

"(B) if applicable, the intended focus on a specific subset of certified electronic health record technology users, such as health care providers, including primary care, specialty care, and care provided in rural settings; hospitals and hospital systems; and patients, consumers, and patients and consumer advocates;

"(C) the plan for widely distributing reports described in paragraph (6);

"(D) the period for which the grant, contract, or agreement is requested, which may be up to 2 years; and

"(E) the budget for reporting program participation, and whether the eligible independent entity intends to continue participation after the period of the grant, contract, or agreement.

"(3) CONSIDERATIONS FOR INDEPENDENT ENTITIES.—In awarding grants, contracts, and agreements under paragraph (1), the Secretary shall give priority to independent entities with appropriate expertise in health information technology usability, interoperability, and security (especially entities with such expertise in electronic health records) with respect to—

"(A) health care providers, including primary care, specialty care, and care provided in rural settings;

"(B) hospitals and hospital systems; and

"(C) patients, consumers, and patient and consumer advocates.

"(4) LIMITATIONS.—

"(A) ASSESSMENT AND REDETERMINATION.—Not later than 4 years after the date of enactment of the 21st Century Cures Act and every 2 years thereafter, the Secretary, in consultation with stakeholders, shall—

"(i) assess performance of the recipients of the grants, contracts, and agreements under paragraph (1) based on quality and usability of reports described in paragraph (6); and

"(ii) re-determine grants, contracts, and agreements as necessary.

"(B) PROHIBITIONS ON PARTICIPATION.—The Secretary may not award a grant, contract, or cooperative agreement under paragraph (1) to—

"(i) a proprietor of certified health information technology or a business affiliate of such a proprietor;

"(ii) a developer of certified health information technology; or

"(iii) a State or local government agency.

"(5) FEEDBACK.—Based on reporting criteria established under subsection (a), the recipients of grants, contracts, and agreements under paragraph (1) shall develop and implement a process to collect and verify confidential feedback on such criteria from—

"(A) health care providers, patients, and other users of certified electronic health record technology; and

"(B) developers of certified electronic health record technology.

"(6) REPORTS.—

"(A) DEVELOPMENT OF REPORTS.—Each recipient of a grant, contract, or agreement under paragraph (1) shall report on the information reported to such recipient pursuant to subsection (a) and the user feedback collected under paragraph (5) by preparing summary reports and detailed reports of such information.

"(B) DISTRIBUTION OF REPORTS.—Each recipient of a grant, contract, or agreement under paragraph (1) shall submit the reports prepared under subparagraph (A) to the Secretary for public distribution in accordance with subsection (d).

"(d) PUBLICATION.—The Secretary shall distribute widely, as appropriate, and publish, on the Internet website of the Office of the National Coordinator—

"(1) the reporting criteria developed under subsection (a); and

"(2) the summary and detailed reports under subsection (c)(6).

"(e) REVIEW.—Each recipient of a grant, contract, or agreement under paragraph (1) shall develop and implement a process through which participating electronic health record technology developers may review and recommend changes to the reports created under subsection (c)(6) for products developed by such developer prior to the publication of such report under subsection (d).

"(f) ADDITIONAL RESOURCES.—The Secretary may provide additional resources on the Internet website of the Office of the National

Coordinator to better inform consumers of health information technology. Such reports may be carried out through partnerships with private organizations with appropriate expertise.".

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $15,000,000 for purposes of carrying out subparagraph (D) of section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11) (as added by subsection (a)) and section 3009A of the Public Health Service Act (as added by subsection (b)), including for purposes of administering any contracts, grants, or agreements, to remain available until expended.

SEC. 4003. INTEROPERABILITY.

(a) DEFINITION.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended—

(1) by redesignating paragraphs (10) through (14), as paragraphs (11) through (15), respectively; and

(2) by inserting after paragraph (9) the following:

"(10) INTEROPERABILITY.—The term 'interoperability', with respect to health information technology, means such health information technology that—

"(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

"(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

"(C) does not constitute information blocking as defined in section 3022(a).".

(b) SUPPORT FOR INTEROPERABLE NETWORK EXCHANGE.—Section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj–11(c)) is amended by adding at the end the following:

"(9) SUPPORT FOR INTEROPERABLE NETWORKS EXCHANGE.—

"(A) IN GENERAL.—The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

"(B) ESTABLISHING A TRUSTED EXCHANGE FRAMEWORK.—

"(i) IN GENERAL.—Not later than 6 months after the date of enactment of the 21st Century Cures Act, the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include—

"(I) a common method for authenticating trusted health information network participants;

"(II) a common set of rules for trusted exchange;

"(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and

"(IV) a process for filing and adjudicating noncompliance with the terms of the common agreement.

"(ii) TECHNICAL ASSISTANCE.—The National Coordinator, in collaboration with the National Institute of Standards and Technology, shall provide technical assistance on how to implement the trusted exchange framework and common agreement under this paragraph.

"(iii) PILOT TESTING.—The National Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement established or supported under this subsection (as authorized under section 13201 of the Health Information Technology for Economic and Clinical Health Act). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.

"(C) PUBLICATION OF A TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—Not later than 1 year after convening stakeholders under subparagraph (A), the National Coordinator shall publish on its public Internet website, and in the Federal register, the trusted exchange framework and common agreement developed or supported under subparagraph (B). Such trusted exchange framework and common agreement shall be published in a manner that protects proprietary and security information, including trade secrets and any other protected intellectual property.

"(D) DIRECTORY OF PARTICIPATING HEALTH INFORMATION NETWORKS.—

"(i) IN GENERAL.—Not later than 2 years after convening stakeholders under subparagraph (A), and annually thereafter, the National Coordinator shall publish on its public Internet website a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement developed or supported under paragraph (B).

"(ii) PROCESS.—The Secretary shall, through notice and comment rulemaking, establish a process for health information networks that voluntarily elect to adopt the trusted exchange framework and common agreement to attest to such adoption of the framework and agreement.

"(E) APPLICATION OF THE TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—As appropriate, Federal agencies contracting or entering into agreements with

health information exchange networks may require that as each such network upgrades health information technology or trust and operational practices, such network may adopt, where available, the trusted exchange framework and common agreement published under subparagraph (C).

"(F) RULE OF CONSTRUCTION.—

"(i) GENERAL ADOPTION.—Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement.

"(ii) ADOPTION WHEN EXCHANGE OF INFORMATION IS WITHIN NETWORK.—Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement for the exchange of electronic health information between participants of the same network.

"(iii) EXISTING FRAMEWORKS AND AGREEMENTS.—The trusted exchange framework and common agreement published under subparagraph (C) shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.

"(iv) APPLICATION BY FEDERAL AGENCIES.—Notwithstanding clauses (i), (ii), and (iii), Federal agencies may require the adoption of the trusted exchange framework and common agreement published under subparagraph (C) for health information exchanges contracting with or entering into agreements pursuant to subparagraph (E).

"(v) CONSIDERATION OF ONGOING WORK.—In carrying out this paragraph, the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts.".

(c) PROVIDER DIGITAL CONTACT INFORMATION INDEX.— 42 USC 300jj–11 note.

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall, directly or through a partnership with a private entity, establish a provider digital contact information index to provide digital contact information for health professionals and health facilities.

(2) USE OF EXISTING INDEX.—In establishing the initial index under paragraph (1), the Secretary may utilize an existing provider directory to make such digital contact information available.

(3) CONTACT INFORMATION.—An index established under this subsection shall ensure that contact information is available at the individual health care provider level and at the health facility or practice level.

(4) RULE OF CONSTRUCTION.—

(A) IN GENERAL.—The purpose of this subsection is to encourage the exchange of electronic health information by providing the most useful, reliable, and comprehensive

index of providers possible. In furthering such purpose, the Secretary shall include all health professionals and health facilities applicable to provide a useful, reliable, and comprehensive index for use in the exchange of health information.

(B) LIMITATION.—In no case shall exclusion from the index of providers be used as a measure to achieve objectives other the objectives described in subparagraph (A).

(d) STANDARDS DEVELOPMENT ORGANIZATIONS.—Section 3004 of the Public Health Service Act (42 U.S.C. 300jj–14) is amended by adding at the end the following:

"(c) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this section, the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards bodies.".

(e) HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE.—

(1) IN GENERAL.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended by striking sections 3002 (42 U.S.C. 300jj–12) and 3003 (42 U.S.C. 300jj–13) and inserting the following:

42 USC 300jj–12.

"SEC. 3002. HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—There is established a Health Information Technology Advisory Committee (referred to in this section as the 'HIT Advisory Committee') to recommend to the National Coordinator, consistent with the implementation of the strategic plan described in section 3001(c)(3), policies, and, for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. Such Committee shall serve to unify the roles of, and replace, the HIT Policy Committee and the HIT Standards Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

"(b) DUTIES.—

"(1) RECOMMENDATIONS ON POLICY FRAMEWORK TO ADVANCE AN INTEROPERABLE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—

"(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator a policy framework for adoption by the Secretary consistent with the strategic plan under section 3001(c)(3) for advancing the target areas described in this subsection. Such policy framework shall seek to prioritize achieving advancements in the target areas specified in subparagraph (B) of paragraph (2) and may, to the extent consistent with this section, incorporate policy recommendations made by the HIT Policy Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

"(B) UPDATES.—The HIT Advisory Committee shall propose updates to such recommendations to the policy framework and make new recommendations, as appropriate.

"(2) GENERAL DUTIES AND TARGET AREAS.—

"(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Such recommendations shall include recommended standards, architectures, and software schemes for access to electronic individually identifiable health information across disparate systems including user vetting, authentication, privilege management, and access control.

"(B) PRIORITY TARGET AREAS.—For purposes of this section, the HIT Advisory Committee shall make recommendations under subparagraph (A) with respect to at least each of the following target areas:

"(i) Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.

"(ii) The promotion and protection of privacy and security of health information in health information technology, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of the regulation promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996), including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care.

"(iii) The facilitation of secure access by an individual to such individual's protected health information and access to such information by a family member, caregiver, or guardian acting on behalf of a patient, including due to age-related and other disability, cognitive impairment, or dementia.

"(iv) Subject to subparagraph (D), any other target area that the HIT Advisory Committee identifies as an appropriate target area to be considered under this subparagraph.

"(C) ADDITIONAL TARGET AREAS.—For purposes of this section, the HIT Advisory Committee may make recommendations under subparagraph (A), in addition to areas described in subparagraph (B), with respect to any of the following areas:

"(i) The use of health information technology to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, reducing medical errors, improving population health,

reducing chronic disease, and advancing research and education.

"(ii) The use of technologies that address the needs of children and other vulnerable populations.

"(iii) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including at a minimum, race, ethnicity, primary language, and gender information.

"(iv) The use of self-service, telemedicine, home health care, and remote monitoring technologies.

"(v) The use of technologies that meet the needs of diverse populations.

"(vi) The use of technologies that support—

"(I) data for use in quality and public reporting programs;

"(II) public health; or

"(III) drug safety.

"(vii) The use of technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in a health information network or transported outside of the secure facilities or systems where the disclosing covered entity is responsible for security conditions.

"(viii) The use of a certified health information technology for each individual in the United States.

"(D) AUTHORITY FOR TEMPORARY ADDITIONAL PRIORITY TARGET AREAS.—For purposes of subparagraph (B)(iv), the HIT Advisory Committee may identify an area to be considered for purposes of recommendations under this subsection as a target area described in subparagraph (B) if—

"(i) the area is so identified for purposes of responding to new circumstances that have arisen in the health information technology community that affect the interoperability, privacy, or security of health information, or affect patient safety; and

"(ii) at least 30 days prior to treating such area as if it were a target area described in subparagraph (B), the National Coordinator provides adequate notice to Congress of the intent to treat such area as so described.

"(E) FOCUS OF COMMITTEE WORK.—It is the sense of Congress that the HIT Advisory Committee shall focus its work on the priority areas described in subparagraph (B) before proceeding to other work under subparagraph (C).

"(3) RULES RELATING TO RECOMMENDATIONS FOR STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—

"(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a), which may include standards, implementation specifications, and certification criteria that have been developed, harmonized, or recognized by the HIT Advisory Committee or predecessor committee.

The HIT Advisory Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B). Such recommendations shall be consistent with the latest recommendations made by the Committee.

"(B) HARMONIZATION.—The HIT Advisory Committee may recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and implementation specification.

"(C) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Advisory Committee for purposes of recommendations under paragraph (2)(B), shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.

"(D) CONSISTENCY.—The standards, implementation specifications, and certification criteria recommended under paragraph (2)(B) shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.

"(E) SPECIAL RULE RELATED TO INTEROPERABILITY.—Any recommendation made by the HIT Advisory Committee after the date of the enactment of this subparagraph with respect to interoperability of health information technology shall be consistent with interoperability as described in section 3000.

"(4) FORUM.—The HIT Advisory Committee shall serve as a forum for the participation of a broad range of stakeholders with specific expertise in policies, including technical expertise, relating to the matters described in paragraphs (1), (2), and (3) to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of health information technology infrastructure nationally and locally that allows for the electronic access, exchange, and use of health information.

"(5) SCHEDULE.—Not later than 30 days after the date on which the HIT Advisory Committee first meets, such HIT Advisory Committee shall develop a schedule for the assessment of policy recommendations developed under paragraph (1). The HIT Advisory Committee shall update such schedule annually. The Secretary shall publish such schedule in the Federal Register.

"(6) PUBLIC INPUT.—The HIT Advisory Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (5) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.

"(c) MEASURED PROGRESS IN ADVANCING PRIORITY AREAS.—

"(1) IN GENERAL.—For purposes of this section, the National Coordinator, in collaboration with the Secretary, shall establish, and update as appropriate, objectives and benchmarks for advancing and measuring the advancement of the priority target areas described in subsection (b)(2)(B).

"(2) ANNUAL PROGRESS REPORTS ON ADVANCING INTEROPERABILITY.—

"(A) IN GENERAL.—The HIT Advisory Committee, in consultation with the National Coordinator, shall annually submit to the Secretary and Congress a report on the progress made during the preceding fiscal year in—

"(i) achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information; and

"(ii) meeting the objectives and benchmarks described in paragraph (1).

"(B) CONTENT.—Each such report shall include, for a fiscal year—

"(i) a description of the work conducted by the HIT Advisory Committee during the preceding fiscal year with respect to the areas described in subsection (b)(2)(B);

"(ii) an assessment of the status of the infrastructure described in subparagraph (A), including the extent to which electronic health information is appropriately and readily available to enhance the access, exchange, and the use of electronic health information between users and across technology offered by different developers;

"(iii) the extent to which advancements have been achieved with respect to areas described in subsection (b)(2)(B);

"(iv) an analysis identifying existing gaps in policies and resources for—

"(I) achieving the objectives and benchmarks established under paragraph (1); and

"(II) furthering interoperability throughout the health information technology infrastructure;

"(v) recommendations for addressing the gaps identified in clause (iii); and

"(vi) a description of additional initiatives as the HIT Advisory Committee and National Coordinator determine appropriate.

"(3) SIGNIFICANT ADVANCEMENT DETERMINATION.—The Secretary shall periodically, based on the reports submitted under this subsection, review the target areas described in subsection (b)(2)(B), and, based on the objectives and benchmarks established under paragraph (1), the Secretary shall determine if significant advancement has been achieved with respect to such an area. Such determination shall be taken into consideration by the HIT Advisory Committee when determining to what extent the Committee makes recommendations for an area other than an area described in subsection (b)(2)(B).

"(d) MEMBERSHIP AND OPERATIONS.—

"(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Advisory Committee.

"(2) MEMBERSHIP.—The membership of the HIT Advisory Committee shall—

"(A) include at least 25 members, of which—

"(i) no fewer than 2 members are advocates for patients or consumers of health information technology;

"(ii) 3 members are appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human Services and 1 of whom shall be a public health official;

"(iii) 2 members are appointed by the majority leader of the Senate;

"(iv) 2 members are appointed by the minority leader of the Senate;

"(v) 2 members are appointed by the Speaker of the House of Representatives;

"(vi) 2 members are appointed by the minority leader of the House of Representatives; and

"(vii) such other members are appointed by the Comptroller General of the United States; and

"(B) at least reflect providers, ancillary health care workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use standards for such activity.

"(3) PARTICIPATION.—The members of the HIT Advisory Committee shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the Committee.

"(4) TERMS.—

"(A) IN GENERAL.—The terms of the members of the HIT Advisory Committee shall be for 3 years, except that the Secretary shall designate staggered terms of the members first appointed.

"(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Advisory Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Advisory Committee shall be filled in the manner in which the original appointment was made.

"(C) LIMITS.—Members of the HIT Advisory Committee shall be limited to two 3-year terms, for a total of not to exceed 6 years of service on the Committee.

"(5) OUTSIDE INVOLVEMENT.—The HIT Advisory Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies and standards for the electronic exchange and use of health information,

including in the areas of health information privacy and security.

"(6) QUORUM.—A majority of the members of the HIT Advisory Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

"(7) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.

"(8) ASSISTANCE.—For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Advisory Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not-for-profit entities that work in the public interest as a party of their mission.

"(e) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the HIT Advisory Committee.

"(f) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all policy recommendations made by the HIT Advisory Committee under this section.".

(2) TECHNICAL AND CONFORMING AMENDMENTS.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended—

(A) by striking—

(i) "HIT Policy Committee" and "HIT Standards Committee" each place that such terms appear (other than within the term "HIT Policy Committee and the HIT Standards Committee" or within the term "HIT Policy Committee or the HIT Standards Committee") and inserting "HIT Advisory Committee";

(ii) "HIT Policy Committee and the HIT Standards Committee" each place that such term appears and inserting "HIT Advisory Committee"; and

(iii) "HIT Policy Committee or the HIT Standards Committee" each place that such term appears and inserting "HIT Advisory Committee";

(B) in section 3000 (42 U.S.C. 300jj)—

(i) by striking paragraphs (7) and (8) and redesignating paragraphs (9) through (14) as paragraphs (8) through (13), respectively; and

(ii) by inserting after paragraph (6) the following paragraph:

"(7) HIT ADVISORY COMMITTEE.—The term 'HIT Advisory Committee' means such Committee established under section 3002(a).";

(C) in section 3001(c) (42 U.S.C. 300jj–11(c))—

(i) in paragraph (1)(A), by striking "under section 3003" and inserting "under section 3002";

(ii) in paragraph (2), by striking subparagraph (B) and inserting the following:

"(B) HIT ADVISORY COMMITTEE.—The National Coordinator shall be a leading member in the establishment

and operations of the HIT Advisory Committee and shall serve as a liaison between that Committee and the Federal Government.";

(D) in section 3004(b)(3) (42 U.S.C. 300jj–14(b)(3)), by striking "3003(b)(2)" and inserting "3002(b)(4)";

(E) in section 3007(b) (42 U.S.C. 300jj–17(b)), by striking "3003(a)" and inserting "3002(a)(2)"; and

(F) in section 3008 (42 U.S.C. 300jj–18)—

(i) in subsection (b), by striking "or 3003"; and

(ii) in subsection (c), by striking "3003(b)(1)(A)" and inserting "3002(b)(2)".

(3) TRANSITION TO THE HIT ADVISORY COMMITTEE.—The Secretary of Health and Human Services shall provide for an orderly and timely transition to the HIT Advisory Committee established under amendments made by this section. 42 USC 300jj–12 note.

(f) PRIORITIES FOR ADOPTION OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), as amended by subsection (e), is further amended by inserting after section 3002 the following:

"SEC. 3003. SETTING PRIORITIES FOR STANDARDS ADOPTION. 42 USC 300jj–13.

"(a) IDENTIFYING PRIORITIES.—

"(1) IN GENERAL.—Not later than 6 months after the date on which the HIT Advisory Committee first meets, the National Coordinator shall periodically convene the HIT Advisory Committee to—

"(A) identify priority uses of health information technology, focusing on priorities—

"(i) arising from the implementation of the incentive programs for the meaningful use of certified EHR technology, the Merit-based Incentive Payment System, Alternative Payment Models, the Hospital Value-Based Purchasing Program, and any other value-based payment program determined appropriate by the Secretary;

"(ii) related to the quality of patient care;

"(iii) related to public health;

"(iv) related to clinical research;

"(v) related to the privacy and security of electronic health information;

"(vi) related to innovation in the field of health information technology;

"(vii) related to patient safety;

"(viii) related to the usability of health information technology;

"(ix) related to individuals' access to electronic health information; and

"(x) other priorities determined appropriate by the Secretary;

"(B) identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet the priorities identified in subparagraph (A); and

"(C) publish a report summarizing the findings of the analysis conducted under subparagraphs (A) and (B) and make appropriate recommendations.

"(2) PRIORITIZATION.—In identifying such standards and implementation specifications under paragraph (1)(B), the HIT Advisory Committee shall prioritize standards and implementation specifications developed by consensus-based standards development organizations.

"(3) GUIDELINES FOR REVIEW OF EXISTING STANDARDS AND SPECIFICATIONS.—In consultation with the consensus-based entity described in section 1890 of the Social Security Act and other appropriate Federal agencies, the analysis of existing standards under paragraph (1)(B) shall include an evaluation of the need for a core set of common data elements and associated value sets to enhance the ability of certified health information technology to capture, use, and exchange structured electronic health information.

"(b) REVIEW OF ADOPTED STANDARDS.—

"(1) IN GENERAL.—Beginning 5 years after the date of enactment of the 21st Century Cures Act and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to—

"(A) maintain the use of such standards and implementation specifications; or

"(B) phase out such standards and implementation specifications.

"(2) PRIORITIES.—The HIT Advisory Committee, in collaboration with the National Institute for Standards and Technology, shall annually and through the use of public input, review and publish priorities for the use of health information technology, standards, and implementation specifications to support those priorities.

"(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent the use or adoption of novel standards that improve upon the existing health information technology infrastructure and facilitate the secure exchange of health information.".

SEC. 4004. INFORMATION BLOCKING.

Subtitle C of title XXX of the Public Health Service Act (42 U.S.C. 300jj–51 et seq.) is amended by adding at the end the following:

42 USC 300jj–52.

"SEC. 3022. INFORMATION BLOCKING.

"(a) DEFINITION.—

"(1) IN GENERAL.—In this section, the term 'information blocking' means a practice that—

"(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

"(B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

"(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is

likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

"(2) PRACTICES DESCRIBED.—The information blocking practices described in paragraph (1) may include—

"(A) practices that restrict authorized access, exchange, or use under applicable State or Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies;

"(B) implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

"(C) implementing health information technology in ways that are likely to—

"(i) restrict the access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between health information technology systems; or

"(ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.

"(3) RULEMAKING.—The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1).

"(4) NO ENFORCEMENT BEFORE EXCEPTION IDENTIFIED.—The term 'information blocking' does not include any practice or conduct occurring prior to the date that is 30 days after the date of enactment of the 21st Century Cures Act.

"(5) CONSULTATION.—The Secretary may consult with the Federal Trade Commission in promulgating regulations under this subsection, to the extent that such regulations define practices that are necessary to promote competition and consumer welfare.

"(6) APPLICATION.—The term 'information blocking', with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity.

"(7) CLARIFICATION.—In carrying out this section, the Secretary shall ensure that health care providers are not penalized for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that such technology meets the requirements to be certified under this title.

"(b) INSPECTOR GENERAL AUTHORITY.—

"(1) IN GENERAL.—The inspector general of the Department of Health and Human Services (referred to in this section as the 'Inspector General') may investigate any claim that—

"(A) a health information technology developer of certified health information technology or other entity offering certified health information technology—

"(i) submitted a false attestation under section 3001(c)(5)(D)(vii); or

"(ii) engaged in information blocking;

"(B) a health care provider engaged in information blocking; or

"(C) a health information exchange or network engaged in information blocking.

"(2) PENALTIES.—

"(A) DEVELOPERS, NETWORKS, AND EXCHANGES.—Any individual or entity described in subparagraph (A) or (C) of paragraph (1) that the Inspector General, following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed $1,000,000 per violation. Such determination shall take into account factors such as the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted.

"(B) PROVIDERS.—Any individual or entity described in subparagraph (B) of paragraph (1) determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.

"(C) PROCEDURE.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b) of such section) shall apply to a civil money penalty applied under this paragraph in the same manner as such provisions apply to a civil money penalty or proceeding under such section 1128A(a).

"(D) RECOVERED PENALTY FUNDS.—The amounts recovered under this paragraph shall be allocated as follows:

"(i) ANNUAL OPERATING EXPENSES.—Each year following the establishment of the authority under this subsection, the Office of the Inspector General shall provide to the Secretary an estimate of the costs to carry out investigations under this section. Such estimate may include reasonable reserves to account for variance in annual amounts recovered under this paragraph. There is authorized to be appropriated for purposes of carrying out this section an amount equal to the amount specified in such estimate for the fiscal year.

"(ii) APPLICATION TO OTHER PROGRAMS.—The amounts recovered under this paragraph and remaining after amounts are made available under clause (i) shall be transferred to the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act, in such proportion as the Secretary determines appropriate.

"(E) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Office of the Inspector General to carry out this section $10,000,000, to remain available until expended.

"(3) RESOLUTION OF CLAIMS.—

"(A) IN GENERAL.—The Office of the Inspector General, if such Office determines that a consultation regarding the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) will resolve an information blocking claim, may refer such instances of information blocking to the Office for Civil Rights of the Department of Health and Human Services for resolution.

"(B) LIMITATION ON LIABILITY.—If a health care provider or health information technology developer makes information available based on a good faith reliance on consultations with the Office for Civil Rights of the Department of Health and Human Services pursuant to a referral under subparagraph (A), with respect to such information, the health care provider or developer shall not be liable for such disclosure or disclosures made pursuant to subparagraph (A).

"(c) IDENTIFYING BARRIERS TO EXCHANGE OF CERTIFIED HEALTH INFORMATION TECHNOLOGY.—

"(1) TRUSTED EXCHANGE DEFINED.—In this section, the term 'trusted exchange' with respect to certified electronic health records means that the certified electronic health record technology has the technical capability to enable secure health information exchange between users and multiple certified electronic health record technology systems.

"(2) GUIDANCE.—The National Coordinator, in consultation with the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance on common legal, governance, and security barriers that prevent the trusted exchange of electronic health information.

"(3) REFERRAL.—The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services may refer to the Inspector General instances or patterns of refusal to exchange health information with an individual or entity using certified electronic health record technology that is technically capable of trusted exchange and under conditions when exchange is legally permissible.

"(d) ADDITIONAL PROVISIONS.—

"(1) INFORMATION SHARING PROVISIONS.—The National Coordinator may serve as a technical consultant to the Inspector General and the Federal Trade Commission for purposes of carrying out this section. The National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (b) with the Federal Trade Commission for purposes of such investigations and shall share information with the Inspector General, as required by law.

"(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—

"(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section;

"(B) shall be exempt from mandatory disclosure under section 552 of title 5, United States Code, as provided by subsection (b)(3) of such section; and

"(C) may be used by the Inspector General or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.

"(3) STANDARDIZED PROCESS.—

"(A) IN GENERAL.—The National Coordinator shall implement a standardized process for the public to submit reports on claims of—

"(i) health information technology products or developers of such products (or other entities offering such products to health care providers) not being interoperable or resulting in information blocking;

"(ii) actions described in subsection (b)(1) that result in information blocking as described in subsection (a); and

"(iii) any other act described in subsection (a).

"(B) COLLECTION OF INFORMATION.—The standardized process implemented under subparagraph (A) shall provide for the collection of such information as the originating institution, location, type of transaction, system and version, timestamp, terminating institution, locations, system and version, failure notice, and other related information.

"(4) NONDUPLICATION OF PENALTY STRUCTURES.—In carrying out this subsection, the Secretary shall, to the extent possible, ensure that penalties do not duplicate penalty structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before the date of the enactment of this section.".

42 USC 300jj–14 note.

SEC. 4005. LEVERAGING ELECTRONIC HEALTH RECORDS TO IMPROVE PATIENT CARE.

(a) REQUIREMENT RELATING TO REGISTRIES.—

(1) IN GENERAL.—To be certified in accordance with title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), electronic health records shall be capable of transmitting to, and where applicable, receiving and accepting data from, registries in accordance with standards recognized by the Office of the National Coordinator for Health Information Technology, including clinician-led clinical data registries, that are also certified to be technically capable of receiving and accepting from, and where applicable, transmitting data to certified electronic health record technology in accordance with such standards.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the certification of registries beyond the technical capability to exchange data in accordance with applicable recognized standards.

(b) DEFINITION.—For purposes of this Act, the term "clinician-led clinical data registry" means a clinical data repository—

(1) that is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986), professional society or other similar clinician-led or -controlled organization, or such

organization's controlled affiliate, devoted to the care of a population defined by a particular disease, condition, exposure or therapy;

(2) that is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures;

(3) that provides feedback to participants who submit reports to the repository;

(4) that meets standards for data quality including—

(A) systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and

(B) being subject to regular data checks or audits to verify completeness and validity; and

(5) that provides ongoing participant training and support.

(c) TREATMENT OF HEALTH INFORMATION TECHNOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.—

(1) IN GENERAL.—In applying part C of title IX of the Public Health Service Act (42 U.S.C. 299b–21 et seq.), a health information technology developer shall be treated as a provider (as defined in section 921 of such Act) for purposes of reporting and conducting patient safety activities concerning improving clinical care through the use of health information technology that could result in improved patient safety, health care quality, or health care outcomes.

(2) REPORT.—Not later than 4 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning best practices and current trends voluntarily provided, without identifying individual providers or disclosing or using protected health information or individually identifiable information, by patient safety organizations to improve the integration of health information technology into clinical practice.

SEC. 4006. EMPOWERING PATIENTS AND IMPROVING PATIENT ACCESS TO THEIR ELECTRONIC HEALTH INFORMATION.

(a) USE OF HEALTH INFORMATION EXCHANGES FOR PATIENT ACCESS.—Section 3009 of the Public Health Service Act (42 U.S.C. 300jj–19) is amended by adding at the end the following:

"(c) PROMOTING PATIENT ACCESS TO ELECTRONIC HEALTH INFORMATION THROUGH HEALTH INFORMATION EXCHANGES .—

"(1) IN GENERAL.—The Secretary shall use existing authorities to encourage partnerships between health information exchange organizations and networks and health care providers, health plans, and other appropriate entities with the goal of offering patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.

"(2) EDUCATION OF PROVIDERS.—The Secretary, in coordination with the Office for Civil Rights of the Department of Health and Human Services, shall—

"(A) educate health care providers on ways of leveraging the capabilities of health information exchanges

(or other relevant platforms) to provide patients with access to their electronic health information;

"(B) clarify misunderstandings by health care providers about using health information exchanges (or other relevant platforms) for patient access to electronic health information; and

"(C) to the extent practicable, educate providers about health information exchanges (or other relevant platforms) that employ some or all of the capabilities described in paragraph (1).

"(3) REQUIREMENTS.—In carrying out paragraph (1), the Secretary, in coordination with the Office for Civil Rights, shall issue guidance to health information exchanges related to best practices to ensure that the electronic health information provided to patients is—

"(A) private and secure;

"(B) accurate;

"(C) verifiable; and

"(D) where a patient's authorization to exchange information is required by law, easily exchanged pursuant to such authorization.

"(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to preempt State laws applicable to patient consent for the access of information through a health information exchange (or other relevant platform) that provide protections to patients that are greater than the protections otherwise provided for under applicable Federal law.

"(d) EFFORTS TO PROMOTE ACCESS TO HEALTH INFORMATION.—The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services shall jointly promote patient access to health information in a manner that would ensure that such information is available in a form convenient for the patient, in a reasonable manner, without burdening the health care provider involved.

"(e) ACCESSIBILITY OF PATIENT RECORDS.—

"(1) ACCESSIBILITY AND UPDATING OF INFORMATION.—

"(A) IN GENERAL.—The Secretary, in consultation with the National Coordinator, shall promote policies that ensure that a patient's electronic health information is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent.

"(B) UPDATING EDUCATION ON ACCESSING AND EXCHANGING PERSONAL HEALTH INFORMATION.—To promote awareness that an individual has a right of access to inspect, obtain a copy of, and transmit to a third party a copy of such individual's protected health information pursuant to the Health Information Portability and Accountability Act, Privacy Rule (subpart E of part 164 of title 45, Code of Federal Regulations), the Director of the Office for Civil Rights, in consultation with the National Coordinator, shall assist individuals and health care providers in understanding a patient's rights to access and protect personal health information under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191), including providing best practices

for requesting personal health information in a computable format, including using patient portals or third-party applications and common cases when a provider is permitted to exchange and provide access to health information.".

"(2) CERTIFYING USABILITY FOR PATIENTS.—In carrying out certification programs under section 3001(c)(5), the National Coordinator may require that—

"(A) the certification criteria support—

"(i) patient access to their electronic health information, including in a single longitudinal format that is easy to understand, secure, and may be updated automatically;

"(ii) the patient's ability to electronically communicate patient-reported information (such as family history and medical history); and

"(iii) patient access to their personal electronic health information for research at the option of the patient; and

"(B) the HIT Advisory Committee develop and prioritize standards, implementation specifications, and certification criteria required to help support patient access to electronic health information, patient usability, and support for technologies that offer patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.".

(b) ACCESS TO INFORMATION IN AN ELECTRONIC FORMAT.—Section 13405(e) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17935) is amended—

(1) in paragraph (1), by striking "and" at the end;

(2) by redesignating paragraph (2) as paragraph (3); and

(3) by inserting after paragraph (1), the following:

"(2) if the individual makes a request to a business associate for access to, or a copy of, protected health information about the individual, or if an individual makes a request to a business associate to grant such access to, or transmit such copy directly to, a person or entity designated by the individual, a business associate may provide the individual with such access or copy, which may be in an electronic form, or grant or transmit such access or copy to such person or entity designated by the individual; and".

SEC. 4007. GAO STUDY ON PATIENT MATCHING.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study to—

(1) review the policies and activities of the Office of the National Coordinator for Health Information Technology and other relevant stakeholders, which may include standards development organizations, experts in the technical aspects of health information technology, health information technology developers, providers of health services, health care suppliers, health care payers, health care quality organizations, States, health information technology policy experts, and other appropriate entities, to ensure appropriate patient matching to protect patient privacy and security with respect to electronic

health records and the exchange of electronic health information; and

(2) survey ongoing efforts related to the policies and activities described in paragraph (1) and the effectiveness of such efforts occurring in the private sector.

(b) AREAS OF CONCENTRATION.—In conducting the study under subsection (a), the Comptroller General shall—

(1) evaluate current methods used in certified electronic health records for patient matching based on performance related to factors such as—

(A) the privacy of patient information;

(B) the security of patient information;

(C) improving matching rates;

(D) reducing matching errors; and

(E) reducing duplicate records; and

(2) determine whether the Office of the National Coordinator for Health Information Technology could improve patient matching by taking steps including—

(A) defining additional data elements to assist in patient data matching;

(B) agreeing on a required minimum set of elements that need to be collected and exchanged;

(C) requiring electronic health records to have the ability to make certain fields required and use specific standards; and

(D) other options recommended by the relevant stakeholders consulted pursuant to subsection (a).

(c) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General shall submit to the appropriate committees of Congress a report concerning the findings of the study conducted under subsection (a).

SEC. 4008. GAO STUDY ON PATIENT ACCESS TO HEALTH INFORMATION.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States (referred to in this section as the "Comptroller General") shall build on prior Government Accountability Office studies and other literature review and conduct a study to review patient access to their own protected health information, including barriers to such patient access and complications or difficulties providers experience in providing access to patients. In conducting such study, the Comptroller General shall consider the increase in adoption of health information technology and the increasing prevalence of protected health information that is maintained electronically.

(2) AREAS OF CONCENTRATION.—In conducting the review under paragraph (1), the Comptroller General shall consider—

(A) instances when covered entities charge individuals, including patients, third parties, and health care providers, for record requests, including records that are requested in an electronic format;

(B) examples of the amounts and types of fees charged to individuals for record requests, including instances when the record is requested to be transmitted to a third party;

(C) the extent to which covered entities are unable to provide the access requested by individuals in the form

and format requested by the individual, including examples of such instances;

(D) instances in which third parties may request protected health information through patients' individual right of access, including instances where such requests may be used to circumvent appropriate fees that may be charged to third parties;

(E) opportunities that permit covered entities to charge appropriate fees to third parties for patient records while providing patients with access to their protected health information at low or no cost;

(F) the ability of providers to distinguish between requests originating from an individual that require limitation to a cost-based fee and requests originating from third parties that may not be limited to cost-based fees; and

(G) other circumstances that may inhibit the ability of providers to provide patients with access to their records, and the ability of patients to gain access to their records.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General shall submit a report to Congress on the findings of the study conducted under subsection (a).

SEC. 4009. IMPROVING MEDICARE LOCAL COVERAGE DETERMINATIONS.

(a) IN GENERAL.—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following new subparagraph:

"(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

"(i) Such determination in its entirety.

"(ii) Where and when the proposed determination was first made public.

"(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

"(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

"(v) An explanation of the rationale that supports such determination.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to local coverage determinations that are proposed or revised on or after the date that is 180 days after the date of enactment of this Act. 42 USC 1395y note.

SEC. 4010. MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.

Section 1808 of the Social Security Act (42 U.S.C. 1395b–9) is amended by adding at the end the following new subsection:

"(d) PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.—

"(1) IN GENERAL.—Not later than 12 months after the date of enactment of this paragraph, the Secretary shall provide

for a pharmaceutical and technology ombudsman within the Centers for Medicare & Medicaid Services who shall receive and respond to complaints, grievances, and requests that—

"(A) are from entities that manufacture pharmaceutical, biotechnology, medical device, or diagnostic products that are covered or for which coverage is being sought under this title; and

"(B) are with respect to coverage, coding, or payment under this title for such products.

"(2) APPLICATION.—The second sentence of subsection (c)(2) shall apply to the ombudsman under subparagraph (A) in the same manner as such sentence applies to the Medicare Beneficiary Ombudsman under subsection (c).".

SEC. 4011. MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY.

Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

"(t) SITE-OF-SERVICE PRICE TRANSPARENCY.—

"(1) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this title, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Internet website, with respect to an appropriate number of such items and services—

"(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

"(B) the estimated amount of beneficiary liability applicable to the item or service.

"(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a Medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

"(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

"(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

"(B) may utilize mechanisms in existence on the date of enactment of this subsection, such as the portion of the Internet website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare Internet website), to make available such estimated amounts under such paragraph.

"(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2017, to remain available until expended.".

SEC. 4012. TELEHEALTH SERVICES IN MEDICARE.

(a) PROVISION OF INFORMATION BY CENTERS FOR MEDICARE & MEDICAID SERVICES.—Not later than 1 year after the date of enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall provide to the committees of jurisdiction of the House of Representatives and the Senate information on the following:

(1) The populations of Medicare beneficiaries, such as those who are dually eligible for the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.) and those with chronic conditions, whose care may be improved most in terms of quality and efficiency by the expansion, in a manner that meets or exceeds the existing in-person standard of care under the Medicare program under such title XVIII, of telehealth services under section 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

(2) Activities by the Center for Medicare and Medicaid Innovation which examine the use of telehealth services in models, projects, or initiatives funded through section 1115A of such Act (42 U.S.C. 1315a).

(3) The types of high-volume services (and related diagnoses) under such title XVIII which might be suitable to be furnished using telehealth.

(4) Barriers that might prevent the expansion of telehealth services under section 1834(m)(4) of the Social Security Act (42 U.S.C. 1395m(m)(4)) beyond such services that are in effect as of the date of enactment of this Act.

(b) PROVISION OF INFORMATION BY MEDPAC.—Not later than March 15, 2018, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall, using quantitative and qualitative research methods, provide information to the committees of jurisdiction of the House of Representatives and the Senate that identifies—

(1) the telehealth services for which payment can be made, as of the date of enactment of this Act, under the fee-for-service program under parts A and B of title XVIII of such Act;

(2) the telehealth services for which payment can be made, as of such date, under private health insurance plans; and

(3) with respect to services identified under paragraph (2) but not under paragraph (1), ways in which payment for such services might be incorporated into such fee-for-service program (including any recommendations for ways to accomplish this incorporation).

(c) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) eligible originating sites should be expanded beyond those originating sites described in section 1834(m)(4)(C) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)); and

(2) any expansion of telehealth services under the Medicare program under title XVIII of such Act should—

(A) recognize that telemedicine is the delivery of safe, effective, quality health care services, by a health care provider, using technology as the mode of care delivery;

(B) meet or exceed the conditions of coverage and payment with respect to the Medicare program if the service

was furnished in person, including standards of care, unless specifically addressed in subsequent legislation; and

(C) involve clinically appropriate means to furnish such services.

TITLE V—SAVINGS

SEC. 5001. SAVINGS IN THE MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)), as amended by section 704(h) of the Comprehensive Addiction and Recovery Act of 2016, is amended by striking "$140,000,000" and inserting "$270,000,000".

SEC. 5002. MEDICAID REIMBURSEMENT TO STATES FOR DURABLE MEDICAL EQUIPMENT.

Section 1903(i)(27) of the Social Security Act (42 U.S.C. 1396b(i)(27)) is amended by striking "January 1, 2019" and inserting "January 1, 2018".

SEC. 5003. PENALTIES FOR VIOLATIONS OF GRANTS, CONTRACTS, AND OTHER AGREEMENTS.

(a) IN GENERAL.—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) is amended by adding at the end the following new subsections:

"(o) Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (q)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary provides funding—

"(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)) under such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

"(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted in order to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

"(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

"(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation (as defined in subsection (s)) to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

"(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty in cases under paragraph (1), of not more than $10,000 for each specified claim; in cases under paragraph (2), not more than $50,000 for each false statement, omission, or misrepresentation of a material fact; in cases under paragraph (3), not more than $50,000 for each false record or statement; in cases under paragraph (4), not more than $50,000 for each false record or statement or $10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay; or in cases under paragraph (5), not more than $15,000 for each day of the failure described in such paragraph. In addition, in cases under paragraphs (1) and (3), such a person shall be subject to an assessment of not more than 3 times the amount claimed in the specified claim described in such paragraph in lieu of damages sustained by the United States or a specified State agency because of such specified claim, and in cases under paragraphs (2) and (4), such a person shall be subject to an assessment of not more than 3 times the total amount of the funds described in paragraph (2) or (4), respectively (or, in the case of an obligation to transmit property to the Secretary described in paragraph (4), of the value of the property described in such paragraph) in lieu of damages sustained by the United States or a specified State agency because of such case. In addition, the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

"(p) The provisions of subsections (c), (d), (g), and (h) shall apply to a civil money penalty or assessment under subsection (o) in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a). In applying subsection (d), each reference to a claim under such subsection shall be treated as including a reference to a specified claim (as defined in subsection (r)).

"(q) For purposes of this subsection and subsections (o) and (p):

"(1) The term 'Department' means the Department of Health and Human Services.

"(2) The term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

"(3) The term 'other agreement' includes a cooperative agreement, scholarship, fellowship, loan, subsidy, payment for a specified use, donation agreement, award, or subaward (regardless of whether one or more of the persons entering into the agreement is a contractor or subcontractor).

"(4) The term 'program beneficiary' means, in the case of a grant, contract, or other agreement designed to accomplish the objective of awarding or otherwise furnishing benefits or assistance to individuals and for which the Secretary provides funding, an individual who applies for, or who receives, such benefits or assistance from such grant, contract, or other agreement. Such term does not include, with respect to such grant, contract, or other agreement, an officer, employee, or agent of a person or entity that receives such grant or that enters into such contract or other agreement.

"(5) The term 'recipient' includes a subrecipient or subcontractor.

"(6) The term 'specified State agency' means an agency of a State government established or designated to administer or supervise the administration of a grant, contract, or other agreement funded in whole or in part by the Secretary.

"(r) For purposes of this section, the term 'specified claim' means any application, request, or demand under a grant, contract, or other agreement for money or property, whether or not the United States or a specified State agency has title to the money or property, that is not a claim (as defined in subsection (i)(2)) and that—

"(1) is presented or caused to be presented to an officer, employee, or agent of the Department or agency thereof, or of any specified State agency; or

"(2) is made to a contractor, grantee, or any other recipient if the money or property is to be spent or used on the Department's behalf or to advance a Department program or interest, and if the Department—

"(A) provides or has provided any portion of the money or property requested or demanded; or

"(B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

"(s) For purposes of subsection (o), the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, for a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.".

(b) CONFORMING AMENDMENTS.—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) is amended—

(1) in subsection (e), by inserting "or specified claim" after "claim" in the first sentence; and

(2) in subsection (f)—

(A) in the matter preceding paragraph (1)—

(i) by inserting "or specified claim (as defined in subsection (r))" after "district where the claim"; and

(ii) by inserting "(or, with respect to a person described in subsection (o), the person)" after "claimant"; and

(B) in the matter following paragraph (4), by inserting "(or, in the case of a penalty or assessment under subsection (o), by a specified State agency (as defined in subsection (q)(6)),' after "or a State agency".

SEC. 5004. REDUCING OVERPAYMENTS OF INFUSION DRUGS.

(a) TREATMENT OF INFUSION DRUGS FURNISHED THROUGH DURABLE MEDICAL EQUIPMENT.—Section 1842(o)(1) of the Social Security Act (42 U.S.C. 1395u(o)(1)) is amended—

(1) in subparagraph (C), by inserting "(and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017)" after "2005"; and

(2) in subparagraph (D)—

(A) by striking "infusion drugs" and inserting "infusion drugs or biologicals" each place it appears; and

(B) in clause (i)—

(i) by striking "2004" and inserting "2004, and before January 1, 2017"; and

(ii) by striking "for such drug".

(b) NONINCLUSION OF DME INFUSION DRUGS UNDER DME COMPETITIVE ACQUISITION PROGRAMS.—

(1) IN GENERAL.—Section 1847(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)(A)) is amended—

(A) by striking "and excluding" and inserting ", excluding"; and

(B) by inserting before the period at the end the following: ", and excluding drugs and biologicals described in section 1842(o)(1)(D)".

(2) CONFORMING AMENDMENT.—Section 1842(o)(1)(D)(ii) of the Social Security Act (42 U.S.C. 1395u(o)(1)(D)(ii)) is amended by striking "2007" and inserting "2007, and before the date of the enactment of the 21st Century Cures Act.".

SEC. 5005. INCREASING OVERSIGHT OF TERMINATION OF MEDICAID PROVIDERS.

(a) INCREASED OVERSIGHT AND REPORTING.—

(1) STATE REPORTING REQUIREMENTS.—Section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)) is amended—

(A) by redesignating paragraph (8) as paragraph (9); and

(B) by inserting after paragraph (7) the following new paragraph:

"(8) PROVIDER TERMINATIONS.—

"(A) IN GENERAL.—Beginning on July 1, 2018, in the case of a notification under subsection (a)(41) with respect to a termination for a reason specified in section 455.101 of title 42, Code of Federal Regulations (as in effect on November 1, 2015) or for any other reason specified by the Secretary, of the participation of a provider of services or any other person under the State plan (or under a waiver of the plan), the State, not later than 30 days after the effective date of such termination, submits to the Secretary with respect to any such provider or person, as appropriate—

"(i) the name of such provider or person;

"(ii) the provider type of such provider or person;

"(iii) the specialty of such provider's or person's practice;

"(iv) the date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of such provider or person (if applicable);

"(v) the reason for the termination;

"(vi) a copy of the notice of termination sent to the provider or person;

"(vii) the date on which such termination is effective, as specified in the notice; and

"(viii) any other information required by the Secretary.

"(B) EFFECTIVE DATE DEFINED.—For purposes of this paragraph, the term 'effective date' means, with respect

to a termination described in subparagraph (A), the later of—

"(i) the date on which such termination is effective, as specified in the notice of such termination; or

"(ii) the date on which all appeal rights applicable to such termination have been exhausted or the timeline for any such appeal has expired.".

(2) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—Section 1932(d) of the Social Security Act (42 U.S.C. 1396u–2(d)) is amended by adding at the end the following new paragraph:

"(5) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—With respect to any contract with a managed care entity under section 1903(m) or 1905(t)(3) (as applicable), no later than July 1, 2018, such contract shall include a provision that providers of services or persons terminated (as described in section 1902(kk)(8)) from participation under this title, title XVIII, or title XXI shall be terminated from participating under this title as a provider in any network of such entity that serves individuals eligible to receive medical assistance under this title.".

(3) TERMINATION NOTIFICATION DATABASE.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended by adding at the end the following new subsection:

"(ll) TERMINATION NOTIFICATION DATABASE.—In the case of a provider of services or any other person whose participation under this title or title XXI is terminated (as described in subsection (kk)(8)), the Secretary shall, not later than 30 days after the date on which the Secretary is notified of such termination under subsection (a)(41) (as applicable), review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 1395cc note; Public Law 111–148).".

(4) NO FEDERAL FUNDS FOR ITEMS AND SERVICES FURNISHED BY TERMINATED PROVIDERS.—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended—

(A) in subsection (i)(2)—

(i) in subparagraph (A), by striking the comma at the end and inserting a semicolon;

(ii) in subparagraph (B), by striking "or" at the end; and

(iii) by adding at the end the following new subparagraph:

"(D) beginning on July 1, 2018, under the plan by any provider of services or person whose participation in the State plan is terminated (as described in section 1902(kk)(8)) after the date that is 60 days after the date on which such termination is included in the database or other system under section 1902(ll); or"; and

(B) in subsection (m), by inserting after paragraph (2) the following new paragraph:

"(3) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by a managed care entity (as defined under section 1932(a)(1)) under the State plan under this title (or under a waiver of the plan) unless the State—

"(A) beginning on July 1, 2018, has a contract with such entity that complies with the requirement specified in section 1932(d)(5); and

"(B) beginning on January 1, 2018, complies with the requirement specified in section 1932(d)(6)(A).".

(5) DEVELOPMENT OF UNIFORM TERMINOLOGY FOR REASONS FOR PROVIDER TERMINATION.—Not later than July 1, 2017, the Secretary of Health and Human Services shall, in consultation with the heads of State agencies administering State Medicaid plans (or waivers of such plans), issue regulations establishing uniform terminology to be used with respect to specifying reasons under subparagraph (A)(v) of paragraph (8) of section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)), as added by paragraph (1), for the termination (as described in such paragraph (8)) of the participation of certain providers in the Medicaid program under title XIX of such Act or the Children's Health Insurance Program under title XXI of such Act. 42 USC 1396a note.

(6) CONFORMING AMENDMENT.—Section 1902(a)(41) of the Social Security Act (42 U.S.C. 1396a(a)(41)) is amended by striking "provide that whenever" and inserting "provide, in accordance with subsection (kk)(8) (as applicable), that whenever".

(b) INCREASING AVAILABILITY OF MEDICAID PROVIDER INFORMATION.—

(1) FFS PROVIDER ENROLLMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended by inserting after paragraph (77) the following new paragraph:

"(78) provide that, not later than January 1, 2017, in the case of a State that pursuant to its State plan or waiver of the plan for medical assistance pays for medical assistance on a fee-for-service basis, the State shall require each provider furnishing items and services to, or ordering, prescribing, referring, or certifying eligibility for, services for individuals eligible to receive medical assistance under such plan to enroll with the State agency and provide to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of the provider (if applicable);".

(2) MANAGED CARE PROVIDER ENROLLMENT.—Section 1932(d) of the Social Security Act (42 U.S.C. 1396u–2(d)), as amended by subsection (a)(2), is amended by adding at the end the following new paragraph:

"(6) ENROLLMENT OF PARTICIPATING PROVIDERS.—

"(A) IN GENERAL.—Beginning not later than January 1, 2018, a State shall require that, in order to participate as a provider in the network of a managed care entity that provides services to, or orders, prescribes, refers, or certifies eligibility for services for, individuals who are eligible for medical assistance under the State plan under this title (or under a waiver of the plan) and who are enrolled with the entity, the provider is enrolled consistent with section 1902(kk) with the State agency administering the State plan under this title. Such enrollment shall

include providing to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier, Federal taxpayer identification number, and the State license or certification number of the provider.

"(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as requiring a provider described in such subparagraph to provide services to individuals who are not enrolled with a managed care entity under this title.".

(c) COORDINATION WITH CHIP.—

(1) IN GENERAL.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)) is amended—

(A) by redesignating subparagraphs (B), (C), (D), (E), (F), (G), (H), (I), (J), (K), (L), (M), (N), and (O) as subparagraphs (D), (E), (F), (G), (H), (I), (J), (K), (M), (N), (O), (P), (Q), and (R), respectively;

(B) by inserting after subparagraph (A) the following new subparagraphs:

"(B) Section 1902(a)(39) (relating to termination of participation of certain providers).

"(C) Section 1902(a)(78) (relating to enrollment of providers participating in State plans providing medical assistance on a fee-for-service basis).";

(C) by inserting after subparagraph (K) (as redesignated by subparagraph (A)) the following new subparagraph:

"(L) Section 1903(m)(3) (relating to limitation on payment with respect to managed care).''; and

(D) in subparagraph (P) (as redesignated by subparagraph (A)), by striking "(a)(2)(C) and (h)" and inserting "(a)(2)(C) (relating to Indian enrollment), (d)(5) (relating to contract requirement for managed care entities), (d)(6) (relating to enrollment of providers participating with a managed care entity), and (h) (relating to special rules with respect to Indian enrollees, Indian health care providers, and Indian managed care entities)".

(2) EXCLUDING FROM MEDICAID PROVIDERS EXCLUDED FROM CHIP.—Section 1902(a)(39) of the Social Security Act (42 U.S.C. 1396a(a)(39)) is amended by striking "title XVIII or any other State plan under this title" and inserting "title XVIII, any other State plan under this title (or waiver of the plan), or any State child health plan under title XXI (or waiver of the plan) and such termination is included by the Secretary in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act".

42 USC 1396a note.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as changing or limiting the appeal rights of providers or the process for appeals of States under the Social Security Act.

(e) OIG REPORT.—Not later than March 31, 2020, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the implementation of the amendments made by this section. Such report shall include the following:

(1) An assessment of the extent to which providers who are included under subsection (ll) of section 1902 of the Social Security Act (42 U.S.C. 1396a) (as added by subsection (a)(3))

in the database or similar system referred to in such subsection are terminated (as described in paragraph (8) of subsection (kk) of such section, as added by subsection (a)(1)) from participation in all State plans under title XIX of such Act (or waivers of such plans).

(2) Information on the amount of Federal financial participation paid to States under section 1903 of such Act in violation of the limitation on such payment specified in subparagraph (D) of subsection (i)(2) of such section and paragraph (3) of subsection (m) of such section, as added by subsection (a)(4).

(3) An assessment of the extent to which contracts with managed care entities under title XIX of such Act comply with the requirement specified in paragraph (5) of section 1932(d) of such Act, as added by subsection (a)(2).

(4) An assessment of the extent to which providers have been enrolled under section 1902(a)(78) or 1932(d)(6)(A) of such Act (42 U.S.C. 1396a(a)(78), 1396u–2(d)(6)(A)) with State agencies administering State plans under title XIX of such Act (or waivers of such plans).

SEC. 5006. REQUIRING PUBLICATION OF FEE-FOR-SERVICE PROVIDER DIRECTORY.

(a) IN GENERAL.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(1) in paragraph (81), by striking "and" at the end;

(2) in paragraph (82), by striking the period at the end and inserting "; and"; and

(3) by inserting after paragraph (82) the following new paragraph:

"(83) provide that, not later than January 1, 2017, in the case of a State plan (or waiver of the plan) that provides medical assistance on a fee-for-service basis or through a primary care case-management system described in section 1915(b)(1) (other than a primary care case management entity (as defined by the Secretary)), the State shall publish (and update on at least an annual basis) on the public website of the State agency administering the State plan, a directory of the physicians described in subsection (mm) and, at State option, other providers described in such subsection that—

"(A) includes—

"(i) with respect to each such physician or provider—

"(I) the name of the physician or provider;

"(II) the specialty of the physician or provider;

"(III) the address at which the physician or provider provides services; and

"(IV) the telephone number of the physician or provider; and

"(ii) with respect to any such physician or provider participating in such a primary care case-management system, information regarding—

"(I) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title; and

"(II) the physician's or provider's cultural and linguistic capabilities, including the languages spoken by the physician or provider or by the

skilled medical interpreter providing interpretation services at the physician's or provider's office; and

"(B) may include, at State option, with respect to each such physician or provider—

"(i) the Internet website of such physician or provider; or

"(ii) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title.".

(b) DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by section 5005(a)(3), is further amended by adding at the end the following new subsection:

"(mm) DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.—A physician or provider described in this subsection is—

"(1) in the case of a physician or provider of a provider type for which the State agency, as a condition on receiving payment for items and services furnished by the physician or provider to individuals eligible to receive medical assistance under the State plan, requires the enrollment of the physician or provider with the State agency, a physician or a provider that—

"(A) is enrolled with the agency as of the date on which the directory is published or updated (as applicable) under subsection (a)(83); and

"(B) received payment under the State plan in the 12-month period preceding such date; and

"(2) in the case of a physician or provider of a provider type for which the State agency does not require such enrollment, a physician or provider that received payment under the State plan (or a waiver of the plan) in the 12-month period preceding the date on which the directory is published or updated (as applicable) under subsection (a)(83).".

42 USC 1396a note.

(c) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—The amendment made by subsection (a) shall not be construed to apply in the case of a State (as defined for purposes of title XIX of the Social Security Act) in which all the individuals enrolled in the State plan under such title (or under a waiver of such plan), other than individuals described in paragraph (2), are enrolled with a medicaid managed care organization (as defined in section 1903(m)(1)(A) of such Act (42 U.S.C. 1396b(m)(1)(A))), including prepaid inpatient health plans and prepaid ambulatory health plans (as defined by the Secretary of Health and Human Services).

(2) INDIVIDUALS DESCRIBED.—An individual described in this paragraph is an individual who is an Indian (as defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)) or an Alaska Native.

42 USC 1396a note.

(d) EXCEPTION FOR STATE LEGISLATION.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), which the Secretary of Health and Human Services determines requires State legislation in order for the respective plan to meet one or more additional requirements imposed by amendments made by this section, the respective plan shall not be regarded as failing to comply with the requirements of such title

solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the State legislature.

SEC. 5007. FAIRNESS IN MEDICAID SUPPLEMENTAL NEEDS TRUSTS.

(a) IN GENERAL.—Section 1917(d)(4)(A) of the Social Security Act (42 U.S.C. 1396p(d)(4)(A)) is amended by inserting "the individual," after "for the benefit of such individual by".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to trusts established on or after the date of the enactment of this Act. 42 USC 1396p note.

SEC. 5008. ELIMINATING FEDERAL FINANCIAL PARTICIPATION WITH RESPECT TO EXPENDITURES UNDER MEDICAID FOR AGENTS USED FOR COSMETIC PURPOSES OR HAIR GROWTH.

(a) IN GENERAL.—Section 1903(i)(21) of the Social Security Act (42 U.S.C. 1396b(i)(21)) is amended by inserting "section 1927(d)(2)(C) (relating to drugs when used for cosmetic purposes or hair growth), except where medically necessary, and" after "drugs described in".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to calendar quarters beginning on or after the date of the enactment of this Act. 42 USC 1396b note.

SEC. 5009. AMENDMENT TO THE PREVENTION AND PUBLIC HEALTH FUND.

Section 4002(b) of the Patient Protection and Affordable Care Act (42 U.S.C. 300u–11(b)) is amended—

(1) in paragraph (3), by striking "$1,250,000,000" and inserting "$900,000,000";

(2) in paragraph (4), by striking "$1,500,000,000" and inserting "$1,000,000,000"; and

(3) by striking paragraph (5) and inserting the following:

"(5) for fiscal year 2022, $1,500,000,000;

"(6) for fiscal year 2023, $1,000,000,000;

"(7) for fiscal year 2024, $1,700,000,000; and

"(8) for fiscal year 2025 and each fiscal year thereafter, $2,000,000,000.".

SEC. 5010. STRATEGIC PETROLEUM RESERVE DRAWDOWN.

(a) DRAWDOWN AND SALE.— 42 USC 6241 note.

(1) IN GENERAL.—Notwithstanding section 161 of the Energy Policy and Conservation Act (42 U.S.C. 6241), except as provided in subsections (b) and (c), the Secretary of Energy shall drawdown and sell from the Strategic Petroleum Reserve—

(A) 10,000,000 barrels of crude oil during fiscal year 2017;

(B) 9,000,000 barrels of crude oil during fiscal year 2018; and

(C) 6,000,000 barrels of crude oil during fiscal year 2019.

(2) DEPOSIT OF AMOUNTS RECEIVED FROM SALE.—Amounts received from a sale under paragraph (1) shall be deposited in the general fund of the Treasury during the fiscal year in which the sale occurs.

42 USC 6241 note.

(b) EMERGENCY PROTECTION.—The Secretary shall not draw down and sell crude oil under this section in quantities that would limit the authority to sell petroleum products under section 161(h) of the Energy Policy and Conservation Act (42 U.S.C. 6241(h)) in the full quantity authorized by that subsection.

(c) STRATEGIC PETROLEUM DRAWDOWN LIMITATIONS.—Subparagraphs (C) and (D) of section 161(h)(2) of the Energy Policy and Conservation Act (42 U.S.C. 6241(h)(2)(C) and (D)) are both amended by striking "500,000,000" and inserting "450,000,000".

SEC. 5011. RESCISSION OF PORTION OF ACA TERRITORY FUNDING.

Of the unobligated amounts available under section 1323(c)(1) of the Patient Protection and Affordable Care Act (42 U.S.C. 18043(c)(1)), $464,000,000 is rescinded immediately upon the date of the enactment of this Act.

SEC. 5012. MEDICARE COVERAGE OF HOME INFUSION THERAPY.

(a) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)—

(A) by striking "and" at the end of subparagraph (EE);

(B) by inserting "and" at the end of subparagraph (FF); and

(C) by inserting at the end the following new subparagraph:

"(GG) home infusion therapy (as defined in subsection (iii)(1));"; and

(2) by adding at the end the following new subsection:

"(iii) HOME INFUSION THERAPY.—(1) The term 'home infusion therapy' means the items and services described in paragraph (2) furnished by a qualified home infusion therapy supplier (as defined in paragraph (3)(D)) which are furnished in the individual's home (as defined in paragraph (3)(B)) to an individual—

"(A) who is under the care of an applicable provider (as defined in paragraph (3)(A)); and

"(B) with respect to whom a plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished such individual has been established by a physician (as defined in subsection (r)(1)) and is periodically reviewed by a physician (as so defined) in coordination with the furnishing of home infusion drugs (as defined in paragraph (3)(C)) under part B.

"(2) The items and services described in this paragraph are the following:

"(A) Professional services, including nursing services, furnished in accordance with the plan.

"(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

"(3) For purposes of this subsection:

"(A) The term 'applicable provider' means—

"(i) a physician;

"(ii) a nurse practitioner; and

"(iii) a physician assistant.

"(B) The term 'home' means a place of residence used as the home of an individual (as defined for purposes of subsection (n)).

"(C) The term 'home infusion drug' means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:

"(i) Insulin pump systems.

"(ii) A self-administered drug or biological on a self-administered drug exclusion list.

"(D)(i) The term 'qualified home infusion therapy supplier' means a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that—

"(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

"(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

"(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and

"(IV) meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

"(ii) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements of this subparagraph.".

(b) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by section 4011, is further amended by adding at the end the following new subsection:

"(u) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—

"(1) PAYMENT.—

"(A) SINGLE PAYMENT.—

"(i) IN GENERAL.—Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement a payment system under which a single payment is made under this title to a qualified home infusion therapy supplier for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished by a qualified home infusion therapy supplier (as defined in section 1861(iii)(3)(D)) in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C)) under this part.

"(ii) UNIT OF SINGLE PAYMENT.—A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single

payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

"(iii) LIMITATION.—The single payment amount determined under this subparagraph after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

"(B) REQUIRED ADJUSTMENTS.—The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1861(iii)(1) to reflect other factors such as—

"(i) a geographic wage index and other costs that may vary by region; and

"(ii) patient acuity and complexity of drug administration.

"(C) DISCRETIONARY ADJUSTMENTS.—

"(i) IN GENERAL.—Subject to clause (ii), the Secretary may adjust the single payment amount determined under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

"(ii) REQUIREMENT OF BUDGET NEUTRALITY.—Any adjustment under this subparagraph shall be made in a budget neutral manner.

"(2) CONSIDERATIONS.—In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

"(3) ANNUAL UPDATES.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by the percentage increase in the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

"(B) ADJUSTMENT.—For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

"(4) AUTHORITY TO APPLY PRIOR AUTHORIZATION.—The Secretary may, as determined appropriate by the Secretary, apply

prior authorization for home infusion therapy services under section 1861(iii)(1).

"(5) ACCREDITATION OF QUALIFIED HOME INFUSION THERAPY SUPPLIERS.—

"(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

"(i) The ability of the organization to conduct timely reviews of accreditation applications.

"(ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

"(iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

"(iv) Such other factors as the Secretary determines appropriate.

"(B) DESIGNATION.—Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

"(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

"(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

"(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

"(D) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

"(6) NOTIFICATION OF INFUSION THERAPY OPTIONS AVAILABLE PRIOR TO FURNISHING HOME INFUSION THERAPY.—Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.".

(c) CONFORMING AMENDMENTS.—

(1) PAYMENT REFERENCE.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking "and" before "(AA)"; and

(B) by inserting before the semicolon at the end the following: ", and (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u)".

(2) DIRECT PAYMENT.—The first sentence of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)) is amended—

(A) by striking "and" before "(H)"; and

(B) by inserting before the period at the end the following: ", and (I) in the case of home infusion therapy, payment shall be made to the qualified home infusion therapy supplier".

(3) EXCLUSION FROM HOME HEALTH SERVICES.—Section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) is amended, in the first sentence, by inserting the following before the period at the end: "and home infusion therapy (as defined in subsection (iii)(i))".

42 USC 13951 note.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after January 1, 2021.

Helping Families in Mental Health Crisis Reform Act of 2016.

DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

42 USC 201 note.

SEC. 6000. SHORT TITLE.

This division may be cited as the "Helping Families in Mental Health Crisis Reform Act of 2016".

TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

Subtitle A—Leadership

SEC. 6001. ASSISTANT SECRETARY FOR MENTAL HEALTH AND SUBSTANCE USE.

(a) ASSISTANT SECRETARY.—Section 501(c) of the Public Health Service Act (42 U.S.C. 290aa(c)) is amended to read as follows:

"(c) ASSISTANT SECRETARY AND DEPUTY ASSISTANT SECRETARY.—

"(1) ASSISTANT SECRETARY.—The Administration shall be headed by an official to be known as the Assistant Secretary for Mental Health and Substance Use (hereinafter in this title referred to as the 'Assistant Secretary') who shall be appointed by the President, by and with the advice and consent of the Senate.

"(2) DEPUTY ASSISTANT SECRETARY.—The Assistant Secretary, with the approval of the Secretary, may appoint a Deputy Assistant Secretary and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.".

(b) TRANSFER OF AUTHORITIES.—The Secretary of Health and Human Services shall delegate to the Assistant Secretary for Mental Health and Substance Use all duties and authorities that— 42 USC 290aa note.

(1) as of the day before the date of enactment of this Act, were vested in the Administrator of the Substance Abuse and Mental Health Services Administration; and

(2) are not terminated by this Act.

(c) CONFORMING AMENDMENTS.—Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by the previous provisions of this section, is further amended—

(1) by striking "Administrator of the Substance Abuse and Mental Health Services Administration" each place it appears and inserting "Assistant Secretary for Mental Health and Substance Use"; and

(2) by striking "Administrator" or "ADMINISTRATOR" each place it appears (including in any headings) and inserting "Assistant Secretary" or "ASSISTANT SECRETARY", respectively, except where the term "Administrator" appears—

(A) in each of subsections (e) and (f) of section 501 of such Act (42 U.S.C. 290aa), including the headings of such subsections, within the term "Associate Administrator";

(B) in section 507(b)(6) of such Act (42 U.S.C. 290bb(b)(6)), within the term "Administrator of the Health Resources and Services Administration";

(C) in section 507(b)(6) of such Act (42 U.S.C. 290bb(b)(6)), within the term "Administrator of the Centers for Medicare & Medicaid Services";

(D) in section 519B(c)(1)(B) of such Act (42 U.S.C. 290bb–25b(c)(1)(B)), within the term "Administrator of the National Highway Traffic Safety Administration"; or

(E) in each of sections 519B(c)(1)(B), 520C(a), and 520D(a) of such Act (42 U.S.C. 290bb–25b(c)(1)(B), 290bb–34(a), 290bb–35(a)), within the term "Administrator of the Office of Juvenile Justice and Delinquency Prevention".

(d) REFERENCES.—After executing subsections (a), (b), and (c), any reference in statute, regulation, or guidance to the Administrator of the Substance Abuse and Mental Health Services Administration shall be construed to be a reference to the Assistant Secretary for Mental Health and Substance Use. 42 USC 290aa note.

SEC. 6002. STRENGTHENING THE LEADERSHIP OF THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by section 6001, is further amended—

(1) in subsection (b)—

(A) in the subsection heading, by striking "AGENCIES" and inserting "CENTERS"; and

(B) in the matter preceding paragraph (1), by striking "entities" and inserting "Centers";

(2) in subsection (d)—

(A) in paragraph (1)—

(i) by striking "agencies" each place the term appears and inserting "Centers"; and

(ii) by striking "such agency" and inserting "such Center";

(B) in paragraph (2)—

(i) by striking "agencies" and inserting "Centers";

(ii) by striking "with respect to substance abuse" and inserting "with respect to substance use disorders"; and

(iii) by striking "and individuals who are substance abusers" and inserting "and individuals with substance use disorders";

(C) in paragraph (5), by striking "substance abuse" and inserting "substance use disorder";

(D) in paragraph (6)—

(i) by striking "the Centers for Disease Control" and inserting "the Centers for Disease Control and Prevention,";

(ii) by striking "Administration develop" and inserting "Administration, develop";

(iii) by striking "HIV or tuberculosis among substance abusers and individuals with mental illness" and inserting "HIV, hepatitis, tuberculosis, and other communicable diseases among individuals with mental or substance use disorders,"; and

(iv) by striking "illnesses" at the end and inserting "diseases or disorders";

(E) in paragraph (7), by striking "abuse utilizing anti-addiction medications, including methadone" and inserting "use disorders, including services that utilize drugs or devices approved or cleared by the Food and Drug Administration for the treatment of substance use disorders";

(F) in paragraph (8)—

(i) by striking "Agency for Health Care Policy Research" and inserting "Agency for Healthcare Research and Quality"; and

(ii) by striking "treatment and prevention" and inserting "prevention and treatment";

(G) in paragraph (9)—

(i) by inserting "and maintenance" after "development";

(ii) by striking "Agency for Health Care Policy Research" and inserting "Agency for Healthcare Research and Quality"; and

(iii) by striking "treatment and prevention services" and inserting "prevention, treatment, and recovery support services and are appropriately incorporated into programs carried out by the Administration";

(H) in paragraph (10), by striking "abuse" and inserting "use disorder";

(I) by striking paragraph (11) and inserting the following:

"(11) work with relevant agencies of the Department of Health and Human Services on integrating mental health promotion and substance use disorder prevention with general health promotion and disease prevention and integrating mental and substance use disorders treatment services with physical health treatment services;";

(J) in paragraph (13)—

(i) in the matter preceding subparagraph (A), by striking "this title, assure that" and inserting "this title or part B of title XIX, or grant programs otherwise funded by the Administration";

(ii) in subparagraph (A)—

(I) by inserting "require that" before "all grants"; and

(II) by striking "and" at the end;

(iii) by redesignating subparagraph (B) as subparagraph (C);

(iv) by inserting after subparagraph (A) the following:

"(B) ensure that the director of each Center of the Administration consistently documents the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded;";

(v) in subparagraph (C), as so redesignated—

(I) by inserting "require that" before "all grants"; and

(II) in clause (ii), by inserting "and" after the semicolon at the end; and

(vi) by adding at the end the following:

"(D) inform a State when any funds are awarded through such a grant to any entity within such State;";

(K) in paragraph (16), by striking "abuse and mental health information" and inserting "use disorder information, including evidence-based and promising best practices for prevention, treatment, and recovery support services for individuals with mental and substance use disorders,";

(L) in paragraph (17)—

(i) by striking "substance abuse" and inserting "substance use disorder"; and

(ii) by striking "and" at the end;

(M) in paragraph (18), by striking the period and inserting a semicolon; and

(N) by adding at the end the following:

"(19) consult with State, local, and tribal governments, nongovernmental entities, and individuals with mental illness, particularly adults with a serious mental illness, children with a serious emotional disturbance, and the family members of

such adults and children, with respect to improving community-based and other mental health services;

"(20) collaborate with the Secretary of Defense and the Secretary of Veterans Affairs to improve the provision of mental and substance use disorder services provided by the Department of Defense and the Department of Veterans Affairs to members of the Armed Forces, veterans, and the family members of such members and veterans, including through the provision of services using the telehealth capabilities of the Department of Defense and the Department of Veterans Affairs;

"(21) collaborate with the heads of relevant Federal agencies and departments, States, communities, and nongovernmental experts to improve mental and substance use disorders services for chronically homeless individuals, including by designing strategies to provide such services in supportive housing;

"(22) work with States and other stakeholders to develop and support activities to recruit and retain a workforce addressing mental and substance use disorders;

"(23) collaborate with the Attorney General and representatives of the criminal justice system to improve mental and substance use disorders services for individuals who have been arrested or incarcerated;

"(24) after providing an opportunity for public input, set standards for grant programs under this title for mental and substance use disorders services and prevention programs, which standards may address—

"(A) the capacity of the grantee to implement the award;

"(B) requirements for the description of the program implementation approach;

"(C) the extent to which the grant plan submitted by the grantee as part of its application must explain how the grantee will reach the population of focus and provide a statement of need, which may include information on how the grantee will increase access to services and a description of measurable objectives for improving outcomes;

"(D) the extent to which the grantee must collect and report on required performance measures; and

"(E) the extent to which the grantee is proposing to use evidence-based practices; and

"(25) advance, through existing programs, the use of performance metrics, including those based on the recommendations on performance metrics from the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016."; and

(3) in subsection (m), by adding at the end the following:

"(4) EMERGENCY RESPONSE.—Amounts made available for carrying out this subsection shall remain available through the end of the fiscal year following the fiscal year for which such amounts are appropriated.".

SEC. 6003. CHIEF MEDICAL OFFICER.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by sections 6001 and 6002, is further amended—

(1) by redesignating subsections (g) through (j) and subsections (k) through (o) as subsections (h) through (k) and subsections (m) through (q), respectively;

(2) in subsection (e)(3)(C), by striking "subsection (k)" and inserting "subsection (m)";

(3) in subsection (f)(2)(C)(iii), by striking "subsection (k)" and inserting "subsection (m)"; and

(4) by inserting after subsection (f) the following:

"(g) CHIEF MEDICAL OFFICER.—

"(1) IN GENERAL.—The Assistant Secretary, with the approval of the Secretary, shall appoint a Chief Medical Officer to serve within the Administration.

"(2) ELIGIBLE CANDIDATES.—The Assistant Secretary shall select the Chief Medical Officer from among individuals who—

"(A) have a doctoral degree in medicine or osteopathic medicine;

"(B) have experience in the provision of mental or substance use disorder services;

"(C) have experience working with mental or substance use disorder programs;

"(D) have an understanding of biological, psychosocial, and pharmaceutical treatments of mental or substance use disorders; and

"(E) are licensed to practice medicine in one or more States.

"(3) DUTIES.—The Chief Medical Officer shall—

"(A) serve as a liaison between the Administration and providers of mental and substance use disorders prevention, treatment, and recovery services;

"(B) assist the Assistant Secretary in the evaluation, organization, integration, and coordination of programs operated by the Administration;

"(C) promote evidence-based and promising best practices, including culturally and linguistically appropriate practices, as appropriate, for the prevention and treatment of, and recovery from, mental and substance use disorders, including serious mental illness and serious emotional disturbances;

"(D) participate in regular strategic planning with the Administration;

"(E) coordinate with the Assistant Secretary for Planning and Evaluation to assess the use of performance metrics to evaluate activities within the Administration related to mental and substance use disorders; and

"(F) coordinate with the Assistant Secretary to ensure mental and substance use disorders grant programs within the Administration consistently utilize appropriate performance metrics and evaluation designs.".

SEC. 6004. IMPROVING THE QUALITY OF BEHAVIORAL HEALTH PROGRAMS.

Section 505 of the Public Health Service Act (42 U.S.C. 290aa–4), as amended by section 6001(c), is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 505. CENTER FOR BEHAVIORAL HEALTH STATISTICS AND QUALITY.";

(2) by redesignating subsections (a) through (d) as subsections (b) through (e), respectively;

(3) before subsection (b), as redesignated by paragraph (2), by inserting the following:

"(a) IN GENERAL.—The Assistant Secretary shall maintain within the Administration a Center for Behavioral Health Statistics and Quality (in this section referred to as the 'Center'). The Center shall be headed by a Director (in this section referred to as the 'Director') appointed by the Secretary from among individuals with extensive experience and academic qualifications in research and analysis in behavioral health care or related fields.";

(4) in subsection (b), as redesignated by paragraph (2)—

(A) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(B) by striking "The Secretary, acting" and all that follows through "year on—" and inserting "The Director shall—

"(1) coordinate the Administration's integrated data strategy, including by collecting data each year on—";

(C) in the subparagraph (B), as redesignated by subparagraph (A), by striking "Assistant Secretary" and inserting "Director"; and

(D) by adding at the end the following new paragraphs:

"(2) provide statistical and analytical support for activities of the Administration;

"(3) recommend a core set of performance metrics to evaluate activities supported by the Administration; and

"(4) coordinate with the Assistant Secretary, the Assistant Secretary for Planning and Evaluation, and the Chief Medical Officer appointed under section 501(g), as appropriate, to improve the quality of services provided by programs of the Administration and the evaluation of activities carried out by the Administration.".

(5) in subsection (c), as so redesignated—

(A) by striking "With respect to the activities" and inserting "MENTAL HEALTH.—With respect to the activities";

(B) by striking "Assistant Secretary" each place it appears and inserting "Director"; and

(C) by striking "subsection (a)" and inserting "subsection (b)(1)";

(6) in subsection (d), as so redesignated—

(A) by striking the subsection designation and all that follows through "With respect to the activities" and inserting the following:

"(d) SUBSTANCE ABUSE.—

"(1) IN GENERAL.—With respect to the activities";

(B) in paragraph (1)—

(i) in the matter before subparagraph (A)—

(I) by striking "subsection (a)" and inserting "subsection (b)(1)"; and

(II) by striking "Assistant Secretary" each place it appears and inserting "Director"; and

(ii) in subparagraph (B), by inserting "in coordination with the Centers for Disease Control and Prevention" before the semicolon at the end; and

(C) in paragraph (2), by striking "ANNUAL SURVEYS" and inserting "ANNUAL SURVEYS; PUBLIC AVAILABILITY OF DATA.—Annual surveys"; and

(7) in subsection (e), as so redesignated—

(A) by striking "After consultation" and inserting "CONSULTATION.—After consultation"; and

(B) by striking "Assistant Secretary shall develop" and inserting "Assistant Secretary shall use existing standards and best practices to develop".

SEC. 6005. STRATEGIC PLAN.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by sections 6001 through 6003, is further amended by inserting after subsection (k), as redesignated by section 6003, the following:

"(l) STRATEGIC PLAN.—

"(1) IN GENERAL.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall develop and carry out a strategic plan in accordance with this subsection for the planning and operation of activities carried out by the Administration, including evidence-based programs.

"(2) COORDINATION.—In developing and carrying out the strategic plan under this subsection, the Assistant Secretary shall take into consideration the findings and recommendations of the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016 and the report of the Interdepartmental Serious Mental Illness Coordinating Committee under section 6031 of such Act.

"(3) PUBLICATION OF PLAN.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall—

"(A) submit the strategic plan developed under paragraph (1) to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate; and

"(B) post such plan on the Internet website of the Administration.

"(4) CONTENTS.—The strategic plan developed under paragraph (1) shall—

"(A) identify strategic priorities, goals, and measurable objectives for mental and substance use disorders activities and programs operated and supported by the Administration, including priorities to prevent or eliminate the burden of mental and substance use disorders;

"(B) identify ways to improve the quality of services for individuals with mental and substance use disorders, and to reduce homelessness, arrest, incarceration, violence, including self-directed violence, and unnecessary hospitalization of individuals with a mental or substance use disorder, including adults with a serious mental illness or children with a serious emotional disturbance;

"(C) ensure that programs provide, as appropriate, access to effective and evidence-based prevention, diagnosis, intervention, treatment, and recovery services, including culturally and linguistically appropriate services, as appropriate, for individuals with a mental or substance use disorder;

"(D) identify opportunities to collaborate with the Health Resources and Services Administration to develop or improve—

"(i) initiatives to encourage individuals to pursue careers (especially in rural and underserved areas and with rural and underserved populations) as psychiatrists, including child and adolescent psychiatrists, psychologists, psychiatric nurse practitioners, physician assistants, clinical social workers, certified peer support specialists, licensed professional counselors, or other licensed or certified mental health or substance use disorder professionals, including such professionals specializing in the diagnosis, evaluation, or treatment of adults with a serious mental illness or children with a serious emotional disturbance; and

"(ii) a strategy to improve the recruitment, training, and retention of a workforce for the treatment of individuals with mental or substance use disorders, or co-occurring disorders;

"(E) identify opportunities to improve collaboration with States, local governments, communities, and Indian tribes and tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act); and

"(F) specify a strategy to disseminate evidence-based and promising best practices related to prevention, diagnosis, early intervention, treatment, and recovery services related to mental illness, particularly for adults with a serious mental illness and children with a serious emotional disturbance, and for individuals with a substance use disorder.".

SEC. 6006. BIENNIAL REPORT CONCERNING ACTIVITIES AND PROGRESS.

(a) IN GENERAL.—Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as so amended, is further amended by amending subsection (m), as redesignated by section 6003, to read as follows:

"(m) BIENNIAL REPORT CONCERNING ACTIVITIES AND PROGRESS.—Not later than September 30, 2020, and every 2 years thereafter, the Assistant Secretary shall prepare and submit to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and post on the Internet website of the Administration, a report containing at a minimum—

"(1) a review of activities conducted or supported by the Administration, including progress toward strategic priorities, goals, and objectives identified in the strategic plan developed under subsection (l);

"(2) an assessment of programs and activities carried out by the Assistant Secretary, including the extent to which programs and activities under this title and part B of title XIX meet identified goals and performance measures developed for the respective programs and activities;

"(3) a description of the progress made in addressing gaps in mental and substance use disorders prevention, treatment, and recovery services and improving outcomes by the Administration, including with respect to serious mental illnesses, serious emotional disturbances, and co-occurring disorders;

"(4) a description of the manner in which the Administration coordinates and partners with other Federal agencies and departments related to mental and substance use disorders, including activities related to—

"(A) the implementation and dissemination of research findings into improved programs, including with respect to how advances in serious mental illness and serious emotional disturbance research have been incorporated into programs;

"(B) the recruitment, training, and retention of a mental and substance use disorders workforce;

"(C) the integration of mental disorder services, substance use disorder services, and physical health services;

"(D) homelessness; and

"(E) veterans;

"(5) a description of the manner in which the Administration promotes coordination by grantees under this title, and part B of title XIX, with State or local agencies; and

"(6) a description of the activities carried out under section 501A(e), with respect to mental and substance use disorders, including—

"(A) the number and a description of grants awarded;

"(B) the total amount of funding for grants awarded;

"(C) a description of the activities supported through such grants, including outcomes of programs supported; and

"(D) information on how the National Mental Health and Substance Use Policy Laboratory is consulting with the Assistant Secretary for Planning and Evaluation and collaborating with the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, the Center for Behavioral Health Statistics and Quality, and the Center for Mental Health Services to carry out such activities; and

"(7) recommendations made by the Assistant Secretary for Planning and Evaluation under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 to improve programs within the Administration, and actions taken in response to such recommendations to improve programs within the Administration.

The Assistant Secretary may meet reporting requirements established under this title by providing the contents of such reports as an addendum to the biennial report established under this subsection, notwithstanding the timeline of other reporting requirements in this title. Nothing in this subsection shall be construed to alter the content requirements of such reports or authorize the Assistant Secretary to alter the timeline of any such reports

to be less frequent than biennially, unless as specified in this title.".

(b) CONFORMING AMENDMENT.—Section 508(p) of the Public Health Service Act (42 U.S.C. 290bb–1(p)) is amended by striking "section 501(k)" and inserting "section 501(m)".

SEC. 6007. AUTHORITIES OF CENTERS FOR MENTAL HEALTH SERVICES, SUBSTANCE ABUSE PREVENTION, AND SUBSTANCE ABUSE TREATMENT.

(a) CENTER FOR MENTAL HEALTH SERVICES.—Section 520(b) of the Public Health Service Act (42 U.S.C. 290bb–31(b)) is amended—

(1) by redesignating paragraphs (3) through (15) as paragraphs (4) through (16), respectively;

(2) by inserting after paragraph (2) the following:

"(3) collaborate with the Director of the National Institute of Mental Health and the Chief Medical Officer, appointed under section 501(g), to ensure that, as appropriate, programs related to the prevention and treatment of mental illness and the promotion of mental health and recovery support are carried out in a manner that reflects the best available science and evidence-based practices, including culturally and linguistically appropriate services, as appropriate;";

(3) in paragraph (5), as so redesignated, by inserting ", including through programs that reduce risk and promote resiliency" before the semicolon;

(4) in paragraph (6), as so redesignated, by inserting "in collaboration with the Director of the National Institute of Mental Health," before "develop";

(5) in paragraph (8), as so redesignated, by inserting ", increase meaningful participation of individuals with mental illness in programs and activities of the Administration," before "and protect the legal";

(6) in paragraph (10), as so redesignated, by striking "professional and paraprofessional personnel pursuant to section 303" and inserting "health paraprofessional personnel and health professionals";

(7) in paragraph (11), as so redesignated, by inserting "and tele-mental health" after "rural mental health";

(8) in paragraph (12), as so redesignated, by striking "establish a clearinghouse for mental health information to assure the widespread dissemination of such information" and inserting "disseminate mental health information, including evidence-based practices,";

(9) in paragraph (15), as so redesignated, by striking "and" at the end;

(10) in paragraph (16), as so redesignated, by striking the period and inserting "; and"; and

(11) by adding at the end the following:

"(17) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded.".

(b) DIRECTOR OF THE CENTER FOR SUBSTANCE ABUSE PREVENTION.—Section 515 of the Public Health Service Act (42 U.S.C. 290bb–21) is amended—

(1) in the section heading, by striking "OFFICE" and inserting "CENTER";

(2) in subsection (a)—

(A) by striking "an Office" and inserting "a Center"; and

(B) by striking "The Office" and inserting "The Prevention Center"; and

(3) in subsection (b)—

(A) in paragraph (1), by inserting "through the reduction of risk and the promotion of resiliency" before the semicolon;

(B) by redesignating paragraphs (3) through (11) as paragraphs (4) through (12), respectively;

(C) by inserting after paragraph (2) the following:

"(3) collaborate with the Director of the National Institute on Drug Abuse, the Director of the National Institute on Alcohol Abuse and Alcoholism, and States to promote the study of substance abuse prevention and the dissemination and implementation of research findings that will improve the delivery and effectiveness of substance abuse prevention activities;";

(D) in paragraph (4), as so redesignated, by striking "literature on the adverse effects of cocaine free base (known as crack)" and inserting "educational information on the effects of drugs abused by individuals, including drugs that are emerging as abused drugs";

(E) in paragraph (6), as so redesignated—

(i) by striking "substance abuse counselors" and inserting "health professionals who provide substance use and misuse prevention and treatment services"; and

(ii) by striking "drug abuse education, prevention," and inserting "illicit drug use education and prevention";

(F) by amending paragraph (7), as so redesignated, to read as follows:

"(7) in cooperation with the Director of the Centers for Disease Control and Prevention, develop and disseminate educational materials to increase awareness for individuals at greatest risk for substance use disorders to prevent the transmission of communicable diseases, such as HIV, hepatitis, tuberculosis, and other communicable diseases;";

(G) in paragraph (9), as so redesignated—

(i) by striking "to discourage" and inserting "that reduce the risk of"; and

(ii) by inserting before the semicolon "and promote resiliency";

(H) in paragraph (11), as so redesignated, by striking "and" after the semicolon;

(I) in paragraph (12), as so redesignated, by striking the period and inserting a semicolon; and

(J) by adding at the end the following:

"(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded; and

"(14) assist and support States in preventing illicit drug use, including emerging illicit drug use issues.".

(c) DIRECTOR OF THE CENTER FOR SUBSTANCE ABUSE TREATMENT.—Section 507 of the Public Health Service Act (42 U.S.C. 290bb) is amended—

(1) in subsection (a)—

(A) by striking "treatment of substance abuse" and inserting "treatment of substance use disorders"; and

(B) by striking "abuse treatment systems" and inserting "use disorder treatment systems"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "abuse" and inserting "use disorder";

(B) in paragraph (3), by striking "abuse" and inserting "use disorder";

(C) in paragraph (4), by striking "individuals who abuse drugs" and inserting "individuals who illicitly use drugs";

(D) in paragraph (9), by striking "carried out by the Director";

(E) by striking paragraph (10);

(F) by redesignating paragraphs (11) through (14) as paragraphs (10) through (13), respectively;

(G) in paragraph (12), as so redesignated, by striking "; and" and inserting a semicolon; and

(H) by striking paragraph (13), as so redesignated, and inserting the following:

"(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded; and

"(14) work with States, providers, and individuals in recovery, and their families, to promote the expansion of recovery support services and systems of care oriented toward recovery.".

SEC. 6008. ADVISORY COUNCILS.

Section 502(b) of the Public Health Service Act (42 U.S.C. 290aa–1(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (E), by striking "and" after the semicolon;

(B) by redesignating subparagraph (F) as subparagraph (J); and

(C) by inserting after subparagraph (E), the following:

"(F) the Chief Medical Officer, appointed under section 501(g);

"(G) the Director of the National Institute of Mental Health for the advisory councils appointed under subsections (a)(1)(A) and (a)(1)(D);

"(H) the Director of the National Institute on Drug Abuse for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C);

"(I) the Director of the National Institute on Alcohol Abuse and Alcoholism for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C); and"; and

(2) in paragraph (3), by adding at the end the following:

"(C) Not less than half of the members of the advisory council appointed under subsection (a)(1)(D)—

"(i) shall—

"(I) have a medical degree;

"(II) have a doctoral degree in psychology; or

"(III) have an advanced degree in nursing or social work from an accredited graduate school or be a certified physician assistant; and

"(ii) shall specialize in the mental health field.

"(D) Not less than half of the members of the advisory councils appointed under subsections (a)(1)(B) and (a)(1)(C)—

"(i) shall—

"(I) have a medical degree;

"(II) have a doctoral degree; or

"(III) have an advanced degree in nursing, public health, behavioral or social sciences, or social work from an accredited graduate school or be a certified physician assistant; and

"(ii) shall have experience in the provision of substance use disorder services or the development and implementation of programs to prevent substance misuse.".

SEC. 6009. PEER REVIEW.

Section 504(b) of the Public Health Service Act (42 U.S.C. 290aa–3(b)) is amended by adding at the end the following: "In the case of any such peer review group that is reviewing a grant, cooperative agreement, or contract related to mental illness treatment, not less than half of the members of such peer review group shall be licensed and experienced professionals in the prevention, diagnosis, or treatment of, or recovery from, mental illness or co-occurring mental illness and substance use disorders and have a medical degree, a doctoral degree in psychology, or an advanced degree in nursing or social work from an accredited program, and the Secretary, in consultation with the Assistant Secretary, shall, to the extent possible, ensure such peer review groups include broad geographic representation, including both urban and rural representatives.".

Subtitle B—Oversight and Accountability

SEC. 6021. IMPROVING OVERSIGHT OF MENTAL AND SUBSTANCE USE DISORDERS PROGRAMS THROUGH THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION.

42 USC 290aa note.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation, shall ensure efficient and effective planning and evaluation of mental and substance use disorders prevention and treatment programs and related activities.

(b) EVALUATION STRATEGY.—In carrying out subsection (a), the Assistant Secretary for Planning and Evaluation shall, not later than 180 days after the date of enactment of this Act, develop a strategy for conducting ongoing evaluations that identifies priority programs to be evaluated by the Assistant Secretary for Planning and Evaluation and priority programs to be evaluated by other relevant offices and agencies within the Department of Health and Human Services. The strategy shall—

(1) include a plan for evaluating programs related to mental and substance use disorders, including co-occurring disorders, across agencies, as appropriate, including programs related to—

(A) prevention, intervention, treatment, and recovery support services, including such services for adults with a serious mental illness or children with a serious emotional disturbance;

(B) the reduction of homelessness and incarceration among individuals with a mental or substance use disorder; and

(C) public health and health services; and

(2) include a plan for assessing the use of performance metrics to evaluate activities carried out by entities receiving grants, contracts, or cooperative agreements related to mental and substance use disorders prevention and treatment services under title V or title XIX of the Public Health Service Act (42 U.S.C. 290aa et seq.; 42 U.S.C. 300w et seq.).

(c) CONSULTATION.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall consult, as appropriate, with the Assistant Secretary for Mental Health and Substance Use, the Chief Medical Officer of the Substance Abuse and Mental Health Services Administration appointed under section 501(g) of the Public Health Service Act (42 U.S.C. 290aa(g)), as amended by section 6003, the Behavioral Health Coordinating Council of the Department of Health and Human Services, other agencies within the Department of Health and Human Services, and other relevant Federal departments and agencies.

(d) RECOMMENDATIONS.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall provide recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Mental Health and Substance Use, and the Congress on improving the quality of prevention and treatment programs and activities related to mental and substance use disorders, including recommendations for the use of performance metrics. The Assistant Secretary for Mental Health and Substance Use shall include such recommendations in the biennial report required by subsection 501(m) of the Public Health Service Act, as redesignated by section 6003 of this Act.

SEC. 6022. REPORTING FOR PROTECTION AND ADVOCACY ORGANIZATIONS.

(a) PUBLIC AVAILABILITY OF REPORTS.—Section 105(a)(7) of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10805(a)(7)) is amended by striking "is located a report" and inserting "is located, and make publicly available, a report".

(b) DETAILED ACCOUNTING.—Section 114(a) of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10824(a)) is amended—

(1) in paragraph (3), by striking "and" at the end;

(2) in paragraph (4), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(5) using data from the existing required annual program progress reports submitted by each system funded under this title, a detailed accounting for each such system of how funds are spent, disaggregated according to whether the funds were

received from the Federal Government, the State government, a local government, or a private entity.".

SEC. 6023. GAO STUDY.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services and the Assistant Secretary for Mental Health and Substance Use, shall conduct an independent evaluation, and submit a report, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, on programs funded by allotments made under title I of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10801 et seq.).

(b) CONTENTS.—The report and evaluation required under subsection (a) shall include—

(1) a review of the programs described in such subsection that are carried out by State agencies and such programs that are carried out by private, nonprofit organizations; and

(2) a review of the compliance of the programs described in subsection (a) with statutory and regulatory responsibilities, such as—

(A) responsibilities relating to family engagement;

(B) responsibilities relating to the grievance procedure for clients or prospective clients of the system to assure that individuals with mental illness have full access to the services of the system, for individuals who have received or are receiving mental health services, and for family members of such individuals with mental illness, or representatives of such individuals or family members, to assure that the eligible system is operating in compliance with the provisions of the Protection and Advocacy for Individuals with Mental Illness Act, as required to be established by section 105(a)(9) of such Act (42 U.S.C. 10805(a)(9));

(C) investigation of alleged abuse and neglect of persons with mental illness;

(D) availability of adequate medical and behavioral health treatment;

(E) denial of rights for persons with mental illness; and

(F) compliance with the Federal prohibition on lobbying.

Subtitle C—Interdepartmental Serious Mental Illness Coordinating Committee

SEC. 6031. INTERDEPARTMENTAL SERIOUS MENTAL ILLNESS COORDINATING COMMITTEE.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 3 months after the date of enactment of this Act, the Secretary of Health and Human Services, or the designee of the Secretary, shall establish a committee to be known as the Interdepartmental Serious Mental Illness Coordinating Committee (in this section referred to as the "Committee").

(2) FEDERAL ADVISORY COMMITTEE ACT.—Except as provided in this section, the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Committee.

(b) MEETINGS.—The Committee shall meet not fewer than 2 times each year.

(c) RESPONSIBILITIES.—Not later than 1 year after the date of enactment of this Act, and 5 years after such date of enactment, the Committee shall submit to Congress and any other relevant Federal department or agency a report including—

(1) a summary of advances in serious mental illness and serious emotional disturbance research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of serious mental illnesses, serious emotional disturbances, and advances in access to services and support for adults with a serious mental illness or children with a serious emotional disturbance;

(2) an evaluation of the effect Federal programs related to serious mental illness have on public health, including public health outcomes such as—

(A) rates of suicide, suicide attempts, incidence and prevalence of serious mental illnesses, serious emotional disturbances, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment;

(B) increased rates of employment and enrollment in educational and vocational programs;

(C) quality of mental and substance use disorders treatment services; or

(D) any other criteria as may be determined by the Secretary; and

(3) specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance.

(d) COMMITTEE EXTENSION.—Upon the submission of the second report under subsection (c), the Secretary shall submit a recommendation to Congress on whether to extend the operation of the Committee.

(e) MEMBERSHIP.—

(1) FEDERAL MEMBERS.—The Committee shall be composed of the following Federal representatives, or the designees of such representatives—

(A) the Secretary of Health and Human Services, who shall serve as the Chair of the Committee;

(B) the Assistant Secretary for Mental Health and Substance Use;

(C) the Attorney General;

(D) the Secretary of Veterans Affairs;

(E) the Secretary of Defense;

(F) the Secretary of Housing and Urban Development;

(G) the Secretary of Education;

(H) the Secretary of Labor;

(I) the Administrator of the Centers for Medicare & Medicaid Services; and

(J) the Commissioner of Social Security.

(2) NON-FEDERAL MEMBERS.—The Committee shall also include not less than 14 non-Federal public members appointed by the Secretary of Health and Human Services, of which—

(A) at least 2 members shall be an individual who has received treatment for a diagnosis of a serious mental illness;

(B) at least 1 member shall be a parent or legal guardian of an adult with a history of a serious mental illness or a child with a history of a serious emotional disturbance;

(C) at least 1 member shall be a representative of a leading research, advocacy, or service organization for adults with a serious mental illness;

(D) at least 2 members shall be—

(i) a licensed psychiatrist with experience in treating serious mental illnesses;

(ii) a licensed psychologist with experience in treating serious mental illnesses or serious emotional disturbances;

(iii) a licensed clinical social worker with experience treating serious mental illnesses or serious emotional disturbances; or

(iv) a licensed psychiatric nurse, nurse practitioner, or physician assistant with experience in treating serious mental illnesses or serious emotional disturbances;

(E) at least 1 member shall be a licensed mental health professional with a specialty in treating children and adolescents with a serious emotional disturbance;

(F) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with minorities;

(G) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with medically underserved populations;

(H) at least 1 member shall be a State certified mental health peer support specialist;

(I) at least 1 member shall be a judge with experience in adjudicating cases related to criminal justice or serious mental illness;

(J) at least 1 member shall be a law enforcement officer or corrections officer with extensive experience in interfacing with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

(K) at least 1 member shall have experience providing services for homeless individuals and working with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis.

(3) TERMS.—A member of the Committee appointed under subsection (e)(2) shall serve for a term of 3 years, and may be reappointed for 1 or more additional 3-year terms. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has been appointed.

(f) WORKING GROUPS.—In carrying out its functions, the Committee may establish working groups. Such working groups shall be composed of Committee members, or their designees, and may hold such meetings as are necessary.

(g) SUNSET.—The Committee shall terminate on the date that is 6 years after the date on which the Committee is established under subsection (a)(1).

TITLE VII—ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY

SEC. 7001. ENCOURAGING INNOVATION AND EVIDENCE-BASED PROGRAMS.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by inserting after section 501 (42 U.S.C. 290aa) the following:

42 USC 290aa–0.

"SEC. 501A. NATIONAL MENTAL HEALTH AND SUBSTANCE USE POLICY LABORATORY.

"(a) IN GENERAL.—There shall be established within the Administration a National Mental Health and Substance Use Policy Laboratory (referred to in this section as the 'Laboratory').

"(b) RESPONSIBILITIES.—The Laboratory shall—

"(1) continue to carry out the authorities and activities that were in effect for the Office of Policy, Planning, and Innovation as such Office existed prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016;

"(2) identify, coordinate, and facilitate the implementation of policy changes likely to have a significant effect on mental health, mental illness, recovery supports, and the prevention and treatment of substance use disorder services;

"(3) work with the Center for Behavioral Health Statistics and Quality to collect, as appropriate, information from grantees under programs operated by the Administration in order to evaluate and disseminate information on evidence-based practices, including culturally and linguistically appropriate services, as appropriate, and service delivery models;

"(4) provide leadership in identifying and coordinating policies and programs, including evidence-based programs, related to mental and substance use disorders;

"(5) periodically review programs and activities operated by the Administration relating to the diagnosis or prevention of, treatment for, and recovery from, mental and substance use disorders to—

"(A) identify any such programs or activities that are duplicative;

"(B) identify any such programs or activities that are not evidence-based, effective, or efficient; and

"(C) formulate recommendations for coordinating, eliminating, or improving programs or activities identified

under subparagraph (A) or (B) and merging such programs or activities into other successful programs or activities; and

"(6) carry out other activities as deemed necessary to continue to encourage innovation and disseminate evidence-based programs and practices.

"(c) EVIDENCE-BASED PRACTICES AND SERVICE DELIVERY MODELS.—

"(1) IN GENERAL.—In carrying out subsection (b)(3), the Laboratory—

"(A) may give preference to models that improve—

"(i) the coordination between mental health and physical health providers;

"(ii) the coordination among such providers and the justice and corrections system; and

"(iii) the cost effectiveness, quality, effectiveness, and efficiency of health care services furnished to adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

"(B) may include clinical protocols and practices that address the needs of individuals with early serious mental illness.

"(2) CONSULTATION.—In carrying out this section, the Laboratory shall consult with—

"(A) the Chief Medical Officer appointed under section 501(g);

"(B) representatives of the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, on an ongoing basis;

"(C) other appropriate Federal agencies;

"(D) clinical and analytical experts with expertise in psychiatric medical care and clinical psychological care, health care management, education, corrections health care, and mental health court systems, as appropriate; and

"(E) other individuals and agencies as determined appropriate by the Assistant Secretary.

"(d) DEADLINE FOR BEGINNING IMPLEMENTATION.—The Laboratory shall begin implementation of this section not later than January 1, 2018.

"(e) PROMOTING INNOVATION.—

"(1) IN GENERAL.—The Assistant Secretary, in coordination with the Laboratory, may award grants to States, local governments, Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), educational institutions, and nonprofit organizations to develop evidence-based interventions, including culturally and linguistically appropriate services, as appropriate, for—

"(A) evaluating a model that has been scientifically demonstrated to show promise, but would benefit from further applied development, for—

"(i) enhancing the prevention, diagnosis, intervention, and treatment of, and recovery from, mental illness, serious emotional disturbances, substance use disorders, and co-occurring illness or disorders; or

"(ii) integrating or coordinating physical health services and mental and substance use disorders services; and

"(B) expanding, replicating, or scaling evidence-based programs across a wider area to enhance effective screening, early diagnosis, intervention, and treatment with respect to mental illness, serious mental illness, serious emotional disturbances, and substance use disorders, primarily by—

"(i) applying such evidence-based programs to the delivery of care, including by training staff in effective evidence-based treatments; or

"(ii) integrating such evidence-based programs into models of care across specialties and jurisdictions.

"(2) CONSULTATION.—In awarding grants under this subsection, the Assistant Secretary shall, as appropriate, consult with the Chief Medical Officer, appointed under section 501(g), the advisory councils described in section 502, the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, as appropriate.

"(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

"(A) to carry out paragraph (1)(A), $7,000,000 for the period of fiscal years 2018 through 2020; and

"(B) to carry out paragraph (1)(B), $7,000,000 for the period of fiscal years 2018 through 2020.".

SEC. 7002. PROMOTING ACCESS TO INFORMATION ON EVIDENCE-BASED PROGRAMS AND PRACTICES.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by inserting after section 543 of such Act (42 U.S.C. 290dd–2) the following:

42 USC 290dd–2a.

"SEC. 543A. PROMOTING ACCESS TO INFORMATION ON EVIDENCE-BASED PROGRAMS AND PRACTICES.

"(a) IN GENERAL.—The Assistant Secretary shall, as appropriate, improve access to reliable and valid information on evidence-based programs and practices, including information on the strength of evidence associated with such programs and practices, related to mental and substance use disorders for States, local communities, nonprofit entities, and other stakeholders, by posting on the Internet website of the Administration information on evidence-based programs and practices that have been reviewed by the Assistant Secretary in accordance with the requirements of this section.

"(b) APPLICATIONS.—

"(1) APPLICATION PERIOD.—In carrying out subsection (a), the Assistant Secretary may establish a period for the submission of applications for evidence-based programs and practices to be posted publicly in accordance with subsection (a).

"(2) NOTICE.—In establishing the application period under paragraph (1), the Assistant Secretary shall provide for the public notice of such application period in the Federal Register.

Such notice may solicit applications for evidence-based programs and practices to address gaps in information identified by the Assistant Secretary, the National Mental Health and Substance Use Policy Laboratory established under section 501A, or the Assistant Secretary for Planning and Evaluation, including pursuant to the evaluation and recommendations under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 or priorities identified in the strategic plan under section 501(l).

"(c) REQUIREMENTS.—The Assistant Secretary may establish minimum requirements for the applications submitted under subsection (b), including applications related to the submission of research and evaluation.

"(d) REVIEW AND RATING.—

"(1) IN GENERAL.—The Assistant Secretary shall review applications prior to public posting in accordance with subsection (a), and may prioritize the review of applications for evidence-based programs and practices that are related to topics included in the notice provided under subsection (b)(2).

"(2) SYSTEM.—In carrying out paragraph (1), the Assistant Secretary may utilize a rating and review system, which may include information on the strength of evidence associated with the evidence-based programs and practices and a rating of the methodological rigor of the research supporting the applications.

"(3) PUBLIC ACCESS TO METRICS AND RATING.—The Assistant Secretary shall make the metrics used to evaluate applications under this section, and any resulting ratings of such applications, publicly available.".

SEC. 7003. PRIORITY MENTAL HEALTH NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 520A of the Public Health Service Act (42 U.S.C. 290bb–32) is amended—

(1) in subsection (a)—

(A) in paragraph (4), by inserting before the period ", which may include technical assistance centers"; and

(B) in the flush sentence following paragraph (4)—

(i) by inserting ", contracts," before "or cooperative agreements"; and

(ii) by striking "Indian tribes and tribal organizations" and inserting "Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or"; and

(2) by amending subsection (f) to read as follows:

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $394,550,000 for each of fiscal years 2018 through 2022.".

SEC. 7004. PRIORITY SUBSTANCE USE DISORDER TREATMENT NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 509 of the Public Health Service Act (42 U.S.C. 290bb–2) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "abuse" and inserting "use disorder";

(B) in paragraph (3), by inserting before the period "that permit States, local governments, communities, and Indian tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are defined in section 4 of the Indian Self-Determination and Education Assistance Act) to focus on emerging trends in substance abuse and co-occurrence of substance use disorders with mental illness or other conditions"; and

(C) in the flush sentence following paragraph (3)—

(i) by inserting ", contracts," before "or cooperative agreements"; and

(ii) by striking "Indian tribes and tribal organizations," and inserting "Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or";

(2) in subsection (b)—

(A) in paragraph (1), by striking "abuse" and inserting "use disorder"; and

(B) in paragraph (2), by striking "abuse" and inserting "use disorder";

(3) in subsection (e), by striking "abuse" and inserting "use disorder"; and

(4) in subsection (f), by striking "$300,000,000" and all that follows through the period and inserting "$333,806,000 for each of fiscal years 2018 through 2022.".

SEC. 7005. PRIORITY SUBSTANCE USE DISORDER PREVENTION NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 516 of the Public Health Service Act (42 U.S.C. 290bb–22) is amended—

(1) in the section heading, by striking "**ABUSE**" and inserting "**USE DISORDER**";

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "abuse" and inserting "use disorder";

(B) in paragraph (3), by inserting before the period ", including such programs that focus on emerging drug abuse issues"; and

(C) in the flush sentence following paragraph (3)—

(i) by inserting ", contracts," before "or cooperative agreements"; and

(ii) by striking "Indian tribes and tribal organizations," and inserting "Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service,";

(3) in subsection (b)—

(A) in paragraph (1), by striking "abuse" and inserting "use disorder"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "; and" at the end and inserting ";";

(ii) in subparagraph (B)—

(I) by striking "abuse" and inserting "use disorder"; and

(II) by striking the period and inserting "; and"; and

(iii) by adding at the end the following:

"(C) substance use disorder prevention among high-risk groups.";

(4) in subsection (e), by striking "abuse" and inserting "use disorder"; and

(5) in subsection (f), by striking "$300,000,000" and all that follows through the period and inserting "$211,148,000 for each of fiscal years 2018 through 2022.".

TITLE VIII—SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS

SEC. 8001. COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT.

(a) FORMULA GRANTS.—Section 1911(b) of the Public Health Service Act (42 U.S.C. 300x(b)) is amended—

(1) by redesignating paragraphs (1) through (3) as paragraphs (2) through (4), respectively; and

(2) by inserting before paragraph (2) (as so redesignated) the following:

"(1) providing community mental health services for adults with a serious mental illness and children with a serious emotional disturbance as defined in accordance with section 1912(c);".

(b) STATE PLAN.—Section 1912(b) of the Public Health Service Act (42 U.S.C. 300x–1(b)) is amended—

(1) in paragraph (3), by redesignating subparagraphs (A) through (C) as clauses (i) through (iii), respectively, and realigning the margins accordingly;

(2) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (E), respectively, and realigning the margins accordingly;

(3) in the matter preceding subparagraph (A) (as so redesignated), by striking "With respect to" and all that follows through "are as follows:" and inserting "In accordance with subsection (a), a State shall submit to the Secretary a plan every two years that, at a minimum, includes each of the following:";

(4) by inserting before subparagraph (A) (as so redesignated) the following:

"(1) SYSTEM OF CARE.—A description of the State's system of care that contains the following:";

(5) by striking subparagraph (A) (as so redesignated) and inserting the following:

"(A) COMPREHENSIVE COMMUNITY-BASED HEALTH SYSTEMS.—The plan shall—

"(i) identify the single State agency to be responsible for the administration of the program under the grant, including any third party who administers mental health services and is responsible for complying with the requirements of this part with respect to the grant;

"(ii) provide for an organized community-based system of care for individuals with mental illness, and describe available services and resources in a comprehensive system of care, including services for individuals with co-occurring disorders;

"(iii) include a description of the manner in which the State and local entities will coordinate services to maximize the efficiency, effectiveness, quality, and cost-effectiveness of services and programs to produce the best possible outcomes (including health services, rehabilitation services, employment services, housing services, educational services, substance use disorder services, legal services, law enforcement services, social services, child welfare services, medical and dental care services, and other support services to be provided with Federal, State, and local public and private resources) with other agencies to enable individuals receiving services to function outside of inpatient or residential institutions, to the maximum extent of their capabilities, including services to be provided by local school systems under the Individuals with Disabilities Education Act;

"(iv) include a description of how the State promotes evidence-based practices, including those evidence-based programs that address the needs of individuals with early serious mental illness regardless of the age of the individual at onset, provide comprehensive individualized treatment, or integrate mental and physical health services;

"(v) include a description of case management services;

"(vi) include a description of activities that seek to engage adults with a serious mental illness or children with a serious emotional disturbance and their caregivers where appropriate in making health care decisions, including activities that enhance communication among individuals, families, caregivers, and treatment providers; and

"(vii) as appropriate to, and reflective of, the uses the State proposes for the block grant funds, include—

"(I) a description of the activities intended to reduce hospitalizations and hospital stays using the block grant funds;

"(II) a description of the activities intended to reduce incidents of suicide using the block grant funds;

"(III) a description of how the State integrates mental health and primary care using the block grant funds, which may include providing, in the case of individuals with co-occurring mental and

substance use disorders, both mental and substance use disorders services in primary care settings or arrangements to provide primary and specialty care services in community-based mental and substance use disorders settings; and

"(IV) a description of recovery and recovery support services for adults with a serious mental illness and children with a serious emotional disturbance.";

(6) in subparagraph (B) (as so redesignated)—

(A) by striking "The plan contains" and inserting "The plan shall contain"; and

(B) by striking "presents quantitative targets to be achieved in the implementation of the system described in paragraph (1)" and inserting "present quantitative targets and outcome measures for programs and services provided under this subpart";

(7) in subparagraph (C) (as so redesignated)—

(A) by striking "serious emotional disturbance" in the matter preceding clause (i) (as so redesignated) and all that follows through "substance abuse services" in clause (i) (as so redesignated) and inserting the following: "a serious emotional disturbance (as defined pursuant to subsection (c)), the plan shall provide for a system of integrated social services, educational services, child welfare services, juvenile justice services, law enforcement services, and substance use disorder services";

(B) by striking "Education Act);" and inserting "Education Act)."; and

(C) by striking clauses (ii) and (iii) (as so redesignated);

(8) in subparagraph (D) (as so redesignated), by striking "plan describes" and inserting "plan shall describe";

(9) in subparagraph (E) (as so redesignated)—

(A) in the subparagraph heading by striking "SYSTEMS" and inserting "SERVICES";

(B) in the first sentence, by striking "plan describes" and all that follows through "and provides for" and inserting "plan shall describe the financial resources available, the existing mental health workforce, and the workforce trained in treating individuals with co-occurring mental and substance use disorders, and shall provide for"; and

(C) in the second sentence—

(i) by striking "further describes" and inserting "shall further describe"; and

(ii) by striking "involved." and inserting "involved, and the manner in which the State intends to comply with each of the funding agreements in this subpart and subpart III.";

(10) by striking the flush matter at the end; and

(11) by adding at the end the following:

"(2) GOALS AND OBJECTIVES.—The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.".

(c) EARLY SERIOUS MENTAL ILLNESS.—Section 1920 of the Public Health Service Act (42 U.S.C. 300x–9) is amended by adding at the end the following:

"(c) EARLY SERIOUS MENTAL ILLNESS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), a State shall expend not less than 10 percent of the amount the State receives for carrying out this section for each fiscal year to support evidence-based programs that address the needs of individuals with early serious mental illness, including psychotic disorders, regardless of the age of the individual at onset.

"(2) STATE FLEXIBILITY.—In lieu of expending 10 percent of the amount the State receives under this section for a fiscal year as required under paragraph (1), a State may elect to expend not less than 20 percent of such amount by the end of such succeeding fiscal year.".

(d) ADDITIONAL PROVISIONS.—Section 1915(b) of the Public Health Service Act (42 U.S.C. 300x–4(b)) is amended—

(1) in paragraph (3)—

(A) by striking "The Secretary" and inserting the following:

"(A) IN GENERAL.—The Secretary";

(B) by striking "paragraph (1) if" and inserting "paragraph (1) in whole or in part if";

(C) by striking "State justify the waiver." and inserting "State in the fiscal year involved or in the previous fiscal year justify the waiver"; and

(D) by adding at the end the following:

"(B) DATE CERTAIN FOR ACTION UPON REQUEST.—The Secretary shall approve or deny a request for a waiver under this paragraph not later than 120 days after the date on which the request is made.

"(C) APPLICABILITY OF WAIVER.—A waiver provided by the Secretary under this paragraph shall be applicable only to the fiscal year involved."; and

(2) in paragraph (4)—

(A) in subparagraph (A)—

(i) by inserting after the subparagraph designation the following: "IN GENERAL.—";

(ii) by striking "In making a grant" and inserting the following:

"(i) DETERMINATION.—In making a grant"; and

(iii) by inserting at the end the following:

"(ii) ALTERNATIVE.—A State that has failed to comply with paragraph (1) and would otherwise be subject to a reduction in the State's allotment under section 1911 may, upon request by the State, in lieu of having the amount of the allotment under section 1911 for the State reduced for the fiscal year of the grant, agree to comply with a negotiated agreement that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement."; and

(B) in subparagraph (B)—

(i) by inserting after the subparagraph designation the following: "SUBMISSION OF INFORMATION TO THE SECRETARY.—"; and

(ii) by striking "subparagraph (A)" and inserting "subparagraph (A)(i)".

(e) APPLICATION FOR GRANT.—Section 1917(a) of the Public Health Service Act (42 U.S.C. 300x–6(a)) is amended—

(1) in paragraph (1), by striking "1941" and inserting "1942(a)"; and

(2) in paragraph (5), by striking "1915(b)(3)(B)" and inserting "1915(b)".

(f) FUNDING.—Section 1920 of the Public Health Service Act (42 U.S.C. 300x–9) is amended—

(1) in subsection (a)—

(A) by striking "section 505" and inserting "section 505(c)"; and

(B) by striking "$450,000,000" and all that follows through the period and inserting "$532,571,000 for each of fiscal years 2018 through 2022."; and

(2) in subsection (b)(2) by striking "sections 505 and" and inserting "sections 505(c) and".

SEC. 8002. SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT.

(a) FORMULA GRANTS.—Section 1921(b) of the Public Health Service Act (42 U.S.C. 300x–21(b)) is amended—

(1) by inserting "carrying out the plan developed in accordance with section 1932(b) and for" after "for the purpose of"; and

(2) by striking "abuse" and inserting "use disorders".

(b) OUTREACH TO PERSONS WHO INJECT DRUGS.—Section 1923(b) of the Public Health Service Act (42 U.S.C. 300x–23(b)) is amended—

(1) in the subsection heading, by striking "REGARDING INTRAVENOUS SUBSTANCE ABUSE" and inserting "TO PERSONS WHO INJECT DRUGS"; and

(2) by striking "for intravenous drug abuse" and inserting "for persons who inject drugs".

(c) REQUIREMENTS REGARDING TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS.—Section 1924 of the Public Health Service Act (42 U.S.C. 300x–24) is amended—

(1) in subsection (a)(1)—

(A) in the matter preceding subparagraph (A), by striking "substance abuse" and inserting "substance use disorders"; and

(B) in subparagraph (A), by striking "such abuse" and inserting "such disorders";

(2) in subsection (b)—

(A) in paragraph (1)(A), by striking "substance abuse" and inserting "substance use disorders";

(B) in paragraph (2), by inserting "and Prevention" after "Disease Control";

(C) in paragraph (3)—

(i) in the paragraph heading, by striking "ABUSE" and inserting "USE DISORDERS"; and

(ii) by striking "substance abuse" and inserting "substance use disorders"; and

(D) in paragraph (6)(B), by striking "substance abuse" and inserting "substance use disorders";

(3) by striking subsection (d); and

(4) by redesignating subsection (e) as subsection (d).

(d) GROUP HOMES.—Section 1925 of the Public Health Service Act (42 U.S.C. 300x–25) is amended—

(1) in the section heading, by striking "**RECOVERING SUBSTANCE ABUSERS**" and inserting "**PERSONS IN RECOVERY FROM SUBSTANCE USE DISORDERS**"; and

(2) in subsection (a), in the matter preceding paragraph (1), by striking "recovering substance abusers" and inserting "persons in recovery from substance use disorders".

(e) ADDITIONAL AGREEMENTS.—Section 1928 of the Public Health Service Act (42 U.S.C. 300x–28) is amended—

(1) in subsection (a), by striking "(relative to fiscal year 1992)";

(2) by striking subsection (b) and inserting the following:

"(b) PROFESSIONAL DEVELOPMENT.—A funding agreement for a grant under section 1921 is that the State involved will ensure that prevention, treatment, and recovery personnel operating in the State's substance use disorder prevention, treatment, and recovery systems have an opportunity to receive training, on an ongoing basis, concerning—

"(1) recent trends in substance use disorders in the State;

"(2) improved methods and evidence-based practices for providing substance use disorder prevention and treatment services;

"(3) performance-based accountability;

"(4) data collection and reporting requirements; and

"(5) any other matters that would serve to further improve the delivery of substance use disorder prevention and treatment services within the State."; and

(3) in subsection (d)(1), by striking "substance abuse" and inserting "substance use disorders".

(f) REPEAL.—Section 1929 of the Public Health Service Act (42 U.S.C. 300x–29) is repealed.

(g) MAINTENANCE OF EFFORT.—Section 1930 of the Public Health Service Act (42 U.S.C. 300x–30) is amended—

(1) in subsection (c)(1), by striking "in the State justify the waiver" and inserting "exist in the State, or any part of the State, to justify the waiver"; and

(2) in subsection (d), by inserting at the end the following:

"(3) ALTERNATIVE.—A State that has failed to comply with this section and would otherwise be subject to a reduction in the State's allotment under section 1921, may, upon request by the State, in lieu of having the State's allotment under section 1921 reduced, agree to comply with a negotiated agreement that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement.".

(h) RESTRICTIONS ON EXPENDITURES.—Section 1931(b)(1) of the Public Health Service Act (42 U.S.C. 300x–31(b)(1)) is amended by striking "substance abuse" and inserting "substance use disorders".

(i) APPLICATION.—Section 1932 of the Public Health Service Act (42 U.S.C. 300x–32) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "subsections (c) and (d)(2)" and inserting "subsection (c)"; and

(B) in paragraph (5), by striking "the information required in section 1929, the information required in section 1930(c)(2), and";

(2) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—In order for a State to be in compliance with subsection (a)(6), the State shall submit to the Secretary a plan that, at a minimum, includes the following:

"(A) A description of the State's system of care that—

"(i) identifies the single State agency responsible for the administration of the program, including any third party who administers substance use disorder services and is responsible for complying with the requirements of the grant;

"(ii) provides information on the need for substance use disorder prevention and treatment services in the State, including estimates on the number of individuals who need treatment, who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

"(iii) provides aggregate information on the number of individuals in treatment within the State, including the number of such individuals who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

"(iv) provides a description of the system that is available to provide services by modality, including the provision of recovery support services;

"(v) provides a description of the State's comprehensive statewide prevention efforts, including the number of individuals being served in the system, target populations, and priority needs, and provides a description of the amount of funds from the prevention set-aside expended on primary prevention;

"(vi) provides a description of the financial resources available;

"(vii) describes the existing substance use disorders workforce and workforce trained in treating co-occurring substance use and mental disorders;

"(viii) includes a description of how the State promotes evidence-based practices; and

"(ix) describes how the State integrates substance use disorder services and primary health care, which in the case of those individuals with co-occurring mental health and substance use disorders may include

providing both mental health and substance use disorder services in primary care settings or providing primary and specialty care services in community-based mental health and substance use disorder service settings.

"(B) The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.

"(C) A description of how the State will comply with each funding agreement for a grant under section 1921 that is applicable to the State, including a description of the manner in which the State intends to expend grant funds."; and

(B) in paragraph (2)—

(i) in the paragraph heading, by striking "AUTHORITY OF SECRETARY REGARDING MODIFICATIONS" and inserting "MODIFICATIONS";

(ii) by striking "As a condition" and inserting the following:

"(A) AUTHORITY OF SECRETARY.—As a condition;"; and

(iii) by adding at the end the following:

"(B) STATE REQUEST FOR MODIFICATION.—If the State determines that a modification to such plan is necessary, the State may request the Secretary to approve the modification. Any such modification shall be in accordance with paragraph (1) and section 1941."; and

(C) in paragraph (3), by inserting, ", including any modification under paragraph (2)" after "subsection (a)(6)"; and

(3) in subsection (e)(2), by striking "section 1922(c)" and inserting "section 1922(b)".

(j) DEFINITIONS.—Section 1934 of the Public Health Service Act (42 U.S.C. 300x–34) is amended—

(1) in paragraph (3), by striking "substance abuse" and inserting "substance use disorders"; and

(2) in paragraph (7), by striking "substance abuse" and inserting "substance use disorders".

(k) FUNDING.—Section 1935 of the Public Health Service Act (42 U.S.C. 300x–35) is amended—

(1) in subsection (a)—

(A) by striking "section 505" and inserting "section 505(d)"; and

(B) by striking "$2,000,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" and inserting "$1,858,079,000 for each of fiscal years 2018 through 2022."; and

(2) in subsection (b)(1)(B) by striking "sections 505 and" and inserting "sections 505(d) and".

SEC. 8003. ADDITIONAL PROVISIONS RELATED TO THE BLOCK GRANTS.

Subpart III of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–51 et seq.) is amended—

(1) in section 1943(a)(3) (42 U.S.C. 300x–53(a)(3)), by striking "section 505" and inserting "subsections (c) and (d) of section 505";

(2) in section 1953(b) (42 U.S.C. 300x–63(b)), by striking "substance abuse" and inserting "substance use disorder"; and

(3) by adding at the end the following:

"SEC. 1957. PUBLIC HEALTH EMERGENCIES. 42 USC 300x–67.

"In the case of a public health emergency (as determined under section 319), the Secretary, on a State by State basis, may, as the circumstances of the emergency reasonably require and for the period of the emergency, grant an extension, or waive application deadlines or compliance with any other requirement, of a grant authorized under section 521, 1911, or 1921 or an allotment authorized under Public Law 99–319 (42 U.S.C. 10801 et seq.).

"SEC. 1958. JOINT APPLICATIONS. 42 USC 300x–68.

"The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall permit a joint application to be submitted for grants under subpart I and subpart II upon the request of a State. Such application may be jointly reviewed and approved by the Secretary with respect to such subparts, consistent with the purposes and authorized activities of each such grant program. A State submitting such a joint application shall otherwise meet the requirements with respect to each such subpart.".

SEC. 8004. STUDY OF DISTRIBUTION OF FUNDS UNDER THE SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT AND THE COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, shall through a grant or contract, or through an agreement with a third party, conduct a study on the formulas for distribution of funds under the substance abuse prevention and treatment block grant, and the community mental health services block grant, under part B of title XIX of the Public Health Service Act (42 U.S.C. 300x et seq.) and recommend changes if necessary. Such study shall include—

(1) an analysis of whether the distributions under such block grants accurately reflect the need for the services under the grants in the States;

(2) an examination of whether the indices used under the formulas for distribution of funds under such block grants are appropriate, and if not, alternatives recommended by the Secretary;

(3) where recommendations are included under paragraph (2) for the use of different indices, a description of the variables and data sources that should be used to determine the indices;

(4) an evaluation of the variables and data sources that are being used for each of the indices involved, and whether such variables and data sources accurately represent the need for services, the cost of providing services, and the ability of the States to pay for such services;

(5) the effect that the minimum allotment requirements for each such block grant have on each State's final allotment and the effect of such requirements, if any, on each State's formula-based allotment;

(6) recommendations for modifications to the minimum allotment provisions to ensure an appropriate distribution of funds; and

(7) any other information that the Secretary determines appropriate.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report containing the findings and recommendations of the study conducted under subsection (a) and the study conducted under section 9004(g).

TITLE IX—PROMOTING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER CARE

Subtitle A—Helping Individuals and Families

SEC. 9001. GRANTS FOR TREATMENT AND RECOVERY FOR HOMELESS INDIVIDUALS.

Section 506 of the Public Health Service Act (42 U.S.C. 290aa–5) is amended—

(1) in subsection (a), by striking "substance abuse" and inserting "substance use disorder";

(2) in subsection (b)—

(A) in paragraphs (1) and (3), by striking "substance abuse" each place the term appears and inserting "substance use disorder"; and

(B) in paragraph (4), by striking "substance abuse" and inserting "a substance use disorder";

(3) in subsection (c)—

(A) in paragraph (1), by striking "substance abuse disorder" and inserting "substance use disorder"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "substance abuse" and inserting "a substance use disorder"; and

(ii) in subparagraph (B), by striking "substance abuse" and inserting "substance use disorder"; and

(4) in subsection (e), by striking ", $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" and inserting "$41,304,000 for each of fiscal years 2018 through 2022".

SEC. 9002. GRANTS FOR JAIL DIVERSION PROGRAMS.

Section 520G of the Public Health Service Act (42 U.S.C. 290bb–38) is amended—

(1) by striking "substance abuse" each place such term appears and inserting "substance use disorder";

(2) in subsection (a)—

(A) by striking "Indian tribes, and tribal organizations" and inserting "and Indian tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are

defined in section 4 of the Indian Self-Determination and Education Assistance Act)"; and

(B) by inserting "or a health facility or program operated by or in accordance with a contract or grant with the Indian Health Service," after "entities,";

(3) in subsection (c)(2)(A)(i), by striking "the best known" and inserting "evidence-based";

(4) by redesignating subsections (d) through (i) as subsections (e) through (j), respectively;

(5) by inserting after subsection (c) the following:

"(d) SPECIAL CONSIDERATION REGARDING VETERANS.—In awarding grants under subsection (a), the Secretary shall, as appropriate, give special consideration to entities proposing to use grant funding to support jail diversion services for veterans.";

(6) in subsection (e), as so redesignated—

(A) in paragraph (3), by striking "; and" and inserting a semicolon;

(B) in paragraph (4), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(5) develop programs to divert individuals prior to booking or arrest."; and

(7) in subsection (j), as so redesignated, by striking "$10,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003" and inserting "$4,269,000 for each of fiscal years 2018 through 2022".

SEC. 9003. PROMOTING INTEGRATION OF PRIMARY AND BEHAVIORAL HEALTH CARE.

Section 520K of the Public Health Service Act (42 U.S.C. 290bb–42) is amended to read as follows:

"SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOPERATIVE AGREEMENTS.

"(a) DEFINITIONS.—In this section:

"(1) ELIGIBLE ENTITY.—The term 'eligible entity' means a State, or other appropriate State agency, in collaboration with 1 or more qualified community programs as described in section 1913(b)(1) or 1 or more community health centers as described in section 330.

"(2) INTEGRATED CARE.—The term 'integrated care' means collaborative models or practices offering mental and physical health services, which may include practices that share the same space in the same facility.

"(3) SPECIAL POPULATION.—The term 'special population' means—

"(A) adults with a mental illness who have co-occurring physical health conditions or chronic diseases;

"(B) adults with a serious mental illness who have co-occurring physical health conditions or chronic diseases;

"(C) children and adolescents with a serious emotional disturbance with co-occurring physical health conditions or chronic diseases; or

"(D) individuals with a substance use disorder.

"(b) GRANTS AND COOPERATIVE AGREEMENTS.—

"(1) IN GENERAL.—The Secretary may award grants and cooperative agreements to eligible entities to support the

improvement of integrated care for primary care and behavioral health care in accordance with paragraph (2).

"(2) PURPOSES.—A grant or cooperative agreement awarded under this section shall be designed to—

"(A) promote full integration and collaboration in clinical practices between primary and behavioral health care;

"(B) support the improvement of integrated care models for primary care and behavioral health care to improve the overall wellness and physical health status of adults with a serious mental illness or children with a serious emotional disturbance; and

"(C) promote integrated care services related to screening, diagnosis, prevention, and treatment of mental and substance use disorders, and co-occurring physical health conditions and chronic diseases.

"(c) APPLICATIONS.—

"(1) IN GENERAL.—An eligible entity seeking a grant or cooperative agreement under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require, including the contents described in paragraph (2).

"(2) CONTENTS.—The contents described in this paragraph are—

"(A) a description of a plan to achieve fully collaborative agreements to provide services to special populations;

"(B) a document that summarizes the policies, if any, that serve as barriers to the provision of integrated care, and the specific steps, if applicable, that will be taken to address such barriers;

"(C) a description of partnerships or other arrangements with local health care providers to provide services to special populations;

"(D) an agreement and plan to report to the Secretary performance measures necessary to evaluate patient outcomes and facilitate evaluations across participating projects; and

"(E) a plan for sustainability beyond the grant or cooperative agreement period under subsection (e).

"(d) GRANT AND COOPERATIVE AGREEMENT AMOUNTS.—

"(1) TARGET AMOUNT.—The target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section shall be $2,000,000.

"(2) ADJUSTMENT PERMITTED.—The Secretary, taking into consideration the quality of the application and the number of eligible entities that received grants under this section prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, may adjust the target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section.

"(3) LIMITATION.—An eligible entity receiving funding under this section may not allocate more than 10 percent of funds awarded under this section to administrative functions, and the remaining amounts shall be allocated to health facilities that provide integrated care.

"(e) DURATION.—A grant or cooperative agreement under this section shall be for a period not to exceed 5 years.

"(f) REPORT ON PROGRAM OUTCOMES.—An eligible entity receiving a grant or cooperative agreement under this section shall submit an annual report to the Secretary that includes—

"(1) the progress made to reduce barriers to integrated care as described in the entity's application under subsection (c); and

"(2) a description of functional outcomes of special populations, including—

"(A) with respect to adults with a serious mental illness, participation in supportive housing or independent living programs, attendance in social and rehabilitative programs, participation in job training opportunities, satisfactory performance in work settings, attendance at scheduled medical and mental health appointments, and compliance with prescribed medication regimes;

"(B) with respect to individuals with co-occurring mental illness and physical health conditions and chronic diseases, attendance at scheduled medical and mental health appointments, compliance with prescribed medication regimes, and participation in learning opportunities related to improved health and lifestyle practices; and

"(C) with respect to children and adolescents with a serious emotional disturbance who have co-occurring physical health conditions and chronic diseases, attendance at scheduled medical and mental health appointments, compliance with prescribed medication regimes, and participation in learning opportunities at school and extracurricular activities.

"(g) TECHNICAL ASSISTANCE FOR PRIMARY-BEHAVIORAL HEALTH CARE INTEGRATION.—

"(1) IN GENERAL.—The Secretary may provide appropriate information, training, and technical assistance to eligible entities that receive a grant or cooperative agreement under this section, in order to help such entities meet the requirements of this section, including assistance with—

"(A) development and selection of integrated care models;

"(B) dissemination of evidence-based interventions in integrated care;

"(C) establishment of organizational practices to support operational and administrative success; and

"(D) other activities, as the Secretary determines appropriate.

"(2) ADDITIONAL DISSEMINATION OF TECHNICAL INFORMATION.—The information and resources provided by the Secretary under paragraph (1) shall, as appropriate, be made available to States, political subdivisions of States, Indian tribes or tribal organizations (as defined in section 4 of the Indian Self-Determination and Education Assistance Act), outpatient mental health and addiction treatment centers, community mental health centers that meet the criteria under section 1913(c), certified community behavioral health clinics described in section 223 of the Protecting Access to Medicare Act of 2014, primary care organizations such as Federally qualified health centers or rural health clinics as defined in section 1861(aa)

of the Social Security Act, other community-based organizations, or other entities engaging in integrated care activities, as the Secretary determines appropriate.

"(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $51,878,000 for each of fiscal years 2018 through 2022.".

SEC. 9004. PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS.

(a) FORMULA GRANTS TO STATES.—Section 521 of the Public Health Service Act (42 U.S.C. 290cc–21) is amended by striking "1991 through 1994" and inserting "2018 through 2022".

(b) PURPOSE OF GRANTS.—Section 522 of the Public Health Service Act (42 U.S.C. 290cc–22) is amended—

(1) in subsection (a)(1)(B), by striking "substance abuse" and inserting "a substance use disorder";

(2) in subsection (b)(6), by striking "substance abuse" and inserting "substance use disorder";

(3) in subsection (c), by striking "substance abuse" and inserting "a substance use disorder";

(4) in subsection (e)—

(A) in paragraph (1), by striking "substance abuse" and inserting "a substance use disorder"; and

(B) in paragraph (2), by striking "substance abuse" and inserting "substance use disorder";

(5) by striking subsection (g) and redesignating subsections (h) and (i) as (g) and (h), accordingly; and

(6) in subsection (g), as redesignated by paragraph (5), by striking "substance abuse" each place such term appears and inserting "substance use disorder".

(c) DESCRIPTION OF INTENDED EXPENDITURES OF GRANT.—Section 527 of the Public Health Service Act (42 U.S.C. 290cc–27) is amended by striking "substance abuse" each place such term appears and inserting "substance use disorder".

(d) TECHNICAL ASSISTANCE.—Section 530 of the Public Health Service Act (42 U.S.C. 290cc–30) is amended by striking "through the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse" and inserting "acting through the Assistant Secretary".

(e) DEFINITIONS.—Section 534(4) of the Public Health Service Act (42 U.S.C. 290cc–34(4)) is amended to read as follows:

"(4) SUBSTANCE USE DISORDER SERVICES.—The term 'substance use disorder services' has the meaning given the term 'substance abuse services' in section 330(h)(5)(C).".

(f) FUNDING.—Section 535(a) of the Public Health Service Act (42 U.S.C. 290cc–35(a)) is amended by striking "$75,000,000 for each of the fiscal years 2001 through 2003" and inserting "$64,635,000 for each of fiscal years 2018 through 2022".

(g) STUDY CONCERNING FORMULA.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Assistant Secretary for Mental Health and Substance Use (referred to in this section as the "Assistant Secretary") shall conduct a study concerning the formula used under section 524 of the Public Health Service Act (42 U.S.C. 290cc–24) for making allotments to States under section 521 of such Act (42 U.S.C. 290cc–21). Such study shall include an evaluation of quality indicators of need for purposes

of revising the formula for determining the amount of each allotment for the fiscal years following the submission of the study.

(2) REPORT.—In accordance with section 8004(b), the Assistant Secretary shall submit to the committees of Congress described in such section a report concerning the results of the study conducted under paragraph (1).

SEC. 9005. NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb–31 et seq.) is amended by inserting after section 520E–2 (42 U.S.C. 290bb–36b) the following:

"SEC. 520E–3. NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM. 42 USC 290bb–36c.

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Suicide Prevention Lifeline program (referred to in this section as the 'program'), authorized under section 520A and in effect prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016.

"(b) ACTIVITIES.—In maintaining the program, the activities of the Secretary shall include—

"(1) coordinating a network of crisis centers across the United States for providing suicide prevention and crisis intervention services to individuals seeking help at any time, day or night;

"(2) maintaining a suicide prevention hotline to link callers to local emergency, mental health, and social services resources; and

"(3) consulting with the Secretary of Veterans Affairs to ensure that veterans calling the suicide prevention hotline have access to a specialized veterans' suicide prevention hotline.

"(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $7,198,000 for each of fiscal years 2018 through 2022.".

SEC. 9006. CONNECTING INDIVIDUALS AND FAMILIES WITH CARE.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb–31 et seq.), as amended by section 9005, is further amended by inserting after section 520E–3 the following:

"SEC. 520E–4. TREATMENT REFERRAL ROUTING SERVICE. 42 USC 290bb–36d.

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Treatment Referral Routing Service (referred to in this section as the 'Routing Service') to assist individuals and families in locating mental and substance use disorders treatment providers.

"(b) ACTIVITIES OF THE SECRETARY.—To maintain the Routing Service, the activities of the Assistant Secretary shall include administering—

"(1) a nationwide, telephone number providing year-round access to information that is updated on a regular basis regarding local behavioral health providers and community-based organizations in a manner that is confidential, without requiring individuals to identify themselves, is in languages that include at least English and Spanish, and is at no cost to the individual using the Routing Service; and

"(2) an Internet website to provide a searchable, online treatment services locator of behavioral health treatment providers and community-based organizations, which shall include information on the name, location, contact information, and basic services provided by such providers and organizations.

"(c) REMOVING PRACTITIONER CONTACT INFORMATION.—In the event that the Internet website described in subsection (b)(2) contains information on any qualified practitioner that is certified to prescribe medication for opioid dependency under section 303(g)(2)(B) of the Controlled Substances Act, the Assistant Secretary—

"(1) shall provide an opportunity to such practitioner to have the contact information of the practitioner removed from the website at the request of the practitioner; and

"(2) may evaluate other methods to periodically update the information displayed on such website.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent the Assistant Secretary from using any unobligated amounts otherwise made available to the Administration to maintain the Routing Service.".

SEC. 9007. STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS.

Section 520F of the Public Health Service Act (42 U.S.C. 290bb–37) is amended to read as follows:

"SEC. 520F. STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS.

"(a) IN GENERAL.—The Secretary shall award competitive grants to—

"(1) State and local governments and Indian tribes and tribal organizations, to enhance community-based crisis response systems; or

"(2) States to develop, maintain, or enhance a database of beds at inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities, for adults with a serious mental illness, children with a serious emotional disturbance, or individuals with a substance use disorder.

"(b) APPLICATIONS.—

"(1) IN GENERAL.—To receive a grant under subsection (a), an entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

"(2) COMMUNITY-BASED CRISIS RESPONSE PLAN.—An application for a grant under subsection (a)(1) shall include a plan for—

"(A) promoting integration and coordination between local public and private entities engaged in crisis response, including first responders, emergency health care providers, primary care providers, law enforcement, court systems, health care payers, social service providers, and behavioral health providers;

"(B) developing memoranda of understanding with public and private entities to implement crisis response services;

"(C) addressing gaps in community resources for crisis intervention and prevention; and

"(D) developing models for minimizing hospital readmissions, including through appropriate discharge planning.

"(3) BEDS DATABASE PLAN.—An application for a grant under subsection (a)(2) shall include a plan for developing, maintaining, or enhancing a real-time, Internet-based bed database to collect, aggregate, and display information about beds in inpatient psychiatric facilities and crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities to facilitate the identification and designation of facilities for the temporary treatment of individuals in mental or substance use disorder crisis.

"(c) DATABASE REQUIREMENTS.—A bed database described in this section is a database that—

"(1) includes information on inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder facilities in the State involved, including contact information for the facility or unit;

"(2) provides real-time information about the number of beds available at each facility or unit and, for each available bed, the type of patient that may be admitted, the level of security provided, and any other information that may be necessary to allow for the proper identification of appropriate facilities for treatment of individuals in mental or substance use disorder crisis; and

"(3) enables searches of the database to identify available beds that are appropriate for the treatment of individuals in mental or substance use disorder crisis.

"(d) EVALUATION.—An entity receiving a grant under subsection (a)(1) shall submit to the Secretary, at such time, in such manner, and containing such information as the Secretary may reasonably require, a report, including an evaluation of the effect of such grant on—

"(1) local crisis response services and measures for individuals receiving crisis planning and early intervention supports;

"(2) individuals reporting improved functional outcomes; and

"(3) individuals receiving regular followup care following a crisis.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $12,500,000 for the period of fiscal years 2018 through 2022.".

SEC. 9008. GARRETT LEE SMITH MEMORIAL ACT REAUTHORIZATION.

(a) SUICIDE PREVENTION TECHNICAL ASSISTANCE CENTER.—Section 520C of the Public Health Service Act (42 U.S.C. 290bb–34), as amended by section 6001, is further amended—

(1) in the section heading, by striking "**YOUTH INTERAGENCY RESEARCH, TRAINING, AND TECHNICAL ASSISTANCE CENTERS**" and inserting "**SUICIDE PREVENTION TECHNICAL ASSISTANCE CENTER**";

(2) in subsection (a), by striking "acting through the Assistant Secretary for Mental Health and Substance Use" and all that follows through the period at the end of paragraph (2) and inserting "acting through the Assistant Secretary, shall establish a research, training, and technical assistance resource

center to provide appropriate information, training, and technical assistance to States, political subdivisions of States, federally recognized Indian tribes, tribal organizations, institutions of higher education, public organizations, or private nonprofit organizations regarding the prevention of suicide among all ages, particularly among groups that are at a high risk for suicide.";

(3) by striking subsections (b) and (c);

(4) by redesignating subsection (d) as subsection (b);

(5) in subsection (b), as so redesignated—

(A) in the subsection heading, by striking "ADDITIONAL CENTER" and inserting "RESPONSIBILITIES OF THE CENTER";

(B) in the matter preceding paragraph (1), by striking "The additional research" and all that follows through "nonprofit organizations for" and inserting "The center established under subsection (a) shall conduct activities for the purpose of";

(C) by striking "youth suicide" each place such term appears and inserting "suicide";

(D) in paragraph (1)—

(i) by striking "the development or continuation of" and inserting "developing and continuing"; and

(ii) by inserting "for all ages, particularly among groups that are at a high risk for suicide" before the semicolon at the end;

(E) in paragraph (2), by inserting "for all ages, particularly among groups that are at a high risk for suicide" before the semicolon at the end;

(F) in paragraph (3), by inserting "and tribal" after "statewide";

(G) in paragraph (5), by inserting "and prevention" after "intervention";

(H) in paragraph (8), by striking "in youth";

(I) in paragraph (9), by striking "and behavioral health" and inserting "health and substance use disorder"; and

(J) in paragraph (10), by inserting "conducting" before "other"; and

(6) by striking subsection (e) and inserting the following:

"(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,988,000 for each of fiscal years 2018 through 2022.

"(d) ANNUAL REPORT.—Not later than 2 years after the date of enactment of this subsection, the Secretary shall submit to Congress a report on the activities carried out by the center established under subsection (a) during the year involved, including the potential effects of such activities, and the States, organizations, and institutions that have worked with the center.".

(b) YOUTH SUICIDE EARLY INTERVENTION AND PREVENTION STRATEGIES.—Section 520E of the Public Health Service Act (42 U.S.C. 290bb–36) is amended—

(1) in paragraph (1) of subsection (a) and in subsection (c), by striking "substance abuse" each place such term appears and inserting "substance use disorder";

(2) in subsection (b)—

(A) in paragraph (2)—

(i) by striking "ensure that each State is awarded only 1 grant or cooperative agreement under this section" and inserting "ensure that a State does not receive more than 1 grant or cooperative agreement under this section at any 1 time"; and

(ii) by striking "been awarded" and inserting "received"; and

(B) by adding after paragraph (2) the following:

"(3) CONSIDERATION.—In awarding grants under this section, the Secretary shall take into consideration the extent of the need of the applicant, including the incidence and prevalence of suicide in the State and among the populations of focus, including rates of suicide determined by the Centers for Disease Control and Prevention for the State or population of focus.";

(3) in subsection (g)(2), by striking "2 years after the date of enactment of this section," and insert "2 years after the date of enactment of Helping Families in Mental Health Crisis Reform Act of 2016,"; and

(4) by striking subsection (m) and inserting the following:

"(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $30,000,000 for each of fiscal years 2018 through 2022.".

SEC. 9009. ADULT SUICIDE PREVENTION.

42 USC 290bb–43.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb–31 et seq.) is amended by adding at the end the following:

"SEC. 520L. ADULT SUICIDE PREVENTION.

"(a) GRANTS.—

"(1) IN GENERAL.—The Assistant Secretary shall award grants to eligible entities described in paragraph (2) to implement suicide prevention and intervention programs, for individuals who are 25 years of age or older, that are designed to raise awareness of suicide, establish referral processes, and improve care and outcomes for such individuals who are at risk of suicide.

"(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be a community-based primary care or behavioral health care setting, an emergency department, a State mental health agency (or State health agency with mental or behavioral health functions), public health agency, a territory of the United States, or an Indian tribe or tribal organization (as the terms 'Indian tribe' and 'tribal organization' are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

"(3) USE OF FUNDS.—The grants awarded under paragraph (1) shall be used to implement programs, in accordance with such paragraph, that include one or more of the following components:

"(A) Screening for suicide risk, suicide intervention services, and services for referral for treatment for individuals at risk for suicide.

"(B) Implementing evidence-based practices to provide treatment for individuals at risk for suicide, including appropriate followup services.

"(C) Raising awareness and reducing stigma of suicide.

"(b) EVALUATIONS AND TECHNICAL ASSISTANCE.—The Assistant Secretary shall—

"(1) evaluate the activities supported by grants awarded under subsection (a), and disseminate, as appropriate, the findings from the evaluation; and

"(2) provide appropriate information, training, and technical assistance, as appropriate, to eligible entities that receive a grant under this section, in order to help such entities to meet the requirements of this section, including assistance with selection and implementation of evidence-based interventions and frameworks to prevent suicide.

"(c) DURATION.—A grant under this section shall be for a period of not more than 5 years.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $30,000,000 for the period of fiscal years 2018 through 2022.".

SEC. 9010. MENTAL HEALTH AWARENESS TRAINING GRANTS.

Section 520J of the Public Health Service Act (42 U.S.C. 290bb–41) is amended—

(1) in the section heading, by inserting "**MENTAL HEALTH AWARENESS**" before "**TRAINING**"; and

(2) in subsection (b)—

(A) in the subsection heading, by striking "ILLNESS" and inserting "HEALTH";

(B) in paragraph (1), by inserting "veterans, law enforcement, and other categories of individuals, as determined by the Secretary," after "emergency services personnel";

(C) in paragraph (5)—

(i) in the matter preceding subparagraph (A), by striking "to" and inserting "for evidence-based programs that provide training and education in accordance with paragraph (1) on matters including"; and

(ii) by striking subparagraphs (A) through (C) and inserting the following:

"(A) recognizing the signs and symptoms of mental illness; and

"(B)(i) resources available in the community for individuals with a mental illness and other relevant resources; or

"(ii) safely de-escalating crisis situations involving individuals with a mental illness."; and

(D) in paragraph (7), by striking ", $25,000,000" and all that follows through the period at the end and inserting "$14,693,000 for each of fiscal years 2018 through 2022.".

SEC. 9011. SENSE OF CONGRESS ON PRIORITIZING AMERICAN INDIANS AND ALASKA NATIVE YOUTH WITHIN SUICIDE PREVENTION PROGRAMS.

(a) FINDINGS.—The Congress finds as follows:

(1) Suicide is the eighth leading cause of death among American Indians and Alaska Natives across all ages.

(2) Among American Indians and Alaska Natives who are 10 to 34 years of age, suicide is the second leading cause of death.

(3) The suicide rate among American Indian and Alaska Native adolescents and young adults ages 15 to 34 (17.9 per

100,000) is approximately 1.3 times higher than the national average for that age group (13.3 per 100,000).

(b) SENSE OF CONGRESS.—It is the sense of Congress that the Secretary of Health and Human Services, in carrying out suicide prevention and intervention programs, should prioritize programs and activities for populations with disproportionately high rates of suicide, such as American Indians and Alaska Natives.

SEC. 9012. EVIDENCE-BASED PRACTICES FOR OLDER ADULTS.

Section 520A(e) of the Public Health Service Act (42 U.S.C. 290bb–32(e)) is amended by adding at the end the following:

"(3) GERIATRIC MENTAL DISORDERS.—The Secretary shall, as appropriate, provide technical assistance to grantees regarding evidence-based practices for the prevention and treatment of geriatric mental disorders and co-occurring mental health and substance use disorders among geriatric populations, as well as disseminate information about such evidence-based practices to States and nongrantees throughout the United States.".

SEC. 9013. NATIONAL VIOLENT DEATH REPORTING SYSTEM.

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, is encouraged to improve, particularly through the inclusion of additional States, the National Violent Death Reporting System as authorized by title III of the Public Health Service Act (42 U.S.C. 241 et seq.). Participation in the system by the States shall be voluntary.

SEC. 9014. ASSISTED OUTPATIENT TREATMENT.

Section 224 of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 290aa note) is amended—

(1) in subsection (e), by striking "and 2018," and inserting "2018, 2019, 2020, 2021, and 2022,"; and

(2) in subsection (g)—

(A) in paragraph (1), by striking "2018" and inserting "2022"; and

(B) in paragraph (2), by striking "is authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2018" and inserting "are authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2017, $20,000,000 for fiscal year 2018, $19,000,000 for each of fiscal years 2019 and 2020, and $18,000,000 for each of fiscal years 2021 and 2022".

SEC. 9015. ASSERTIVE COMMUNITY TREATMENT GRANT PROGRAM.

42 USC 290bb–44.

Part B of title V of the Public Health Service Act (42 U.S.C. 290bb et seq.), as amended by section 9009, is further amended by adding at the end the following:

"SEC. 520M. ASSERTIVE COMMUNITY TREATMENT GRANT PROGRAM.

"(a) IN GENERAL.—The Assistant Secretary shall award grants to eligible entities—

"(1) to establish assertive community treatment programs for adults with a serious mental illness; or

"(2) to maintain or expand such programs.

"(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be a State, political subdivision of a State, Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), mental health system, health care facility, or any other entity the Assistant Secretary deems appropriate.

"(c) SPECIAL CONSIDERATION.—In selecting among applicants for a grant under this section, the Assistant Secretary may give special consideration to the potential of the applicant's program to reduce hospitalization, homelessness, and involvement with the criminal justice system while improving the health and social outcomes of the patient.

"(d) ADDITIONAL ACTIVITIES.—The Assistant Secretary shall—

"(1) not later than the end of fiscal year 2021, submit a report to the appropriate congressional committees on the grant program under this section, including an evaluation of—

"(A) any cost savings and public health outcomes such as mortality, suicide, substance use disorders, hospitalization, and use of services;

"(B) rates of involvement with the criminal justice system of patients;

"(C) rates of homelessness among patients; and

"(D) patient and family satisfaction with program participation; and

"(2) provide appropriate information, training, and technical assistance to grant recipients under this section to help such recipients to establish, maintain, or expand their assertive community treatment programs.

"(e) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—To carry out this section, there is authorized to be appropriated $5,000,000 for the period of fiscal years 2018 through 2022.

"(2) USE OF CERTAIN FUNDS.—Of the funds appropriated to carry out this section in any fiscal year, not more than 5 percent shall be available to the Assistant Secretary for carrying out subsection (d).".

SEC. 9016. SOBER TRUTH ON PREVENTING UNDERAGE DRINKING REAUTHORIZATION.

Section 519B of the Public Health Service Act (42 U.S.C. 290bb–25b) is amended—

(1) in subsection (c)(3), by striking "fiscal year 2007" and all that follows through the period at the end and inserting "each of the fiscal years 2018 through 2022.";

(2) in subsection (d)(4), by striking "fiscal year 2007" and all that follows through the period at the end and inserting "each of the fiscal years 2018 through 2022.";

(3) in subsection (e)(1)(I), by striking "fiscal year 2007" and all that follows through the period at the end and inserting "each of the fiscal years 2018 through 2022.";

(4) in subsection (f)(2), by striking "$6,000,000 for fiscal year 2007" and all that follows through the period at the end and inserting "$3,000,000 for each of the fiscal years 2018 through 2022"; and

(5) by adding at the end the following new subsection:

"(g) REDUCING UNDERAGE DRINKING THROUGH SCREENING AND BRIEF INTERVENTION.—

"(1) GRANTS TO PEDIATRIC HEALTH CARE PROVIDERS TO REDUCE UNDERAGE DRINKING.—The Assistant Secretary may make grants to eligible entities to increase implementation of practices for reducing the prevalence of alcohol use among individuals under the age of 21, including college students.

"(2) PURPOSES.—Grants under this subsection shall be made to improve—

"(A) screening children and adolescents for alcohol use;

"(B) offering brief interventions to children and adolescents to discourage such use;

"(C) educating parents about the dangers of, and methods of discouraging, such use;

"(D) diagnosing and treating alcohol use disorders; and

"(E) referring patients, when necessary, to other appropriate care.

"(3) USE OF FUNDS.—An entity receiving a grant under this subsection may use such funding for the purposes identified in paragraph (2) by—

"(A) providing training to health care providers;

"(B) disseminating best practices, including culturally and linguistically appropriate best practices, as appropriate, and developing and distributing materials; and

"(C) supporting other activities, as determined appropriate by the Assistant Secretary.

"(4) APPLICATION.—To be eligible to receive a grant under this subsection, an entity shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information as the Assistant Secretary may require. Each application shall include—

"(A) a description of the entity;

"(B) a description of activities to be completed;

"(C) a description of how the services specified in paragraphs (2) and (3) will be carried out and the qualifications for providing such services; and

"(D) a timeline for the completion of such activities.

"(5) DEFINITIONS.—For the purpose of this subsection:

"(A) BRIEF INTERVENTION.—The term 'brief intervention' means, after screening a patient, providing the patient with brief advice and other brief motivational enhancement techniques designed to increase the insight of the patient regarding the patient's alcohol use, and any realized or potential consequences of such use, to effect the desired related behavioral change.

"(B) CHILDREN AND ADOLESCENTS.—The term 'children and adolescents' means any person under 21 years of age.

"(C) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity consisting of pediatric health care providers and that is qualified to support or provide the activities identified in paragraph (2).

"(D) PEDIATRIC HEALTH CARE PROVIDER.—The term 'pediatric health care provider' means a provider of primary health care to individuals under the age of 21 years.

"(E) SCREENING.—The term 'screening' means using validated patient interview techniques to identify and assess the existence and extent of alcohol use in a patient.".

SEC. 9017. CENTER AND PROGRAM REPEALS.

Part B of title V of the Public Health Service Act (42 U.S.C. 290bb et seq.) is amended by striking section 506B (42 U.S.C. 290aa–5b), the second section 514 (42 U.S.C. 290bb–9) relating to methamphetamine and amphetamine treatment initiatives, and each of sections 514A, 517, 519A, 519C, 519E, 520B, 520D, and 520H (42 U.S.C. 290bb–8, 290bb–23, 290bb–25a, 290bb–25c, 290bb–25e, 290bb–33, 290bb–35, and 290bb–39).

Subtitle B—Strengthening the Health Care Workforce

SEC. 9021. MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.

Section 756 of the Public Health Service Act (42 U.S.C. 294e–1) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "of higher education"; and

(B) by striking paragraphs (1) through (4) and inserting the following:

"(1) accredited institutions of higher education or accredited professional training programs that are establishing or expanding internships or other field placement programs in mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing (which may include master's and doctoral level programs), social work, school social work, substance use disorder prevention and treatment, marriage and family therapy, occupational therapy, school counseling, or professional counseling, including such programs with a focus on child and adolescent mental health and transitional-age youth;

"(2) accredited doctoral, internship, and post-doctoral residency programs of health service psychology (including clinical psychology, counseling, and school psychology) for the development and implementation of interdisciplinary training of psychology graduate students for providing behavioral health services, including substance use disorder prevention and treatment services, as well as the development of faculty in health service psychology;

"(3) accredited master's and doctoral degree programs of social work for the development and implementation of interdisciplinary training of social work graduate students for providing behavioral health services, including substance use disorder prevention and treatment services, and the development of faculty in social work; and

"(4) State-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay for programs for preservice or in-service training in a behavioral health-related paraprofessional field with preference for preservice or in-service training of paraprofessional child and adolescent mental health workers.";

(2) in subsection (b)—

(A) by striking paragraph (5);

(B) by redesignating paragraphs (1) through (4) as paragraphs (2) through (5), respectively;

(C) by inserting before paragraph (2), as so redesignated, the following:

"(1) an ability to recruit and place the students described in subsection (a) in areas with a high need and high demand population;";

(D) in paragraph (3), as so redesignated, by striking "subsection (a)" and inserting "paragraph (2), especially individuals with mental disorder symptoms or diagnoses, particularly children and adolescents, and transitional-age youth";

(E) in paragraph (4), as so redesignated, by striking ";" and inserting "; and"; and

(F) in paragraph (5), as so redesignated, by striking "; and" and inserting a period;

(3) in subsection (c), by striking "authorized under subsection (a)(1)" and inserting "awarded under paragraphs (2) and (3) of subsection (a)";

(4) by amending subsection (d) to read as follows:

"(d) PRIORITY.—In selecting grant recipients under this section, the Secretary shall give priority to—

"(1) programs that have demonstrated the ability to train psychology, psychiatry, and social work professionals to work in integrated care settings for purposes of recipients under paragraphs (1), (2), and (3) of subsection (a); and

"(2) programs for paraprofessionals that emphasize the role of the family and the lived experience of the consumer and family-paraprofessional partnerships for purposes of recipients under subsection (a)(4).''; and

(5) by striking subsection (e) and inserting the following:

"(e) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary shall include in the biennial report submitted to Congress under section 501(m) an assessment on the effectiveness of the grants under this section in—

"(1) providing graduate students support for experiential training (internship or field placement);

"(2) recruiting students interested in behavioral health practice;

"(3) recruiting students in accordance with subsection (b)(1);

"(4) developing and implementing interprofessional training and integration within primary care;

"(5) developing and implementing accredited field placements and internships; and

"(6) collecting data on the number of students trained in behavioral health care and the number of available accredited internships and field placements.

"(f) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2018 through 2022, there are authorized to be appropriated to carry out this section $50,000,000, to be allocated as follows:

"(1) For grants described in subsection (a)(1), $15,000,000.

"(2) For grants described in subsection (a)(2), $15,000,000.

"(3) For grants described in subsection (a)(3), $10,000,000.

"(4) For grants described in subsection (a)(4), $10,000,000.".

42 USC 294k.

SEC. 9022. STRENGTHENING THE MENTAL AND SUBSTANCE USE DISORDERS WORKFORCE.

Part D of title VII of the Public Health Service Act (42 U.S.C. 294 et seq.) is amended by adding at the end the following:

"SEC. 760. TRAINING DEMONSTRATION PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a training demonstration program to award grants to eligible entities to support—

"(1) training for medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services;

"(2) training for nurse practitioners, physician assistants, health service psychologists, and social workers to provide mental and substance use disorders services in underserved community-based settings that integrate primary care and mental and substance use disorders services; and

"(3) establishing, maintaining, or improving academic units or programs that—

"(A) provide training for students or faculty, including through clinical experiences and research, to improve the ability to be able to recognize, diagnose, and treat mental and substance use disorders, with a special focus on addiction; or

"(B) develop evidence-based practices or recommendations for the design of the units or programs described in subparagraph (A), including curriculum content standards.

"(b) ACTIVITIES.—

"(1) TRAINING FOR RESIDENTS AND FELLOWS.—A recipient of a grant under subsection (a)(1)—

"(A) shall use the grant funds—

"(i)(I) to plan, develop, and operate a training program for medical psychiatry residents and fellows in addiction medicine practicing in eligible entities described in subsection (c)(1); or

"(II) to train new psychiatric residents and fellows in addiction medicine to provide and expand access to integrated mental and substance use disorders services; and

"(ii) to provide at least 1 training track that is—

"(I) a virtual training track that includes an in-person rotation at a teaching health center or in a community-based setting, followed by a virtual rotation in which the resident or fellow continues to support the care of patients at the teaching health center or in the community-based setting through the use of health information technology and, as appropriate, telehealth services;

"(II) an in-person training track that includes a rotation, during which the resident or fellow practices at a teaching health center or in a community-based setting; or

"(III) an in-person training track that includes a rotation during which the resident practices in a community-based setting that specializes in the

treatment of infants, children, adolescents, or pregnant or postpartum women; and

"(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such training.

"(2) TRAINING FOR OTHER PROVIDERS.—A recipient of a grant under subsection (a)(2)—

"(A) shall use the grant funds to plan, develop, or operate a training program to provide mental and substance use disorders services in underserved, community-based settings, as appropriate, that integrate primary care and mental and substance use disorders prevention and treatment services; and

"(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such program.

"(3) ACADEMIC UNITS OR PROGRAMS.—A recipient of a grant under subsection (a)(3) shall enter into a partnership with organizations such as an education accrediting organization (such as the Liaison Committee on Medical Education, the Accreditation Council for Graduate Medical Education, the Commission on Osteopathic College Accreditation, the Accreditation Commission for Education in Nursing, the Commission on Collegiate Nursing Education, the Accreditation Council for Pharmacy Education, the Council on Social Work Education, American Psychological Association Commission on Accreditation, or the Accreditation Review Commission on Education for the Physician Assistant) to carry out activities under subsection (a)(3).

"(c) ELIGIBLE ENTITIES.—

"(1) TRAINING FOR RESIDENTS AND FELLOWS.—To be eligible to receive a grant under subsection (a)(1), an entity shall—

"(A) be a consortium consisting of—

"(i) at least one teaching health center; and

"(ii) the sponsoring institution (or parent institution of the sponsoring institution) of—

"(I) a psychiatry residency program that is accredited by the Accreditation Council of Graduate Medical Education (or the parent institution of such a program); or

"(II) a fellowship in addiction medicine, as determined appropriate by the Secretary; or

"(B) be an entity described in subparagraph (A)(ii) that provides opportunities for residents or fellows to train in community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services.

"(2) TRAINING FOR OTHER PROVIDERS.—To be eligible to receive a grant under subsection (a)(2), an entity shall be—

"(A) a teaching health center (as defined in section 749A(f));

"(B) a Federally qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act);

"(C) a community mental health center (as defined in section 1861(ff)(3)(B) of the Social Security Act);

"(D) a rural health clinic (as defined in section 1861(aa) of the Social Security Act);

"(E) a health center operated by the Indian Health Service, an Indian tribe, a tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or

"(F) an entity with a demonstrated record of success in providing training for nurse practitioners, physician assistants, health service psychologists, and social workers.

"(3) ACADEMIC UNITS OR PROGRAMS.—To be eligible to receive a grant under subsection (a)(3), an entity shall be a school of medicine or osteopathic medicine, a nursing school, a physician assistant training program, a school of pharmacy, a school of social work, an accredited public or nonprofit private hospital, an accredited medical residency program, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant.

"(d) PRIORITY.—

"(1) IN GENERAL.—In awarding grants under subsection (a)(1) or (a)(2), the Secretary shall give priority to eligible entities that—

"(A) demonstrate sufficient size, scope, and capacity to undertake the requisite training of an appropriate number of psychiatric residents, fellows, nurse practitioners, physician assistants, or social workers in addiction medicine per year to meet the needs of the area served;

"(B) demonstrate experience in training providers to practice team-based care that integrates mental and substance use disorder prevention and treatment services with primary care in community-based settings;

"(C) demonstrate experience in using health information technology and, as appropriate, telehealth to support—

"(i) the delivery of mental and substance use disorders services at the eligible entities described in subsections (c)(1) and (c)(2); and

"(ii) community health centers in integrating primary care and mental and substance use disorders treatment; or

"(D) have the capacity to expand access to mental and substance use disorders services in areas with demonstrated need, as determined by the Secretary, such as tribal, rural, or other underserved communities.

"(2) ACADEMIC UNITS OR PROGRAMS.—In awarding grants under subsection (a)(3), the Secretary shall give priority to eligible entities that—

"(A) have a record of training the greatest percentage of mental and substance use disorders providers who enter and remain in these fields or who enter and remain in settings with integrated primary care and mental and substance use disorder prevention and treatment services;

"(B) have a record of training individuals who are from underrepresented minority groups, including native populations, or from a rural or disadvantaged background;

"(C) provide training in the care of vulnerable populations such as infants, children, adolescents, pregnant and

postpartum women, older adults, homeless individuals, victims of abuse or trauma, individuals with disabilities, and other groups as defined by the Secretary;

"(D) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals; or

"(E) provide training in cultural competency and health literacy.

"(e) DURATION.—Grants awarded under this section shall be for a minimum of 5 years.

"(f) STUDY AND REPORT.—

"(1) STUDY.—

"(A) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall conduct a study on the results of the demonstration program under this section.

"(B) DATA SUBMISSION.—Not later than 90 days after the completion of the first year of the training program and each subsequent year that the program is in effect, each recipient of a grant under subsection (a) shall submit to the Secretary such data as the Secretary may require for analysis for the report described in paragraph (2).

"(2) REPORT TO CONGRESS.—Not later than 1 year after receipt of the data described in paragraph (1)(B), the Secretary shall submit to Congress a report that includes—

"(A) an analysis of the effect of the demonstration program under this section on the quality, quantity, and distribution of mental and substance use disorders services;

"(B) an analysis of the effect of the demonstration program on the prevalence of untreated mental and substance use disorders in the surrounding communities of health centers participating in the demonstration; and

"(C) recommendations on whether the demonstration program should be expanded.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2018 through 2022.".

SEC. 9023. CLARIFICATION ON CURRENT ELIGIBILITY FOR LOAN REPAYMENT PROGRAMS.

42 USC 294*l*–1 note.

The Administrator of the Health Resources and Services Administration shall clarify the eligibility pursuant to section 338B(b)(1)(B) of the Public Health Service Act (42 U.S.C. 254l–1(b)(1)(B)) of child and adolescent psychiatrists for the National Health Service Corps Loan Repayment Program under subpart III of part D of title III of such Act (42 U.S.C. 254l et seq.).

SEC. 9024. MINORITY FELLOWSHIP PROGRAM.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by adding at the end the following:

"PART K—MINORITY FELLOWSHIP PROGRAM

"SEC. 597. FELLOWSHIPS.

42 USC 290*ll*.

"(a) IN GENERAL.—The Secretary shall maintain a program, to be known as the Minority Fellowship Program, under which the Secretary shall award fellowships, which may include stipends, for the purposes of—

"(1) increasing the knowledge of mental and substance use disorders practitioners on issues related to prevention, treatment, and recovery support for individuals who are from racial and ethnic minority populations and who have a mental or substance use disorder;

"(2) improving the quality of mental and substance use disorder prevention and treatment services delivered to racial and ethnic minority populations; and

"(3) increasing the number of culturally competent mental and substance use disorders professionals who teach, administer services, conduct research, and provide direct mental or substance use disorder services to racial and ethnic minority populations.

"(b) TRAINING COVERED.—The fellowships awarded under subsection (a) shall be for postbaccalaureate training (including for master's and doctoral degrees) for mental and substance use disorder treatment professionals, including in the fields of psychiatry, nursing, social work, psychology, marriage and family therapy, mental health counseling, and substance use disorder and addiction counseling.

"(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $12,669,000 for each of fiscal years 2018 through 2022.".

SEC. 9025. LIABILITY PROTECTIONS FOR HEALTH PROFESSIONAL VOLUNTEERS AT COMMUNITY HEALTH CENTERS.

Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding at the end the following:

"(q)(1) For purposes of this section, a health professional volunteer at a deemed entity described in subsection (g)(4) shall, in providing a health professional service eligible for funding under section 330 to an individual, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (4)(C). The preceding sentence is subject to the provisions of this subsection.

"(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a health professional volunteer at an entity described in subsection (g)(4) if the following conditions are met:

"(A) The service is provided to the individual at the facilities of an entity described in subsection (g)(4), or through offsite programs or events carried out by the entity.

"(B) The entity is sponsoring the health care practitioner pursuant to paragraph (3)(B).

"(C) The health care practitioner does not receive any compensation for the service from the individual, the entity described in subsection (g)(4), or any third-party payer (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program), except that the health care practitioner may receive repayment from the entity described in subsection (g)(4) for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual, which may include travel expenses to or from the site of services.

"(D) Before the service is provided, the health care practitioner or the entity described in subsection (g)(4) posts a clear

and conspicuous notice at the site where the service is provided of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection.

"(E) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable Federal and State laws regarding the provision of the service.

"(F) At the time the service is provided, the entity described in subsection (g)(4) maintains relevant documentation certifying that the health care practitioner meets the requirements of this subsection.

"(3) Subsection (g) (other than paragraphs (3) and (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (4), and subject to the following:

"(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

"(B) With respect to an entity described in subsection (g)(4), a health care practitioner is not a health professional volunteer at such entity unless the entity sponsors the health care practitioner. For purposes of this subsection, the entity shall be considered to be sponsoring the health care practitioner if—

"(i) with respect to the health care practitioner, the entity submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

"(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

"(C) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a health professional volunteer at such entity, this subsection applies to the health care practitioner (with respect to services performed on behalf of the entity sponsoring the health care practitioner pursuant to subparagraph (B)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

"(D) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

"(4)(A) Amounts in the fund established under subsection (k)(2) shall be available for transfer under subparagraph (C) for purposes of carrying out this subsection.

"(B)(i) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of health professional volunteers, will be paid pursuant to this section during the calendar year that begins in the following fiscal year.

"(ii) Subsection (k)(1)(B) applies to the estimate under clause (i) regarding health professional volunteers to the same extent and in the same manner as such subsection applies to the estimate

under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

"(iii) The report shall include a summary of the data relied upon for the estimate in clause (i), including the number of claims filed and paid from the previous calendar year.

"(C) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subsection (k)(2) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (B) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

"(5)(A) This subsection shall take effect on October 1, 2017, except as provided in subparagraph (B) and paragraph (6).

"(B) Effective on the date of the enactment of this subsection—

"(i) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (3)(B); and

"(ii) reports under paragraph (4)(B) may be submitted to Congress.

"(6) Beginning on October 1, 2022, this subsection shall cease to have any force or effect.".

SEC. 9026. REPORTS.

(a) WORKFORCE DEVELOPMENT REPORT.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Administrator of the Health Resources and Services Administration, in consultation with the Assistant Secretary for Mental Health and Substance Use, shall conduct a study and publicly post on the appropriate Internet website of the Department of Health and Human Services a report on the adult and pediatric mental health and substance use disorder workforce in order to inform Federal, State, and local efforts related to workforce enhancement.

(2) CONTENTS.—The report under this subsection shall contain—

(A) national and State-level projections of the supply and demand of the mental health and substance use disorder health workforce, disaggregated by profession;

(B) an assessment of the mental health and substance use disorder workforce capacity, strengths, and weaknesses as of the date of the report, including the extent to which primary care providers are preventing, screening, or referring for mental and substance use disorder services;

(C) information on trends within the mental health and substance use disorder provider workforce, including the number of individuals expected to enter the mental health workforce over the next 5 years; and

(D) any additional information determined by the Administrator of the Health Resources and Services Administration, in consultation with the Assistant Secretary for Mental Health and Substance Use, to be relevant to the mental health and substance use disorder provider workforce.

(b) PEER-SUPPORT SPECIALIST PROGRAMS.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on peer-support specialist programs in up to 10 States that receive funding from the Substance Abuse and Mental Health Services Administration.

(2) CONTENTS OF STUDY.—In conducting the study under paragraph (1), the Comptroller General of the United States shall examine and identify best practices, in the States selected pursuant to such paragraph, related to training and credential requirements for peer-support specialist programs, such as—

(A) hours of formal work or volunteer experience related to mental and substance use disorders conducted through such programs;

(B) types of peer-support specialist exams required for such programs in the selected States;

(C) codes of ethics used by such programs in the selected States;

(D) required or recommended skill sets for such programs in the selected States; and

(E) requirements for continuing education.

(3) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study conducted under paragraph (1).

Subtitle C—Mental Health on Campus Improvement

SEC. 9031. MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES ON CAMPUS.

Section 520E–2 of the Public Health Service Act (42 U.S.C. 290bb–36b) is amended—

(1) in the section heading, by striking "**AND BEHAVIORAL HEALTH**" and inserting "**HEALTH AND SUBSTANCE USE DISORDER**";

(2) in subsection (a)—

(A) by striking "Services," and inserting "Services and";

(B) by striking "and behavioral health problems" and inserting "health or substance use disorders";

(C) by striking "substance abuse" and inserting "substance use disorders"; and

(D) by adding after, "suicide attempts," the following: "prevent mental and substance use disorders, reduce stigma, and improve the identification and treatment for students at risk,";

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "for—" and inserting "for one or more of the following:"; and

(B) by striking paragraphs (1) through (6) and inserting the following:

"(1) Educating students, families, faculty, and staff to increase awareness of mental and substance use disorders.

"(2) The operation of hotlines.

"(3) Preparing informational material.

"(4) Providing outreach services to notify students about available mental and substance use disorder services.

"(5) Administering voluntary mental and substance use disorder screenings and assessments.

"(6) Supporting the training of students, faculty, and staff to respond effectively to students with mental and substance use disorders.

"(7) Creating a network infrastructure to link institutions of higher education with health care providers who treat mental and substance use disorders.

"(8) Providing mental and substance use disorders prevention and treatment services to students, which may include recovery support services and programming and early intervention, treatment, and management, including through the use of telehealth services.

"(9) Conducting research through a counseling or health center at the institution of higher education involved regarding improving the behavioral health of students through clinical services, outreach, prevention, or academic success, in a manner that is in compliance with all applicable personal privacy laws.

"(10) Supporting student groups on campus, including athletic teams, that engage in activities to educate students, including activities to reduce stigma surrounding mental and behavioral disorders, and promote mental health.

"(11) Employing appropriately trained staff.

"(12) Developing and supporting evidence-based and emerging best practices, including a focus on culturally and linguistically appropriate best practices.";

(4) in subsection (c)(5), by striking "substance abuse" and inserting "substance use disorder";

(5) in subsection (d)—

(A) in the matter preceding paragraph (1), by striking "An institution of higher education desiring a grant under this section" and inserting "To be eligible to receive a grant under this section, an institution of higher education";

(B) by striking paragraph (1) and inserting—

"(1) A description of the population to be targeted by the program carried out under the grant, including veterans whenever possible and appropriate, and of identified mental and substance use disorder needs of students at the institution of higher education.";

(C) in paragraph (2), by inserting ", which may include, as appropriate and in accordance with subsection (b)(7), a plan to seek input from relevant stakeholders in the community, including appropriate public and private entities, in order to carry out the program under the grant" before the period at the end; and

(D) by adding after paragraph (5) the following new paragraphs:

"(6) An outline of the objectives of the program carried out under the grant.

"(7) For an institution of higher education proposing to use the grant for an activity described in paragraph (8) or (9) of subsection (b), a description of the policies and procedures of the institution of higher education that are related to applicable laws regarding access to, and sharing of, treatment records of students at any campus-based mental health center or partner organization, including the policies and State laws governing when such records can be accessed and shared for non-treatment purposes and a description of the process used

by the institution of higher education to notify students of these policies and procedures, including the extent to which written consent is required.

"(8) An assurance that grant funds will be used to supplement and not supplant any other Federal, State, or local funds available to carry out activities of the type carried out under the grant.";

(6) in subsection (e)(1), by striking "and behavioral health problems" and inserting "health and substance use disorders";

(7) in subsection (f)(2)—

(A) by striking "and behavioral health" and inserting "health and substance use disorder"; and

(B) by striking "suicide and substance abuse" and inserting "suicide and substance use disorders";

(8) by redesignating subsection (h) as subsection (i);

(9) by inserting after subsection (g) the following new subsection:

"(h) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to grantees in carrying out this section."; and

(10) in subsection (i), as redesignated by paragraph (8), by striking "$5,000,000 for fiscal year 2005" and all that follows through the period at the end and inserting "$7,000,000 for each of fiscal years 2018 through 2022.".

SEC. 9032. INTERAGENCY WORKING GROUP ON COLLEGE MENTAL HEALTH.

42 USC 290bb–36b note.

(a) PURPOSE.—It is the purpose of this section to provide for the establishment of a College Campus Task Force to discuss mental and behavioral health concerns on campuses of institutions of higher education.

(b) ESTABLISHMENT.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a College Campus Task Force (referred to in this section as the "Task Force") to discuss mental and behavioral health concerns on campuses of institutions of higher education.

(c) MEMBERSHIP.—The Task Force shall be composed of a representative from each Federal agency (as appointed by the head of the agency) that has jurisdiction over, or is affected by, mental health and education policies and projects, including—

(1) the Department of Education;

(2) the Department of Health and Human Services;

(3) the Department of Veterans Affairs; and

(4) such other Federal agencies as the Assistant Secretary for Mental Health and Substance Use, in consultation with the Secretary, determines to be appropriate.

(d) DUTIES.—The Task Force shall—

(1) serve as a centralized mechanism to coordinate a national effort to—

(A) discuss and evaluate evidence and knowledge on mental and behavioral health services available to, and the prevalence of mental illness among, the age population of students attending institutions of higher education in the United States;

(B) determine the range of effective, feasible, and comprehensive actions to improve mental and behavioral health on campuses of institutions of higher education;

(C) examine and better address the needs of the age population of students attending institutions of higher education dealing with mental illness;

(D) survey Federal agencies to determine which policies are effective in encouraging, and how best to facilitate outreach without duplicating, efforts relating to mental and behavioral health promotion;

(E) establish specific goals within and across Federal agencies for mental health promotion, including determinations of accountability for reaching those goals;

(F) develop a strategy for allocating responsibilities and ensuring participation in mental and behavioral health promotion, particularly in the case of competing agency priorities;

(G) coordinate plans to communicate research results relating to mental and behavioral health amongst the age population of students attending institutions of higher education to enable reporting and outreach activities to produce more useful and timely information;

(H) provide a description of evidence-based practices, model programs, effective guidelines, and other strategies for promoting mental and behavioral health on campuses of institutions of higher education;

(I) make recommendations to improve Federal efforts relating to mental and behavioral health promotion on campuses of institutions of higher education and to ensure Federal efforts are consistent with available standards, evidence, and other programs in existence as of the date of enactment of this Act;

(J) monitor Federal progress in meeting specific mental and behavioral health promotion goals as they relate to settings of institutions of higher education; and

(K) examine and disseminate best practices related to intracampus sharing of treatment records;

(2) consult with national organizations with expertise in mental and behavioral health, especially those organizations working with the age population of students attending institutions of higher education; and

(3) consult with and seek input from mental health professionals working on campuses of institutions of higher education as appropriate.

(e) MEETINGS.—

(1) IN GENERAL.—The Task Force shall meet not fewer than three times each year.

(2) ANNUAL CONFERENCE.—The Secretary shall sponsor an annual conference on mental and behavioral health in settings of institutions of higher education to enhance coordination, build partnerships, and share best practices in mental and behavioral health promotion, data collection, analysis, and services.

(f) DEFINITION.—In this section, the term "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $1,000,000 for the period of fiscal years 2018 through 2022.

SEC. 9033. IMPROVING MENTAL HEALTH ON COLLEGE CAMPUSES. 42 USC 290ee–4.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following:

"SEC. 549. MENTAL AND BEHAVIORAL HEALTH OUTREACH AND EDUCATION ON COLLEGE CAMPUSES.

"(a) PURPOSE.—It is the purpose of this section to increase access to, and reduce the stigma associated with, mental health services to ensure that students at institutions of higher education have the support necessary to successfully complete their studies.

"(b) NATIONAL PUBLIC EDUCATION CAMPAIGN.—The Secretary, acting through the Assistant Secretary and in collaboration with the Director of the Centers for Disease Control and Prevention, shall convene an interagency, public-private sector working group to plan, establish, and begin coordinating and evaluating a targeted public education campaign that is designed to focus on mental and behavioral health on the campuses of institutions of higher education. Such campaign shall be designed to—

"(1) improve the general understanding of mental health and mental disorders;

"(2) encourage help-seeking behaviors relating to the promotion of mental health, prevention of mental disorders, and treatment of such disorders;

"(3) make the connection between mental and behavioral health and academic success; and

"(4) assist the general public in identifying the early warning signs and reducing the stigma of mental illness.

"(c) COMPOSITION.—The working group convened under subsection (b) shall include—

"(1) mental health consumers, including students and family members;

"(2) representatives of institutions of higher education;

"(3) representatives of national mental and behavioral health associations and associations of institutions of higher education;

"(4) representatives of health promotion and prevention organizations at institutions of higher education;

"(5) representatives of mental health providers, including community mental health centers; and

"(6) representatives of private-sector and public-sector groups with experience in the development of effective public health education campaigns.

"(d) PLAN.—The working group under subsection (b) shall develop a plan that—

"(1) targets promotional and educational efforts to the age population of students at institutions of higher education and individuals who are employed in settings of institutions of higher education, including through the use of roundtables;

"(2) develops and proposes the implementation of research-based public health messages and activities;

"(3) provides support for local efforts to reduce stigma by using the National Health Information Center as a primary point of contact for information, publications, and service program referrals; and

"(4) develops and proposes the implementation of a social marketing campaign that is targeted at the population of students attending institutions of higher education and individuals who are employed in settings of institutions of higher education.

"(e) DEFINITION.—In this section, the term 'institution of higher education' has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

"(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $1,000,000 for the period of fiscal years 2018 through 2022.".

TITLE X—STRENGTHENING MENTAL AND SUBSTANCE USE DISORDER CARE FOR CHILDREN AND ADOLESCENTS

SEC. 10001. PROGRAMS FOR CHILDREN WITH A SERIOUS EMOTIONAL DISTURBANCE.

(a) COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CHILDREN WITH A SERIOUS EMOTIONAL DISTURBANCE.—Section 561(a)(1) of the Public Health Service Act (42 U.S.C. 290ff(a)(1)) is amended by inserting ", which may include efforts to identify and serve children at risk" before the period.

(b) REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.—Section 562(b) of the Public Health Service Act (42 U.S.C. 290ff–1(b)) is amended by striking "will not provide an individual with access to the system if the individual is more than 21 years of age" and inserting "will provide an individual with access to the system through the age of 21 years".

(c) ADDITIONAL PROVISIONS.—Section 564(f) of the Public Health Service Act (42 U.S.C. 290ff–3(f)) is amended by inserting "(and provide a copy to the State involved)" after "to the Secretary".

(d) GENERAL PROVISIONS.—Section 565 of the Public Health Service Act (42 U.S.C. 290ff–4) is amended—

(1) in subsection (b)(1)—

(A) in the matter preceding subparagraph (A), by striking "receiving a grant under section 561(a)" and inserting ", regardless of whether such public entity is receiving a grant under section 561(a)"; and

(B) in subparagraph (B), by striking "pursuant to" and inserting "described in";

(2) in subsection (d)(1), by striking "not more than 21 years of age" and inserting "through the age of 21 years"; and

(3) in subsection (f)(1), by striking "$100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" and inserting "$119,026,000 for each of fiscal years 2018 through 2022".

SEC. 10002. INCREASING ACCESS TO PEDIATRIC MENTAL HEALTH CARE.

Title III of the Public Health Service Act is amended by inserting after section 330L of such Act (42 U.S.C. 254c–18) the following new section:

"SEC. 330M PEDIATRIC MENTAL HEALTH CARE ACCESS GRANTS. 42 USC 254c–19.

"(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in coordination with other relevant Federal agencies, shall award grants to States, political subdivisions of States, and Indian tribes and tribal organizations (for purposes of this section, as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b)) to promote behavioral health integration in pediatric primary care by—

"(1) supporting the development of statewide or regional pediatric mental health care telehealth access programs; and

"(2) supporting the improvement of existing statewide or regional pediatric mental health care telehealth access programs.

"(b) PROGRAM REQUIREMENTS.—

"(1) IN GENERAL.—A pediatric mental health care telehealth access program referred to in subsection (a), with respect to which a grant under such subsection may be used, shall—

"(A) be a statewide or regional network of pediatric mental health teams that provide support to pediatric primary care sites as an integrated team;

"(B) support and further develop organized State or regional networks of pediatric mental health teams to provide consultative support to pediatric primary care sites;

"(C) conduct an assessment of critical behavioral consultation needs among pediatric providers and such providers' preferred mechanisms for receiving consultation, training, and technical assistance;

"(D) develop an online database and communication mechanisms, including telehealth, to facilitate consultation support to pediatric practices;

"(E) provide rapid statewide or regional clinical telephone or telehealth consultations when requested between the pediatric mental health teams and pediatric primary care providers;

"(F) conduct training and provide technical assistance to pediatric primary care providers to support the early identification, diagnosis, treatment, and referral of children with behavioral health conditions;

"(G) provide information to pediatric providers about, and assist pediatric providers in accessing, pediatric mental health care providers, including child and adolescent psychiatrists, and licensed mental health professionals, such as psychologists, social workers, or mental health counselors and in scheduling and conducting technical assistance;

"(H) assist with referrals to specialty care and community or behavioral health resources; and

"(I) establish mechanisms for measuring and monitoring increased access to pediatric mental health care services by pediatric primary care providers and expanded capacity of pediatric primary care providers to identify, treat, and refer children with mental health problems.

"(2) PEDIATRIC MENTAL HEALTH TEAMS.—In this subsection, the term 'pediatric mental health team' means a team consisting of at least one case coordinator, at least one child and adolescent psychiatrist, and at least one licensed clinical

mental health professional, such as a psychologist, social worker, or mental health counselor. Such a team may be regionally based.

"(c) APPLICATION.—A State, political subdivision of a State, Indian tribe, or tribal organization seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the comprehensive evaluation of activities that are carried out with funds received under such grant.

"(d) EVALUATION.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under this section shall prepare and submit an evaluation of activities that are carried out with funds received under such grant to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a process and outcome evaluation.

"(e) ACCESS TO BROADBAND.—In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed Internet for providers.

"(f) MATCHING REQUIREMENT.—The Secretary may not award a grant under this section unless the State, political subdivision of a State, Indian tribe, or tribal organization involved agrees, with respect to the costs to be incurred by the State, political subdivision of a State, Indian tribe, or tribal organization in carrying out the purpose described in this section, to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 20 percent of Federal funds provided in the grant.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated, $9,000,000 for the period of fiscal years 2018 through 2022.".

SEC. 10003. SUBSTANCE USE DISORDER TREATMENT AND EARLY INTERVENTION SERVICES FOR CHILDREN AND ADOLESCENTS.

The first section 514 of the Public Health Service Act (42 U.S.C. 290bb–7), relating to substance abuse treatment services for children and adolescents, is amended—

(1) in the section heading, by striking "**ABUSE TREATMENT**" and inserting "**USE DISORDER TREATMENT AND EARLY INTERVENTION**";

(2) by striking subsection (a) and inserting the following:

"(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), or health facilities or programs operated by or in accordance with a contract or grant with the Indian Health Service, for the purpose of—

"(1) providing early identification and services to meet the needs of children and adolescents who are at risk of substance use disorders;

"(2) providing substance use disorder treatment services for children, including children and adolescents with co-occurring mental illness and substance use disorders; and

"(3) providing assistance to pregnant women, and parenting women, with substance use disorders, in obtaining treatment services, linking mothers to community resources to support independent family lives, and staying in recovery so that children are in safe, stable home environments and receive appropriate health care services.";

(3) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

"(1) apply evidence-based and cost-effective methods;";

(B) in paragraph (2)—

(i) by striking "treatment"; and

(ii) by inserting "substance abuse," after "child welfare,";

(C) in paragraph (3), by striking "substance abuse disorders" and inserting "substance use disorders, including children and adolescents with co-occurring mental illness and substance use disorders,";

(D) in paragraph (5), by striking "treatment;" and inserting "services; and";

(E) in paragraph (6), by striking "substance abuse treatment; and" and inserting "treatment."; and

(F) by striking paragraph (7); and

(4) in subsection (f), by striking "$40,000,000" and all that follows through the period and inserting "$29,605,000 for each of fiscal years 2018 through 2022.".

SEC. 10004. CHILDREN'S RECOVERY FROM TRAUMA.

The first section 582 of the Public Health Service Act (42 U.S.C. 290hh–1; relating to grants to address the problems of persons who experience violence related stress) is amended—

(1) in subsection (a), by striking "developing programs" and all that follows through the period at the end and inserting the following: "developing and maintaining programs that provide for—

"(1) the continued operation of the National Child Traumatic Stress Initiative (referred to in this section as the 'NCTSI'), which includes a cooperative agreement with a coordinating center, that focuses on the mental, behavioral, and biological aspects of psychological trauma response, prevention of the long-term consequences of child trauma, and early intervention services and treatment to address the long-term consequences of child trauma; and

"(2) the development of knowledge with regard to evidence-based practices for identifying and treating mental, behavioral, and biological disorders of children and youth resulting from witnessing or experiencing a traumatic event.";

(2) in subsection (b)—

(A) by striking "subsection (a) related" and inserting "subsection (a)(2) (related";

(B) by striking "treating disorders associated with psychological trauma" and inserting "treating mental, behavioral, and biological disorders associated with psychological trauma)"; and

(C) by striking "mental health agencies and programs that have established clinical and basic research" and inserting "universities, hospitals, mental health agencies,

and other programs that have established clinical expertise and research";

(3) by redesignating subsections (c) through (g) as subsections (g) through (k), respectively;

(4) by inserting after subsection (b), the following:

"(c) CHILD OUTCOME DATA.—The NCTSI coordinating center described in subsection (a)(1) shall collect, analyze, report, and make publicly available, as appropriate, NCTSI-wide child treatment process and outcome data regarding the early identification and delivery of evidence-based treatment and services for children and families served by the NCTSI grantees.

"(d) TRAINING.—The NCTSI coordinating center shall facilitate the coordination of training initiatives in evidence-based and trauma-informed treatments, interventions, and practices offered to NCTSI grantees, providers, and partners.

"(e) DISSEMINATION AND COLLABORATION.—The NCTSI coordinating center shall, as appropriate, collaborate with—

"(1) the Secretary, in the dissemination of evidence-based and trauma-informed interventions, treatments, products, and other resources to appropriate stakeholders; and

"(2) appropriate agencies that conduct or fund research within the Department of Health and Human Services, for purposes of sharing NCTSI expertise, evaluation data, and other activities, as appropriate.

"(f) REVIEW.—The Secretary shall, consistent with the peer-review process, ensure that NCTSI applications are reviewed by appropriate experts in the field as part of a consensus-review process. The Secretary shall include review criteria related to expertise and experience in child trauma and evidence-based practices.";

(5) in subsection (g) (as so redesignated), by striking "with respect to centers of excellence are distributed equitably among the regions of the country" and inserting "are distributed equitably among the regions of the United States";

(6) in subsection (i) (as so redesignated), by striking "recipient may not exceed 5 years" and inserting "recipient shall not be less than 4 years, but shall not exceed 5 years"; and

(7) in subsection (j) (as so redesignated), by striking "$50,000,000" and all that follows through "2006" and inserting "$46,887,000 for each of fiscal years 2018 through 2022".

SEC. 10005. SCREENING AND TREATMENT FOR MATERNAL DEPRESSION.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317L (42 U.S.C. 247b–13) the following:

42 USC 247b–13a.

"SEC. 317L–1. SCREENING AND TREATMENT FOR MATERNAL DEPRESSION.

"(a) GRANTS.—The Secretary shall make grants to States to establish, improve, or maintain programs for screening, assessment, and treatment services, including culturally and linguistically appropriate services, as appropriate, for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression.

"(b) APPLICATION.—To seek a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may

require. At a minimum, any such application shall include explanations of—

"(1) how a program, or programs, will increase the percentage of women screened and treated, as appropriate, for maternal depression in 1 or more communities; and

"(2) how a program, or programs, if expanded, would increase access to screening and treatment services for maternal depression.

"(c) PRIORITY.—In awarding grants under this section, the Secretary may give priority to States proposing to improve or enhance access to screening services for maternal depression in primary care settings.

"(d) USE OF FUNDS.—The activities eligible for funding through a grant under subsection (a)—

"(1) shall include—

"(A) providing appropriate training to health care providers; and

"(B) providing information to health care providers, including information on maternal depression screening, treatment, and followup support services, and linkages to community-based resources; and

"(2) may include—

"(A) enabling health care providers (including obstetrician-gynecologists, pediatricians, psychiatrists, mental health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely) to aid in the treatment of pregnant and parenting women;

"(B) establishing linkages with and among community-based resources, including mental health resources, primary care resources, and support groups; and

"(C) utilizing telehealth services for rural areas and medically underserved areas (as defined in section 330I(a)).

"(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.".

SEC. 10006. INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT.

Part Q of title III of the Public Health Service Act (42 U.S.C. 280h et seq.) is amended by adding at the end the following:

"SEC. 399Z–2. INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT. 42 USC 280h–6.

"(a) GRANTS.—The Secretary shall—

"(1) award grants to eligible entities to develop, maintain, or enhance infant and early childhood mental health promotion, intervention, and treatment programs, including—

"(A) programs for infants and children at significant risk of developing, showing early signs of, or having been diagnosed with mental illness, including a serious emotional disturbance; and

"(B) multigenerational therapy and other services that support the caregiving relationship; and

"(2) ensure that programs funded through grants under this section are evidence-informed or evidence-based models, practices, and methods that are, as appropriate, culturally and

linguistically appropriate, and can be replicated in other appropriate settings.

"(b) ELIGIBLE CHILDREN AND ENTITIES.—In this section:

"(1) ELIGIBLE CHILD.—The term 'eligible child' means a child from birth to not more than 12 years of age who—

"(A) is at risk for, shows early signs of, or has been diagnosed with a mental illness, including a serious emotional disturbance; and

"(B) may benefit from infant and early childhood intervention or treatment programs or specialized preschool or elementary school programs that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

"(2) ELIGIBLE ENTITY.—The term 'eligible entity' means a human services agency or nonprofit institution that—

"(A) employs licensed mental health professionals who have specialized training and experience in infant and early childhood mental health assessment, diagnosis, and treatment, or is accredited or approved by the appropriate State agency, as applicable, to provide for children from infancy to 12 years of age mental health promotion, intervention, or treatment services; and

"(B) provides services or programs described in subsection (a) that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

"(c) APPLICATION.—An eligible entity seeking a grant under subsection (a) shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(d) USE OF FUNDS FOR EARLY INTERVENTION AND TREATMENT PROGRAMS.—An eligible entity may use amounts awarded under a grant under subsection (a)(1) to carry out the following:

"(1) Provide age-appropriate mental health promotion and early intervention services or mental illness treatment services, which may include specialized programs, for eligible children at significant risk of developing, showing early signs of, or having been diagnosed with a mental illness, including a serious emotional disturbance. Such services may include social and behavioral services as well as multigenerational therapy and other services that support the caregiving relationship.

"(2) Provide training for health care professionals with expertise in infant and early childhood mental health care with respect to appropriate and relevant integration with other disciplines such as primary care clinicians, early intervention specialists, child welfare staff, home visitors, early care and education providers, and others who work with young children and families.

"(3) Provide mental health consultation to personnel of early care and education programs (including licensed or regulated center-based and home-based child care, home visiting, preschool special education, and early intervention programs) who work with children and families.

"(4) Provide training for mental health clinicians in infant and early childhood in promising and evidence-based practices and models for infant and early childhood mental health treatment and early intervention, including with regard to practices

for identifying and treating mental illness and behavioral disorders of infants and children resulting from exposure or repeated exposure to adverse childhood experiences or childhood trauma.

"(5) Provide age-appropriate assessment, diagnostic, and intervention services for eligible children, including early mental health promotion, intervention, and treatment services.

"(e) MATCHING FUNDS.—The Secretary may not award a grant under this section to an eligible entity unless the eligible entity agrees, with respect to the costs to be incurred by the eligible entity in carrying out the activities described in subsection (d), to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 10 percent of the total amount of Federal funds provided in the grant.

"(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $20,000,000 for the period of fiscal years 2018 through 2022.".

TITLE XI—COMPASSIONATE COMMUNICATION ON HIPAA

SEC. 11001. SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) According to the National Survey on Drug Use and Health, in 2015, there were approximately 9,800,000 adults in the United States with serious mental illness.

(2) The Substance Abuse and Mental Health Services Administration defines the term "serious mental illness" as an illness affecting individuals 18 years of age or older as having, at any time in the past year, a diagnosable mental, behavioral, or emotional disorder that results in serious functional impairment and substantially interferes with or limits one or more major life activities.

(3) In reporting on the incidence of serious mental illness, the Substance Abuse and Mental Health Services Administration includes major depression, schizophrenia, bipolar disorder, and other mental disorders that cause serious impairment.

(4) Adults with a serious mental illness are at a higher risk for chronic physical illnesses and premature death.

(5) According to the World Health Organization, adults with a serious mental illness have lifespans that are 10 to 25 years shorter than those without serious mental illness. The vast majority of these deaths are due to chronic physical medical conditions, such as cardiovascular, respiratory, and infectious diseases, as well as diabetes and hypertension.

(6) According to the World Health Organization, the majority of deaths of adults with a serious mental illness that are due to physical medical conditions are preventable.

(7) Supported decision making can facilitate care decisions in areas where serious mental illness may impact the capacity of an individual to determine a course of treatment while still allowing the individual to make decisions independently.

(8) Help should be provided to adults with a serious mental illness to address their acute or chronic physical illnesses, make informed choices about treatment, and understand and follow through with appropriate treatment.

(9) There is confusion in the health care community regarding permissible practices under the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (commonly known as "HIPAA"). This confusion may hinder appropriate communication of health care information or treatment preferences with appropriate caregivers.

(b) SENSE OF CONGRESS.—It is the sense of Congress that clarification is needed regarding the privacy rule promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) regarding existing permitted uses and disclosures of health information by health care professionals to communicate with caregivers of adults with a serious mental illness to facilitate treatment.

SEC. 11002. CONFIDENTIALITY OF RECORDS.

Not later than 1 year after the date on which the Secretary of Health and Human Services (in this title referred to as the "Secretary") first finalizes regulations updating part 2 of title 42, Code of Federal Regulations, relating to confidentiality of alcohol and drug abuse patient records, after the date of enactment of this Act, the Secretary shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.

42 USC 1320d–2 note.

SEC. 11003. CLARIFICATION ON PERMITTED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—The Secretary, acting through the Director of the Office for Civil Rights, shall ensure that health care providers, professionals, patients and their families, and others involved in mental or substance use disorder treatment have adequate, accessible, and easily comprehensible resources relating to appropriate uses and disclosures of protected health information under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(b) GUIDANCE.—

(1) ISSUANCE.—In carrying out subsection (a), not later than 1 year after the date of enactment of this section, the Secretary shall issue guidance clarifying the circumstances under which, consistent with regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, a health care provider or covered entity may use or disclose protected health information.

(2) CIRCUMSTANCES ADDRESSED.—The guidance issued under this section shall address circumstances including those that—

(A) require the consent of the patient;

(B) require providing the patient with an opportunity to object;

(C) are based on the exercise of professional judgment regarding whether the patient would object when the opportunity to object cannot practicably be provided because of the incapacity of the patient or an emergency treatment circumstance; and

(D) are determined, based on the exercise of professional judgment, to be in the best interest of the patient when the patient is not present or otherwise incapacitated.

(3) COMMUNICATION WITH FAMILY MEMBERS AND CAREGIVERS.—In addressing the circumstances described in paragraph (2), the guidance issued under this section shall clarify permitted uses or disclosures of protected health information for purposes of—

(A) communicating with a family member of the patient, caregiver of the patient, or other individual, to the extent that such family member, caregiver, or individual is involved in the care of the patient;

(B) in the case that the patient is an adult, communicating with a family member of the patient, caregiver of the patient, or other individual involved in the care of the patient;

(C) in the case that the patient is a minor, communicating with the parent or caregiver of the patient;

(D) involving the family members or caregivers of the patient, or others involved in the patient's care or care plan, including facilitating treatment and medication adherence;

(E) listening to the patient, or receiving information with respect to the patient from the family or caregiver of the patient;

(F) communicating with family members of the patient, caregivers of the patient, law enforcement, or others when the patient presents a serious and imminent threat of harm to self or others; and

(G) communicating to law enforcement and family members or caregivers of the patient about the admission of the patient to receive care at, or the release of a patient from, a facility for an emergency psychiatric hold or involuntary treatment.

SEC. 11004. DEVELOPMENT AND DISSEMINATION OF MODEL TRAINING PROGRAMS.

42 USC 1320d–2 note.

(a) INITIAL PROGRAMS AND MATERIALS.—Not later than 1 year after the date of the enactment of this Act, the Secretary, in consultation with appropriate experts, shall identify the following model programs and materials, or (in the case that no such programs or materials exist) recognize private or public entities to develop and disseminate each of the following:

(1) Model programs and materials for training health care providers (including physicians, emergency medical personnel, psychiatrists, including child and adolescent psychiatrists, psychologists, counselors, therapists, nurse practitioners, physician assistants, behavioral health facilities and clinics, care managers, and hospitals, including individuals such as general counsels or regulatory compliance staff who are responsible for establishing provider privacy policies) regarding the permitted uses and disclosures, consistent with the standards governing the privacy and security of individually identifiable health information promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and such part C, of the protected health information of patients seeking or undergoing mental or substance use disorder treatment.

(2) A model program and materials for training patients and their families regarding their rights to protect and obtain information under the standards and regulations specified in paragraph (1).

(b) PERIODIC UPDATES.—The Secretary shall—

(1) periodically review and update the model programs and materials identified or developed under subsection (a); and

(2) disseminate the updated model programs and materials to the individuals described in subsection (a).

(c) COORDINATION.—The Secretary shall carry out this section in coordination with the Director of the Office for Civil Rights within the Department of Health and Human Services, the Assistant Secretary for Mental Health and Substance Use, the Administrator of the Health Resources and Services Administration, and the heads of other relevant agencies within the Department of Health and Human Services.

(d) INPUT OF CERTAIN ENTITIES.—In identifying, reviewing, or updating the model programs and materials under subsections (a) and (b), the Secretary shall solicit the input of relevant national, State, and local associations; medical societies; licensing boards; providers of mental and substance use disorder treatment; organizations with expertise on domestic violence, sexual assault, elder abuse, and child abuse; and organizations representing patients and consumers and the families of patients and consumers.

(e) FUNDING.—There are authorized to be appropriated to carry out this section—

(1) $4,000,000 for fiscal year 2018;

(2) $2,000,000 for each of fiscal years 2019 and 2020; and

(3) $1,000,000 for each of fiscal years 2021 and 2022.

TITLE XII—MEDICAID MENTAL HEALTH COVERAGE

42 USC 1396 note.

SEC. 12001. RULE OF CONSTRUCTION RELATED TO MEDICAID COVERAGE OF MENTAL HEALTH SERVICES AND PRIMARY CARE SERVICES FURNISHED ON THE SAME DAY.

Nothing in title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) shall be construed as prohibiting separate payment under the State plan under such title (or under a waiver of the plan) for the provision of a mental health service or primary care service under such plan, with respect to an individual, because such service is—

(1) a primary care service furnished to the individual by a provider at a facility on the same day a mental health service is furnished to such individual by such provider (or another provider) at the facility; or

(2) a mental health service furnished to the individual by a provider at a facility on the same day a primary care service is furnished to such individual by such provider (or another provider) at the facility.

SEC. 12002. STUDY AND REPORT RELATED TO MEDICAID MANAGED CARE REGULATION.

(a) STUDY.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare &

Medicaid Services, shall conduct a study on coverage under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) of services provided through a medicaid managed care organization (as defined in section 1903(m) of such Act (42 U.S.C. 1396b(m)) or a prepaid inpatient health plan (as defined in section 438.2 of title 42, Code of Federal Regulations (or any successor regulation)) with respect to individuals over the age of 21 and under the age of 65 for the treatment of a mental health disorder in institutions for mental diseases (as defined in section 1905(i) of such Act (42 U.S.C. 1396d(i))). Such study shall include information on the following:

(1) The extent to which States, including the District of Columbia and each territory or possession of the United States, are providing capitated payments to such organizations or plans for enrollees who are receiving services in institutions for mental diseases.

(2) The number of individuals receiving medical assistance under a State plan under such title XIX, or a waiver of such plan, who receive services in institutions for mental diseases through such organizations and plans.

(3) The range of and average number of months, and the length of stay during such months, that such individuals are receiving such services in such institutions.

(4) How such organizations or plans determine when to provide for the furnishing of such services through an institution for mental diseases in lieu of other benefits (including the full range of community-based services) under their contract with the State agency administering the State plan under such title XIX, or a waiver of such plan, to address psychiatric or substance use disorder treatment.

(5) The extent to which the provision of services within such institutions has affected the capitated payments for such organizations or plans.

(b) REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a).

SEC. 12003. GUIDANCE ON OPPORTUNITIES FOR INNOVATION.

42 USC 1315 note.

Not later than 1 year after the date of the enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall issue a State Medicaid Director letter regarding opportunities to design innovative service delivery systems, including systems for providing community-based services, for adults with a serious mental illness or children with a serious emotional disturbance who are receiving medical assistance under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.). The letter shall include opportunities for demonstration projects under section 1115 of such Act (42 U.S.C. 1315) to improve care for such adults and children.

SEC. 12004. STUDY AND REPORT ON MEDICAID EMERGENCY PSYCHIATRIC DEMONSTRATION PROJECT.

(a) COLLECTION OF INFORMATION.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall, to the extent practical and data is available, with respect to each State that has participated in the demonstration project established under section 2707

of the Patient Protection and Affordable Care Act (42 U.S.C. 1396a note), collect from each such State information on the following:

(1) The number of institutions for mental diseases (as defined in section 1905(i) of the Social Security Act (42 U.S.C. 1396d(i))) and beds in such institutions that received payment for the provision of services to individuals who receive medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan) through the demonstration project in each such State as compared to the total number of institutions for mental diseases and beds in the State.

(2) The extent to which there is a reduction in expenditures under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) or other spending on the full continuum of physical or mental health care for individuals who receive treatment in an institution for mental diseases under the demonstration project, including outpatient, inpatient, emergency, and ambulatory care, that is attributable to such individuals receiving treatment in institutions for mental diseases under the demonstration project.

(3) The number of forensic psychiatric hospitals, the number of beds in such hospitals, and the number of forensic psychiatric beds in other hospitals in such State, based on the most recent data available, to the extent practical, as determined by such Administrator.

(4) The amount of any disproportionate share hospital payments under section 1923 of the Social Security Act (42 U.S.C. 1396r–4) that institutions for mental diseases in the State received during the period beginning on July 1, 2012, and ending on June 30, 2015, and the extent to which the demonstration project reduced the amount of such payments.

(5) The most recent data regarding all facilities or sites in the State in which any adults with a serious mental illness who are receiving medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan) are treated during the period referred to in paragraph (4), to the extent practical, as determined by the Administrator, including—

(A) the types of such facilities or sites (such as an institution for mental diseases, a hospital emergency department, or other inpatient hospital);

(B) the average length of stay in such a facility or site by such an individual, disaggregated by facility type; and

(C) the payment rate under the State plan (or a waivers of such plan) for services furnished to such an individual for that treatment, disaggregated by facility type, during the period in which the demonstration project is in operation.

(6) The extent to which the utilization of hospital emergency departments during the period in which the demonstration project was is in operation differed, with respect to individuals who are receiving medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan), between—

(A) those individuals who received treatment in an institution for mental diseases under the demonstration project;

(B) those individuals who met the eligibility requirements for the demonstration project but who did not receive treatment in an institution for mental diseases under the demonstration project; and

(C) those adults with a serious mental illness who did not meet such eligibility requirements and did not receive treatment for such illness in an institution for mental diseases.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that summarizes and analyzes the information collected under subsection (a). Such report may be submitted as part of the report required under section 2707(f) of the Patient Protection and Affordable Care Act (42 U.S.C. 1396a note) or separately.

SEC. 12005. PROVIDING EPSDT SERVICES TO CHILDREN IN IMDS.

42 USC 1396d note.

(a) IN GENERAL.—Section 1905(a)(16) of the Social Security Act (42 U.S.C. 1396d(a)(16)) is amended—

(1) by striking "effective January 1, 1973" and inserting "(A) effective January 1, 1973"; and

(2) by inserting before the semicolon at the end the following: ", and, (B) for individuals receiving services described in subparagraph (A), early and periodic screening, diagnostic, and treatment services (as defined in subsection (r)), whether or not such screening, diagnostic, and treatment services are furnished by the provider of the services described in such subparagraph".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to items and services furnished in calendar quarters beginning on or after January 1, 2019.

SEC. 12006. ELECTRONIC VISIT VERIFICATION SYSTEM REQUIRED FOR PERSONAL CARE SERVICES AND HOME HEALTH CARE SERVICES UNDER MEDICAID.

(a) IN GENERAL.—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended by inserting after subsection (k) the following new subsection:

"(l)(1) Subject to paragraphs (3) and (4), with respect to any amount expended for personal care services or home health care services requiring an in-home visit by a provider that are provided under a State plan under this title (or under a waiver of the plan) and furnished in a calendar quarter beginning on or after January 1, 2019 (or, in the case of home health care services, on or after January 1, 2023), unless a State requires the use of an electronic visit verification system for such services furnished in such quarter under the plan or such waiver, the Federal medical assistance percentage shall be reduced—

"(A) in the case of personal care services—

"(i) for calendar quarters in 2019 and 2020, by .25 percentage points;

"(ii) for calendar quarters in 2021, by .5 percentage points;

"(iii) for calendar quarters in 2022, by .75 percentage points; and

"(iv) for calendar quarters in 2023 and each year thereafter, by 1 percentage point; and

"(B) in the case of home health care services—

"(i) for calendar quarters in 2023 and 2024, by .25 percentage points;

"(ii) for calendar quarters in 2025, by .5 percentage points;

"(iii) for calendar quarters in 2026, by .75 percentage points; and

"(iv) for calendar quarters in 2027 and each year thereafter, by 1 percentage point.

"(2) Subject to paragraphs (3) and (4), in implementing the requirement for the use of an electronic visit verification system under paragraph (1), a State shall—

"(A) consult with agencies and entities that provide personal care services, home health care services, or both under the State plan (or under a waiver of the plan) to ensure that such system—

"(i) is minimally burdensome;

"(ii) takes into account existing best practices and electronic visit verification systems in use in the State; and

"(iii) is conducted in accordance with the requirements of HIPAA privacy and security law (as defined in section 3009 of the Public Health Service Act);

"(B) take into account a stakeholder process that includes input from beneficiaries, family caregivers, individuals who furnish personal care services or home health care services, and other stakeholders, as determined by the State in accordance with guidance from the Secretary; and

"(C) ensure that individuals who furnish personal care services, home health care services, or both under the State plan (or under a waiver of the plan) are provided the opportunity for training on the use of such system.

"(3) Paragraphs (1) and (2) shall not apply in the case of a State that, as of the date of the enactment of this subsection, requires the use of any system for the electronic verification of visits conducted as part of both personal care services and home health care services, so long as the State continues to require the use of such system with respect to the electronic verification of such visits.

"(4)(A) In the case of a State described in subparagraph (B), the reduction under paragraph (1) shall not apply—

"(i) in the case of personal care services, for calendar quarters in 2019; and

"(ii) in the case of home health care services, for calendar quarters in 2023.

"(B) For purposes of subparagraph (A), a State described in this subparagraph is a State that demonstrates to the Secretary that the State—

"(i) has made a good faith effort to comply with the requirements of paragraphs (1) and (2) (including by taking steps to adopt the technology used for an electronic visit verification system); and

"(ii) in implementing such a system, has encountered unavoidable system delays.

"(5) In this subsection:

"(A) The term 'electronic visit verification system' means, with respect to personal care services or home health care services, a system under which visits conducted as part of such services are electronically verified with respect to—

"(i) the type of service performed;

"(ii) the individual receiving the service;

"(iii) the date of the service;

"(iv) the location of service delivery;

"(v) the individual providing the service; and

"(vi) the time the service begins and ends.

"(B) The term 'home health care services' means services described in section 1905(a)(7) provided under a State plan under this title (or under a waiver of the plan).

"(C) The term 'personal care services' means personal care services provided under a State plan under this title (or under a waiver of the plan), including services provided under section 1905(a)(24), 1915(c), 1915(i), 1915(j), or 1915(k) or under a wavier under section 1115.

"(6)(A) In the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system operated by the State or a contractor on behalf of the State, the Secretary shall pay to the State, for each quarter, an amount equal to 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such system, and 75 per centum of so much of the sums for the operation and maintenance of such system.

"(B) Subparagraph (A) shall not apply in the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system that is not operated by the State or a contractor on behalf of the State.".

(b) COLLECTION AND DISSEMINATION OF BEST PRACTICES.—Not later than January 1, 2018, the Secretary of Health and Human Services shall, with respect to electronic visit verification systems (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)), collect and disseminate best practices to State Medicaid Directors with respect to— 42 USC 1396b note.

(1) training individuals who furnish personal care services, home health care services, or both under the State plan under title XIX of such Act (or under a waiver of the plan) on such systems and the operation of such systems and the prevention of fraud with respect to the provision of personal care services or home health care services (as defined in such subsection (l)(5)); and

(2) the provision of notice and educational materials to family caregivers and beneficiaries with respect to the use of such electronic visit verification systems and other means to prevent such fraud.

(c) RULES OF CONSTRUCTION.— 42 USC 1396b note.

(1) NO EMPLOYER-EMPLOYEE RELATIONSHIP ESTABLISHED.—Nothing in the amendment made by this section may be construed as establishing an employer-employee relationship between the agency or entity that provides for personal care services or home health care services and the individuals who, under a contract with such an agency or entity, furnish such

services for purposes of part 552 of title 29, Code of Federal Regulations (or any successor regulations).

(2) NO PARTICULAR OR UNIFORM ELECTRONIC VISIT VERIFICATION SYSTEM REQUIRED.—Nothing in the amendment made by this section shall be construed to require the use of a particular or uniform electronic visit verification system (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)) by all agencies or entities that provide personal care services or home health care under a State plan under title XIX of the Social Security Act (or under a waiver of the plan) (42 U.S.C. 1396 et seq.).

(3) NO LIMITS ON PROVISION OF CARE.—Nothing in the amendment made by this section may be construed to limit, with respect to personal care services or home health care services provided under a State plan under title XIX of the Social Security Act (or under a waiver of the plan) (42 U.S.C. 1396 et seq.), provider selection, constrain beneficiaries' selection of a caregiver, or impede the manner in which care is delivered.

(4) NO PROHIBITION ON STATE QUALITY MEASURES REQUIREMENTS.—Nothing in the amendment made by this section shall be construed as prohibiting a State, in implementing an electronic visit verification system (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)), from establishing requirements related to quality measures for such system.

TITLE XIII—MENTAL HEALTH PARITY

SEC. 13001. ENHANCED COMPLIANCE WITH MENTAL HEALTH AND SUBSTANCE USE DISORDER COVERAGE REQUIREMENTS.

(a) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—Section 2726(a) of the Public Health Service Act (42 U.S.C. 300gg–26(a)) is amended by adding at the end the following:

"(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 9812 of the Internal Revenue Code of 1986, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled 'Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance'.

"(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.—

"(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, based on investigations of violations of such sections, including—

"(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

"(II) descriptions of the violations uncovered during the course of such investigations.

"(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

"(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

"(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable; and

"(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this

section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

"(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.".

(b) ADDITIONAL GUIDANCE.—Section 2726(a) of the Public Health Service Act (42 U.S.C. 300gg–26(a)), as amended by subsection (a), is further amended by adding at the end the following:

"(7) ADDITIONAL GUIDANCE.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(B) DISCLOSURE.—

"(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

"(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section,

section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

"(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

"(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

"(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

"(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such respective section), including—

"(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

"(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

"(II) limitations with respect to prescription drug formulary design; and

"(III) use of fail-first or step therapy protocols;

"(ii) examples of methods of determining—

"(I) network admission standards (such as credentialing); and

"(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

"(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

"(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used

by such plans or issuers in performing a nonquantitative treatment limitation analysis;

"(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

"(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

"(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

"(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

"(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.".

(c) AVAILABILITY OF PLAN INFORMATION.—

(1) SOLICITATION OF PUBLIC FEEDBACK.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall solicit feedback from the public on how the disclosure request process for documents containing information that health plans or health insurance issuers are required under Federal or State law to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with existing mental health parity and addiction equity requirements can be improved while continuing to ensure consumers' rights to access all information required by Federal or State law to be disclosed.

(2) PUBLIC AVAILABILITY.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall make such feedback publicly available.

(3) NAIC.—The Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall share feedback obtained pursuant to paragraph (1) directly with the National Association of Insurance Commissioners to the extent such feedback includes recommendations for the development of simplified information disclosure tools to provide consistent information for consumers. Such feedback

may be taken into consideration by the National Association of Insurance Commissioners and other appropriate entities for the voluntary development and voluntary use of common templates and other sample standardized forms to improve consumer access to plan information.

(d) IMPROVING COMPLIANCE.—

42 USC 300gg–26 note.

(1) IN GENERAL.—In the case that the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury determines that a group health plan or health insurance issuer offering group or individual health insurance coverage has violated, at least 5 times, section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), or section 9812 of the Internal Revenue Code of 1986, respectively, the appropriate Secretary shall audit plan documents for such health plan or issuer in the plan year following the Secretary's determination in order to help improve compliance with such section.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority, as in effect on the day before the date of enactment of this Act, of the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury to audit documents of health plans or health insurance issuers.

SEC. 13002. ACTION PLAN FOR ENHANCED ENFORCEMENT OF MENTAL HEALTH AND SUBSTANCE USE DISORDER COVERAGE.

(a) PUBLIC MEETING.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting of stakeholders described in paragraph (2) to produce an action plan for improved Federal and State coordination related to the enforcement of section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986, and any comparable provisions of State law (in this section such sections and provisions are collectively referred to as "mental health parity and addiction equity requirements").

(2) STAKEHOLDERS.—The stakeholders described in this paragraph shall include each of the following:

(A) The Federal Government, including representatives from—

(i) the Department of Health and Human Services;

(ii) the Department of the Treasury;

(iii) the Department of Labor; and

(iv) the Department of Justice.

(B) State governments, including—

(i) State health insurance commissioners;

(ii) appropriate State agencies, including agencies on public health or mental health; and

(iii) State attorneys general or other representatives of State entities involved in the enforcement of mental health parity and addiction equity requirements.

(C) Representatives from key stakeholder groups, including—

(i) the National Association of Insurance Commissioners;

(ii) health insurance issuers;

(iii) providers of mental health and substance use disorder treatment;

(iv) employers; and

(v) patients or their advocates.

(b) ACTION PLAN.—Not later than 6 months after the conclusion of the public meeting under subsection (a), the Secretary of Health and Human Services shall finalize the action plan described in such subsection and make it plainly available on the Internet website of the Department of Health and Human Services.

(c) CONTENT.—The action plan under this section shall—

(1) take into consideration the recommendations of the Mental Health and Substance Use Disorder Parity Task Force in its final report issued in October of 2016, and any subsequent Federal and State actions in relation to such recommendations;

(2) reflect the input of the stakeholders participating in the public meeting under subsection (a);

(3) identify specific strategic objectives regarding how the various Federal and State agencies charged with enforcement of mental health parity and addiction equity requirements will collaborate to improve enforcement of such requirements;

(4) provide a timeline for implementing the action plan; and

(5) provide specific examples of how such objectives may be met, which may include—

(A) providing common educational information and documents, such as the Consumer Guide to Disclosure Rights, to patients about their rights under mental health parity and addiction equity requirements;

(B) facilitating the centralized collection of, monitoring of, and response to patient complaints or inquiries relating to mental health parity and addiction equity requirements, which may be through the development and administration of—

(i) a single, toll-free telephone number; and

(ii) a new parity website—

(I) to help consumers find the appropriate Federal or State agency to assist with their parity complaints, appeals, and other actions; and

(II) that takes into consideration, but is not duplicative of, the parity beta site being tested, and released for public comment, by the Department of Health and Human Services as of the date of the enactment of this Act;

(C) Federal and State law enforcement agencies entering into memoranda of understanding to better coordinate enforcement responsibilities and information sharing—

(i) including whether such agencies should make the results of enforcement actions related to mental health parity and addiction equity requirements publicly available; and

(ii) which may include State Policy Academies on Parity Implementation for State Officials and other forums to bring together national experts to provide technical assistance to teams of State officials on strategies to advance compliance with mental health parity and addiction equity requirements in both the commercial market, and in the Medicaid program under title XIX of the Social Security Act and the State Children's Health Insurance Program under title XXI of such Act; and

(D) recommendations to the Congress regarding the need for additional legal authority to improve enforcement of mental health parity and addiction equity requirements, including the need for additional legal authority to ensure that nonquantitative treatment limitations are applied, and the extent and frequency of the applications of such limitations, both to medical and surgical benefits and to mental health and substance use disorder benefits in a comparable manner.

SEC. 13003. REPORT ON INVESTIGATIONS REGARDING PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and annually thereafter for the subsequent 5 years, the Assistant Secretary of Labor of the Employee Benefits Security Administration, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services and the Secretary of the Treasury, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report summarizing the results of all closed Federal investigations completed during the preceding 12-month period with findings of any serious violation regarding compliance with mental health and substance use disorder coverage requirements under section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986.

(b) CONTENTS.—Subject to subsection (c), a report under subsection (a) shall, with respect to investigations described in such subsection, include each of the following:

(1) The number of closed Federal investigations conducted during the covered reporting period.

(2) Each benefit classification examined by any such investigation conducted during the covered reporting period.

(3) Each subject matter, including compliance with requirements for quantitative and nonquantitative treatment limitations, of any such investigation conducted during the covered reporting period.

(4) A summary of the basis of the final decision rendered for each closed investigation conducted during the covered reporting period that resulted in a finding of a serious violation.

(c) LIMITATION.—Any individually identifiable information shall be excluded from reports under subsection (a) consistent with protections under the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

SEC. 13004. GAO STUDY ON PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report detailing the extent to which group health plans or health insurance issuers offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, medicaid managed care organizations with a contract under section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)), and health plans provided under the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) comply with section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986, including—

(1) how nonquantitative treatment limitations, including medical necessity criteria, of such plans or issuers comply with such sections;

(2) how the responsible Federal departments and agencies ensure that such plans or issuers comply with such sections, including an assessment of how the Secretary of Health and Human Services has used its authority to conduct audits of such plans to ensure compliance;

(3) a review of how the various Federal and State agencies responsible for enforcing mental health parity requirements have improved enforcement of such requirements in accordance with the objectives and timeline described in the action plan under section 13002; and

(4) recommendations for how additional enforcement, education, and coordination activities by responsible Federal and State departments and agencies could better ensure compliance with such sections, including recommendations regarding the need for additional legal authority.

42 USC 237a note.

SEC. 13005. INFORMATION AND AWARENESS ON EATING DISORDERS.

(a) INFORMATION.—The Secretary of Health and Human Services, acting through the Director of the Office on Women's Health, may—

(1) update information, related fact sheets, and resource lists related to eating disorders that are available on the public Internet website of the National Women's Health Information Center sponsored by the Office on Women's Health, to include—

(A) updated findings and current research related to eating disorders, as appropriate; and

(B) information about eating disorders, including information related to males and females;

(2) incorporate, as appropriate, and in coordination with the Secretary of Education, information from publicly available resources into appropriate obesity prevention programs developed by the Office on Women's Health; and

(3) make publicly available (through a public Internet website or other method) information, related fact sheets, and

resource lists, as updated under paragraph (1), and the information incorporated into appropriate obesity prevention programs under paragraph (2).

(b) AWARENESS.—The Secretary of Health and Human Services may advance public awareness on—

(1) the types of eating disorders;

(2) the seriousness of eating disorders, including prevalence, comorbidities, and physical and mental health consequences;

(3) methods to identify, intervene, refer for treatment, and prevent behaviors that may lead to the development of eating disorders;

(4) discrimination and bullying based on body size;

(5) the effects of media on self-esteem and body image; and

(6) the signs and symptoms of eating disorders.

SEC. 13006. EDUCATION AND TRAINING ON EATING DISORDERS.

42 USC 237a note.

The Secretary of Health and Human Services may facilitate the identification of model programs and materials for educating and training health professionals in effective strategies to—

(1) identify individuals with eating disorders;

(2) provide early intervention services for individuals with eating disorders;

(3) refer patients with eating disorders for appropriate treatment;

(4) prevent the development of eating disorders; and

(5) provide appropriate treatment services for individuals with eating disorders.

SEC. 13007. CLARIFICATION OF EXISTING PARITY RULES.

42 USC 300gg–26 note.

If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including residential treatment, such group health plan or health insurance issuer shall provide such benefits consistent with the requirements of section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986.

TITLE XIV—MENTAL HEALTH AND SAFE COMMUNITIES

Subtitle A—Mental Health and Safe Communities

SEC. 14001. LAW ENFORCEMENT GRANTS FOR CRISIS INTERVENTION TEAMS, MENTAL HEALTH PURPOSES.

(a) EDWARD BYRNE MEMORIAL JUSTICE ASSISTANCE GRANT PROGRAM.—Section 501(a)(1) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3751(a)(1)) is amended by adding at the end the following:

"(H) Mental health programs and related law enforcement and corrections programs, including behavioral programs and crisis intervention teams.".

(b) COMMUNITY ORIENTED POLICING SERVICES PROGRAM.—Section 1701(b) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796dd(b)) is amended—

(1) in paragraph (17), by striking "and" at the end;

(2) by redesignating paragraph (18) as paragraph (22);

(3) by inserting after paragraph (17) the following:

"(18) to provide specialized training to law enforcement officers to—

"(A) recognize individuals who have a mental illness; and

"(B) properly interact with individuals who have a mental illness, including strategies for verbal de-escalation of crises;

"(19) to establish collaborative programs that enhance the ability of law enforcement agencies to address the mental health, behavioral, and substance abuse problems of individuals encountered by law enforcement officers in the line of duty;

"(20) to provide specialized training to corrections officers to recognize individuals who have a mental illness;

"(21) to enhance the ability of corrections officers to address the mental health of individuals under the care and custody of jails and prisons, including specialized training and strategies for verbal de-escalation of crises; and"; and

(4) in paragraph (22), as redesignated, by striking "through (17)" and inserting "through (21)".

(c) MODIFICATIONS TO THE STAFFING FOR ADEQUATE FIRE AND EMERGENCY RESPONSE GRANTS.—Section 34(a)(1)(B) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229a(a)(1)(B)) is amended by inserting before the period at the end the following: "and to provide specialized training to paramedics, emergency medical services workers, and other first responders to recognize individuals who have mental illness and how to properly intervene with individuals with mental illness, including strategies for verbal de-escalation of crises".

SEC. 14002. ASSISTED OUTPATIENT TREATMENT PROGRAMS.

(a) IN GENERAL.—Section 2201 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii) is amended in paragraph (2)(B), by inserting before the semicolon the following: ", or court-ordered assisted outpatient treatment when the court has determined such treatment to be necessary".

(b) DEFINITIONS.—Section 2202 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii—1) is amended—

(1) in paragraph (1), by striking "and" at the end;

(2) in paragraph (2), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

"(3) the term 'court-ordered assisted outpatient treatment' means a program through which a court may order a treatment plan for an eligible patient that—

"(A) requires such patient to obtain outpatient mental health treatment while the patient is not currently residing in a correctional facility or inpatient treatment facility; and

"(B) is designed to improve access and adherence by such patient to intensive behavioral health services in order to—

"(i) avert relapse, repeated hospitalizations, arrest, incarceration, suicide, property destruction, and violent behavior; and

"(ii) provide such patient with the opportunity to live in a less restrictive alternative to incarceration or involuntary hospitalization; and

"(4) the term 'eligible patient' means an adult, mentally ill person who, as determined by a court—

"(A) has a history of violence, incarceration, or medically unnecessary hospitalizations;

"(B) without supervision and treatment, may be a danger to self or others in the community;

"(C) is substantially unlikely to voluntarily participate in treatment;

"(D) may be unable, for reasons other than indigence, to provide for any of his or her basic needs, such as food, clothing, shelter, health, or safety;

"(E) has a history of mental illness or a condition that is likely to substantially deteriorate if the person is not provided with timely treatment; or

"(F) due to mental illness, lacks capacity to fully understand or lacks judgment to make informed decisions regarding his or her need for treatment, care, or supervision.".

SEC. 14003. FEDERAL DRUG AND MENTAL HEALTH COURTS.

42 USC 3796ii note.

(a) DEFINITIONS.—In this section—

(1) the term "eligible offender" means a person who—

(A)(i) previously or currently has been diagnosed by a qualified mental health professional as having a mental illness, mental retardation, or co-occurring mental illness and substance abuse disorders; or

(ii) manifests obvious signs of mental illness, mental retardation, or co-occurring mental illness and substance abuse disorders during arrest or confinement or before any court;

(B) comes into contact with the criminal justice system or is arrested or charged with an offense that is not—

(i) a crime of violence, as defined under applicable State law or in section 3156 of title 18, United States Code; or

(ii) a serious drug offense, as defined in section 924(e)(2)(A) of title 18, United States Code; and

(C) is determined by a judge to be eligible; and

(2) the term "mental illness" means a diagnosable mental, behavioral, or emotional disorder—

(A) of sufficient duration to meet diagnostic criteria within the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association; and

(B) that has resulted in functional impairment that substantially interferes with or limits 1 or more major life activities.

(b) ESTABLISHMENT OF PROGRAM.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall establish a pilot program to determine the effectiveness of diverting eligible offenders from Federal prosecution, Federal probation, or a Bureau of Prisons facility, and placing such eligible offenders in drug or mental health courts.

(c) PROGRAM SPECIFICATIONS.—The pilot program established under subsection (b) shall involve—

(1) continuing judicial supervision, including periodic review, of program participants who have a substance abuse problem or mental illness; and

(2) the integrated administration of services and sanctions, which shall include—

(A) mandatory periodic testing, as appropriate, for the use of controlled substances or other addictive substances during any period of supervised release or probation for each program participant;

(B) substance abuse treatment for each program participant who requires such services;

(C) diversion, probation, or other supervised release with the possibility of prosecution, confinement, or incarceration based on noncompliance with program requirements or failure to show satisfactory progress toward completing program requirements;

(D) programmatic offender management, including case management, and aftercare services, such as relapse prevention, health care, education, vocational training, job placement, housing placement, and child care or other family support services for each program participant who requires such services;

(E) outpatient or inpatient mental health treatment, as ordered by the court, that carries with it the possibility of dismissal of charges or reduced sentencing upon successful completion of such treatment;

(F) centralized case management, including—

(i) the consolidation of all cases, including violations of probations, of the program participant; and

(ii) coordination of all mental health treatment plans and social services, including life skills and vocational training, housing and job placement, education, health care, and relapse prevention for each program participant who requires such services; and

(G) continuing supervision of treatment plan compliance by the program participant for a term not to exceed the maximum allowable sentence or probation period for the charged or relevant offense and, to the extent practicable, continuity of psychiatric care at the end of the supervised period.

(d) IMPLEMENTATION; DURATION.—The pilot program established under subsection (b) shall be conducted—

(1) in not less than 1 United States judicial district, designated by the Attorney General in consultation with the Director of the Administrative Office of the United States Courts, as appropriate for the pilot program; and

(2) during fiscal year 2017 through fiscal year 2021.

(e) CRITERIA FOR DESIGNATION.—Before making a designation under subsection (d)(1), the Attorney General shall—

(1) obtain the approval, in writing, of the United States Attorney for the United States judicial district being designated;

(2) obtain the approval, in writing, of the chief judge for the United States judicial district being designated; and

(3) determine that the United States judicial district being designated has adequate behavioral health systems for treatment, including substance abuse and mental health treatment.

(f) ASSISTANCE FROM OTHER FEDERAL ENTITIES.—The Administrative Office of the United States Courts and the United States Probation Offices shall provide such assistance and carry out such functions as the Attorney General may request in monitoring, supervising, providing services to, and evaluating eligible offenders placed in a drug or mental health court under this section.

(g) REPORTS.—The Attorney General, in consultation with the Director of the Administrative Office of the United States Courts, shall monitor the drug and mental health courts under this section, and shall submit a report to Congress on the outcomes of the program at the end of the period described in subsection (d)(2).

SEC. 14004. MENTAL HEALTH IN THE JUDICIAL SYSTEM. 42 USC 3796ii–8.

Part V of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii et seq.) is amended by inserting at the end the following:

"SEC. 2209. MENTAL HEALTH RESPONSES IN THE JUDICIAL SYSTEM.

"(a) PRETRIAL SCREENING AND SUPERVISION.—

"(1) IN GENERAL.—The Attorney General may award grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop, implement, or expand pretrial services programs to improve the identification and outcomes of individuals with mental illness.

"(2) ALLOWABLE USES.—Grants awarded under this subsection may be may be used for—

"(A) behavioral health needs and risk screening of defendants, including verification of interview information, mental health evaluation, and criminal history screening;

"(B) assessment of risk of pretrial misconduct through objective, statistically validated means, and presentation to the court of recommendations based on such assessment, including services that will reduce the risk of pre-trial misconduct;

"(C) followup review of defendants unable to meet the conditions of pretrial release;

"(D) evaluation of process and results of pre-trial service programs;

"(E) supervision of defendants who are on pretrial release, including reminders to defendants of scheduled court dates;

"(F) reporting on process and results of pretrial services programs to relevant public and private mental health stakeholders; and

"(G) data collection and analysis necessary to make available information required for assessment of risk.

"(b) BEHAVIORAL HEALTH ASSESSMENTS AND INTERVENTION.—

"(1) IN GENERAL.—The Attorney General may award grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop,

implement, or expand a behavioral health screening and assessment program framework for State or local criminal justice systems.

"(2) ALLOWABLE USES.—Grants awarded under this subsection may be used for—

"(A) promotion of the use of validated assessment tools to gauge the criminogenic risk, substance abuse needs, and mental health needs of individuals;

"(B) initiatives to match the risk factors and needs of individuals to programs and practices associated with research-based, positive outcomes;

"(C) implementing methods for identifying and treating individuals who are most likely to benefit from coordinated supervision and treatment strategies, and identifying individuals who can do well with fewer interventions; and

"(D) collaborative decision-making among the heads of criminal justice agencies, mental health systems, judicial systems, substance abuse systems, and other relevant systems or agencies for determining how treatment and intensive supervision services should be allocated in order to maximize benefits, and developing and utilizing capacity accordingly.

"(c) USE OF GRANT FUNDS.—A State, unit of local government, territory, Indian Tribe, or nonprofit agency that receives a grant under this section shall, in accordance with subsection (b)(2), use grant funds for the expenses of a treatment program, including—

"(1) salaries, personnel costs, equipment costs, and other costs directly related to the operation of the program, including costs relating to enforcement;

"(2) payments for treatment providers that are approved by the State or Indian Tribe and licensed, if necessary, to provide needed treatment to program participants, including aftercare supervision, vocational training, education, and job placement; and

"(3) payments to public and nonprofit private entities that are approved by the State or Indian Tribe and licensed, if necessary, to provide alcohol and drug addiction treatment to offenders participating in the program.

"(d) SUPPLEMENT OF NON-FEDERAL FUNDS.—

"(1) IN GENERAL.—Grants awarded under this section shall be used to supplement, and not supplant, non-Federal funds that would otherwise be available for programs described in this section.

"(2) FEDERAL SHARE.—The Federal share of a grant made under this section may not exceed 50 percent of the total costs of the program described in an application under subsection (e).

"(e) APPLICATIONS.—To request a grant under this section, a State, unit of local government, territory, Indian Tribe, or nonprofit agency shall submit an application to the Attorney General in such form and containing such information as the Attorney General may reasonably require.

"(f) GEOGRAPHIC DISTRIBUTION.—The Attorney General shall ensure that, to the extent practicable, the distribution of grants under this section is equitable and includes—

"(1) each State; and

"(2) a unit of local government, territory, Indian Tribe, or nonprofit agency—

"(A) in each State; and

"(B) in rural, suburban, Tribal, and urban jurisdictions.

"(g) REPORTS AND EVALUATIONS.—For each fiscal year, each grantee under this section during that fiscal year shall submit to the Attorney General a report on the effectiveness of activities carried out using such grant. Each report shall include an evaluation in such form and containing such information as the Attorney General may reasonably require. The Attorney General shall specify the dates on which such reports shall be submitted.

"(h) ACCOUNTABILITY.—Grants awarded under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice under subparagraph (C) that the audited grantee has used grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 1 year after the date on which final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this section, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of grantees under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) FINAL AUDIT REPORT.—The Inspector General of the Department of Justice shall submit to the Attorney General a final report on each audit conducted under subparagraph (B).

"(D) MANDATORY EXCLUSION.—Grantees under this section about which there is an unresolved audit finding shall not be eligible to receive a grant under this section during the 2 fiscal years beginning after the end of the 1-year period described in subparagraph (A).

"(E) PRIORITY.—In making grants under this section, the Attorney General shall give priority to applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(F) REIMBURSEMENT.—If an entity receives a grant under this section during the 2-fiscal-year period during which the entity is prohibited from receiving grants under subparagraph (D), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant that was improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment under clause (i) from the grantee that was erroneously awarded grant funds.

"(2) NONPROFIT AGENCY REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant program under this section, the term 'nonprofit agency' means an organization that is described in section

501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

"(B) PROHIBITION.—The Attorney General may not award a grant under this section to a nonprofit agency that holds money in an offshore account for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986 (26 U.S.C. 511(a)).

"(C) DISCLOSURE.—Each nonprofit agency that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—Not more than $20,000 of the amounts made available to the Department of Justice to carry out this section may be used by the Attorney General, or by any individual or entity awarded a grant under this section to host, or make any expenditures relating to, a conference unless the Deputy Attorney General provides prior written authorization that the funds may be expended to host the conference or make such expenditure.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives an annual certification—

"(A) indicating whether—

"(i) all final audit reports issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(D) have been issued; and

"(iii) any reimbursements required under paragraph (1)(F) have been made; and

"(B) that includes a list of any grantees excluded under paragraph (1)(D) from the previous year.

"(i) PREVENTING DUPLICATIVE GRANTS.—

"(1) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare the possible grant with any other grants awarded to the applicant under this Act to determine whether the grants are for the same purpose.

"(2) REPORT.—If the Attorney General awards multiple grants to the same applicant for the same purpose, the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(A) a list of all duplicate grants awarded, including the total dollar amount of any such grants awarded; and

"(B) the reason the Attorney General awarded the duplicate grants.".

SEC. 14005. FORENSIC ASSERTIVE COMMUNITY TREATMENT INITIATIVES.

Section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by—

(1) redesignating subsection (j) as subsection (o); and

(2) inserting after subsection (i) the following:

"(j) FORENSIC ASSERTIVE COMMUNITY TREATMENT (FACT) INITIATIVE PROGRAM.—

"(1) IN GENERAL.—The Attorney General may make grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop, implement, or expand Assertive Community Treatment initiatives to develop forensic assertive community treatment (referred to in this subsection as 'FACT') programs that provide high intensity services in the community for individuals with mental illness with involvement in the criminal justice system to prevent future incarcerations.

"(2) ALLOWABLE USES.—Grant funds awarded under this subsection may be used for—

"(A) multidisciplinary team initiatives for individuals with mental illnesses with criminal justice involvement that address criminal justice involvement as part of treatment protocols;

"(B) FACT programs that involve mental health professionals, criminal justice agencies, chemical dependency specialists, nurses, psychiatrists, vocational specialists, forensic peer specialists, forensic specialists, and dedicated administrative support staff who work together to provide recovery oriented, 24/7 wraparound services;

"(C) services such as integrated evidence-based practices for the treatment of co-occurring mental health and substance-related disorders, assertive outreach and engagement, community-based service provision at participants' residence or in the community, psychiatric rehabilitation, recovery oriented services, services to address criminogenic risk factors, and community tenure;

"(D) payments for treatment providers that are approved by the State or Indian Tribe and licensed, if necessary, to provide needed treatment to eligible offenders

participating in the program, including behavioral health services and aftercare supervision; and

"(E) training for all FACT teams to promote high-fidelity practice principles and technical assistance to support effective and continuing integration with criminal justice agency partners.

"(3) SUPPLEMENT AND NOT SUPPLANT.—Grants made under this subsection shall be used to supplement, and not supplant, non-Federal funds that would otherwise be available for programs described in this subsection.

"(4) APPLICATIONS.—To request a grant under this subsection, a State, unit of local government, territory, Indian Tribe, or nonprofit agency shall submit an application to the Attorney General in such form and containing such information as the Attorney General may reasonably require.".

SEC. 14006. ASSISTANCE FOR INDIVIDUALS TRANSITIONING OUT OF SYSTEMS.

Section 2976(f) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797w(f)) is amended—

(1) in paragraph (5), by striking "and" at the end;

(2) in paragraph (6), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

"(7) provide mental health treatment and transitional services for those with mental illnesses or with co-occurring disorders, including housing placement or assistance; and".

SEC. 14007. CO-OCCURRING SUBSTANCE ABUSE AND MENTAL HEALTH CHALLENGES IN DRUG COURTS.

Part EE of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797u et seq.) is amended—

(1) in section 2951(a)(1) (42 U.S.C. 3797u(a)(1)), by inserting ", including co-occurring substance abuse and mental health problems," after "problems"; and

(2) in section 2959(a) (42 U.S.C. 3797u–8(a)), by inserting ", including training for drug court personnel and officials on identifying and addressing co-occurring substance abuse and mental health problems" after "part".

42 USC 3797aa–1 note.

SEC. 14008. MENTAL HEALTH TRAINING FOR FEDERAL UNIFORMED SERVICES.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Defense, the Secretary of Homeland Security, the Secretary of Health and Human Services, and the Secretary of Commerce shall provide the following to each of the uniformed services (as that term is defined in section 101 of title 10, United States Code) under their direction:

(1) TRAINING PROGRAMS.—Programs that offer specialized and comprehensive training in procedures to identify and respond appropriately to incidents in which the unique needs of individuals with mental illnesses are involved.

(2) IMPROVED TECHNOLOGY.—Computerized information systems or technological improvements to provide timely information to Federal law enforcement personnel, other branches of the uniformed services, and criminal justice system personnel to improve the Federal response to mentally ill individuals.

(3) COOPERATIVE PROGRAMS.—The establishment and expansion of cooperative efforts to promote public safety through the use of effective intervention with respect to mentally ill individuals encountered by members of the uniformed services.

SEC. 14009. ADVANCING MENTAL HEALTH AS PART OF OFFENDER REENTRY.

(a) REENTRY DEMONSTRATION PROJECTS.—Section 2976(f) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797w(f)), as amended by section 14006, is amended—

(1) in paragraph (3)(C), by inserting "mental health services," before "drug treatment"; and

(2) by adding at the end the following:

"(8) target offenders with histories of homelessness, substance abuse, or mental illness, including a prerelease assessment of the housing status of the offender and behavioral health needs of the offender with clear coordination with mental health, substance abuse, and homelessness services systems to achieve stable and permanent housing outcomes with appropriate support service.".

(b) MENTORING GRANTS.—Section 211(b)(2) of the Second Chance Act of 2007 (42 U.S.C. 17531(b)(2)) is amended by inserting ", including mental health care" after "community".

SEC. 14010. SCHOOL MENTAL HEALTH CRISIS INTERVENTION TEAMS.

Section 2701(b) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797a(b)) is amended—

(1) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(2) by inserting after paragraph (3) the following:

"(4) The development and operation of crisis intervention teams that may include coordination with law enforcement agencies and specialized training for school officials in responding to mental health crises.".

SEC. 14011. ACTIVE-SHOOTER TRAINING FOR LAW ENFORCEMENT.

42 USC 3752 note.

The Attorney General, as part of the Preventing Violence Against Law Enforcement and Ensuring Officer Resilience and Survivability Initiative (VALOR) of the Department of Justice, may provide safety training and technical assistance to local law enforcement agencies, including active-shooter response training.

SEC. 14012. CO-OCCURRING SUBSTANCE ABUSE AND MENTAL HEALTH CHALLENGES IN RESIDENTIAL SUBSTANCE ABUSE TREATMENT PROGRAMS.

Section 1901(a) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ff(a)) is amended—

(1) in paragraph (1), by striking "and" at the end;

(2) in paragraph (2), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(3) developing and implementing specialized residential substance abuse treatment programs that identify and provide appropriate treatment to inmates with co-occurring mental health and substance abuse disorders or challenges.".

SEC. 14013. MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS.

Title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3711 et seq.) is amended by striking part CC and inserting the following:

"PART CC—MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS

42 USC 3797q.

"SEC. 2901. MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS.

"(a) DEFINITIONS.—In this section—

"(1) the term 'eligible entity' means a State, unit of local government, Indian tribe, or nonprofit organization; and

"(2) the term 'eligible participant' means an individual who—

"(A) comes into contact with the criminal justice system or is arrested or charged with an offense that is not—

"(i) a crime of violence, as defined under applicable State law or in section 3156 of title 18, United States Code; or

"(ii) a serious drug offense, as defined in section 924(e)(2)(A) of title 18, United States Code;

"(B) has a history of, or a current—

"(i) substance use disorder;

"(ii) mental illness; or

"(iii) co-occurring mental illness and substance use disorder; and

"(C) has been approved for participation in a program funded under this section by the relevant law enforcement agency, prosecuting attorney, defense attorney, probation official, corrections official, judge, representative of a mental health agency, or representative of a substance abuse agency, as required by law.

"(b) PROGRAM AUTHORIZED.—The Attorney General may make grants to eligible entities to develop, implement, or expand a treatment alternative to incarceration program for eligible participants, including—

"(1) pre-booking treatment alternative to incarceration programs, including—

"(A) law enforcement training on substance use disorders, mental illness, and co-occurring mental illness and substance use disorders;

"(B) receiving centers as alternatives to incarceration of eligible participants;

"(C) specialized response units for calls related to substance use disorders, mental illness, or co-occurring mental illness and substance use disorders; and

"(D) other arrest and pre-booking treatment alternatives to incarceration models; or

"(2) post-booking treatment alternative to incarceration programs, including—

"(A) specialized clinical case management;

"(B) pre-trial services related to substances use disorders, mental illness, and co-occurring mental illness and substance use disorders;

"(C) prosecutor and defender based programs;

"(D) specialized probation;

"(E) treatment and rehabilitation programs; and

"(F) problem-solving courts, including mental health courts, drug courts, co-occurring mental health and substance abuse courts, DWI courts, and veterans treatment courts.

"(c) APPLICATION.—

"(1) IN GENERAL.—An eligible entity desiring a grant under this section shall submit an application to the Attorney General—

"(A) that meets the criteria under paragraph (2); and

"(B) at such time, in such manner, and accompanied by such information as the Attorney General may require.

"(2) CRITERIA.—An eligible entity, in submitting an application under paragraph (1), shall—

"(A) provide extensive evidence of collaboration with State and local government agencies overseeing health, community corrections, courts, prosecution, substance abuse, mental health, victims services, and employment services, and with local law enforcement agencies;

"(B) demonstrate consultation with the Single State Authority for Substance Abuse of the State (as that term is defined in section 201(e) of the Second Chance Act of 2007);

"(C) demonstrate that evidence-based treatment practices will be utilized; and

"(D) demonstrate that evidence-based screening and assessment tools will be used to place participants in the treatment alternative to incarceration program.

"(d) REQUIREMENTS.—Each eligible entity awarded a grant for a treatment alternative to incarceration program under this section shall—

"(1) determine the terms and conditions of participation in the program by eligible participants, taking into consideration the collateral consequences of an arrest, prosecution or criminal conviction;

"(2) ensure that each substance abuse and mental health treatment component is licensed and qualified by the relevant jurisdiction;

"(3) for programs described in subsection (b)(2), organize an enforcement unit comprised of appropriately trained law enforcement professionals under the supervision of the State, Tribal, or local criminal justice agency involved, the duties of which shall include—

"(A) the verification of addresses and other contact information of each eligible participant who participates or desires to participate in the program; and

"(B) if necessary, the location, apprehension, arrest, and return to custody of an eligible participant in the program who has absconded from the facility of a treatment provider or has otherwise significantly violated the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

"(4) notify the relevant criminal justice entity if any eligible participant in the program absconds from the facility of the treatment provider or otherwise violates the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

"(5) submit periodic reports on the progress of treatment or other measured outcomes from participation in the program of each eligible participant in the program to the relevant State, Tribal, or local criminal justice agency, including mental health courts, drug courts, co-occurring mental health and substance abuse courts, DWI courts, and veterans treatment courts;

"(6) describe the evidence-based methodology and outcome measurements that will be used to evaluate the program, and specifically explain how such measurements will provide valid measures of the impact of the program; and

"(7) describe how the program could be broadly replicated if demonstrated to be effective.

"(e) USE OF FUNDS.—An eligible entity shall use a grant received under this section for expenses of a treatment alternative to incarceration program, including—

"(1) salaries, personnel costs, equipment costs, and other costs directly related to the operation of the program, including the enforcement unit;

"(2) payments for treatment providers that are approved by the relevant State or Tribal jurisdiction and licensed, if necessary, to provide needed treatment to eligible offenders participating in the program, including aftercare supervision, vocational training, education, and job placement; and

"(3) payments to public and nonprofit private entities that are approved by the State or Tribal jurisdiction and licensed, if necessary, to provide alcohol and drug addiction treatment to eligible offenders participating in the program.

"(f) SUPPLEMENT NOT SUPPLANT.—An eligible entity shall use Federal funds received under this section only to supplement the funds that would, in the absence of those Federal funds, be made available from other Federal and non-Federal sources for the activities described in this section, and not to supplant those funds. The Federal share of a grant made under this section may not exceed 50 percent of the total costs of the program described in an application under subsection (d).

"(g) GEOGRAPHIC DISTRIBUTION.—The Attorney General shall ensure that, to the extent practicable, the geographical distribution of grants under this section is equitable and includes a grant to an eligible entity in—

"(1) each State;

"(2) rural, suburban, and urban areas; and

"(3) Tribal jurisdictions.

"(h) REPORTS AND EVALUATIONS.—Each fiscal year, each recipient of a grant under this section during that fiscal year shall submit to the Attorney General a report on the outcomes of activities carried out using that grant in such form, containing such information, and on such dates as the Attorney General shall specify.

"(i) ACCOUNTABILITY.—All grants awarded by the Attorney General under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months from the date on which the final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of recipients of grants under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) MANDATORY EXCLUSION.—A recipient of grant funds under this section that is found to have an unresolved audit finding shall not be eligible to receive grant funds under this section during the first 2 fiscal years beginning after the end of the 12-month period described in subparagraph (A).

"(D) PRIORITY.—In awarding grants under this section, the Attorney General shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(E) REIMBURSEMENT.—If an entity is awarded grant funds under this section during the 2-fiscal-year period during which the entity is barred from receiving grants under subparagraph (C), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

"(2) NONPROFIT ORGANIZATION REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant programs under this part, the term 'nonprofit organization' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

"(B) PROHIBITION.—The Attorney General may not award a grant under this part to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

"(C) DISCLOSURE.—Each nonprofit organization that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used,

and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit, to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives, an annual certification—

"(A) indicating whether—

"(i) all audits issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(C) have been issued; and

"(iii) all reimbursements required under paragraph (1)(E) have been made; and

"(B) that includes a list of any grant recipients excluded under paragraph (1) from the previous year.

"(5) PREVENTING DUPLICATIVE GRANTS.—

"(A) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

"(B) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(i) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(ii) the reason the Attorney General awarded the duplicate grants.".

SEC. 14014. NATIONAL CRIMINAL JUSTICE AND MENTAL HEALTH TRAINING AND TECHNICAL ASSISTANCE.

42 USC 3797aa–1.

Part HH of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa et seq.) is amended by adding at the end the following:

"SEC. 2992. NATIONAL CRIMINAL JUSTICE AND MENTAL HEALTH TRAINING AND TECHNICAL ASSISTANCE.

"(a) AUTHORITY.—The Attorney General may make grants to eligible organizations to provide for the establishment of a National Criminal Justice and Mental Health Training and Technical Assistance Center.

"(b) ELIGIBLE ORGANIZATION.—For purposes of subsection (a), the term 'eligible organization' means a national nonprofit organization that provides technical assistance and training to, and has special expertise and broad, national-level experience in, mental health, crisis intervention, criminal justice systems, law enforcement, translating evidence into practice, training, and research, and education and support of people with mental illness and the families of such individuals.

"(c) USE OF FUNDS.—Any organization that receives a grant under subsection (a) shall collaborate with other grant recipients to establish and operate a National Criminal Justice and Mental Health Training and Technical Assistance Center to—

"(1) provide law enforcement officer training regarding mental health and working with individuals with mental illnesses, with an emphasis on de-escalation of encounters between law enforcement officers and those with mental disorders or in crisis, which shall include support the development of in-person and technical information exchanges between systems and the individuals working in those systems in support of the concepts identified in the training;

"(2) provide education, training, and technical assistance for States, Indian tribes, territories, units of local government, service providers, nonprofit organizations, probation or parole officers, prosecutors, defense attorneys, emergency response providers, and corrections institutions to advance practice and knowledge relating to mental health crisis and approaches to mental health and criminal justice across systems;

"(3) provide training and best practices to mental health providers and criminal justice agencies relating to diversion initiatives, jail and prison strategies, reentry of individuals with mental illnesses into the community, and dispatch protocols and triage capabilities, including the establishment of learning sites;

"(4) develop suicide prevention and crisis intervention training and technical assistance for criminal justice agencies;

"(5) develop a receiving center system and pilot strategy that provides, for a jurisdiction, a single point of entry into the mental health and substance abuse system for assessments and appropriate placement of individuals experiencing a crisis;

"(6) collect data and best practices in mental health and criminal health and criminal justice initiatives and policies from grantees under this part, other recipients of grants under this section, Federal, State, and local agencies involved in the provision of mental health services, and nongovernmental organizations involved in the provision of mental health services;

"(7) develop and disseminate to mental health providers and criminal justice agencies evaluation tools, mechanisms, and measures to better assess and document performance measures and outcomes relating to the provision of mental health services;

"(8) disseminate information to States, units of local government, criminal justice agencies, law enforcement agencies, and other relevant entities about best practices, policy standards, and research findings relating to the provision of mental health services; and

"(9) provide education and support to individuals with mental illness involved with, or at risk of involvement with, the criminal justice system, including the families of such individuals.

"(d) ACCOUNTABILITY.—Grants awarded under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice under subparagraph (C) that the audited grantee has used grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 1 year after the date on which the final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this section, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of grantees under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) FINAL AUDIT REPORT.—The Inspector General of the Department of Justice shall submit to the Attorney General a final report on each audit conducted under subparagraph (B).

"(D) MANDATORY EXCLUSION.—Grantees under this section about which there is an unresolved audit finding shall not be eligible to receive a grant under this section during the 2 fiscal years beginning after the end of the 1-year period described in subparagraph (A).

"(E) PRIORITY.—In making grants under this section, the Attorney General shall give priority to applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(F) REIMBURSEMENT.—If an entity receives a grant under this section during the 2-fiscal-year period during

which the entity is prohibited from receiving grants under subparagraph (D), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant that was improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment under clause (i) from the grantee that was erroneously awarded grant funds.

"(2) NONPROFIT AGENCY REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant program under this section, the term 'nonprofit agency' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

"(B) PROHIBITION.—The Attorney General may not award a grant under this section to a nonprofit agency that holds money in an offshore account for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986 (26 U.S.C. 511(a)).

"(C) DISCLOSURE.—Each nonprofit agency that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit to the Committee on the

Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives an annual certification—

"(A) indicating whether—

"(i) all final audit reports issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(D) have been issued; and

"(iii) any reimbursements required under paragraph (1)(F) have been made; and

"(B) that includes a list of any grantees excluded under paragraph (1)(D) from the previous year.

"(5) PREVENTING DUPLICATIVE GRANTS.—

"(A) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

"(B) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(i) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(ii) the reason the Attorney General awarded the duplicate grants.".

28 USC 534 note.

SEC. 14015. IMPROVING DEPARTMENT OF JUSTICE DATA COLLECTION ON MENTAL ILLNESS INVOLVED IN CRIME.

(a) IN GENERAL.—Notwithstanding any other provision of law, on or after the date that is 90 days after the date on which the Attorney General promulgates regulations under subsection (b), any data prepared by, or submitted to, the Attorney General or the Director of the Federal Bureau of Investigation with respect to the incidences of homicides, law enforcement officers killed, seriously injured, and assaulted, or individuals killed or seriously injured by law enforcement officers shall include data with respect to the involvement of mental illness in such incidences, if any.

(b) REGULATIONS.—Not later than 90 days after the date of the enactment of this Act, the Attorney General shall promulgate or revise regulations as necessary to carry out subsection (a).

SEC. 14016. REPORTS ON THE NUMBER OF MENTALLY ILL OFFENDERS IN PRISON.

(a) REPORT ON THE COST OF TREATING THE MENTALLY ILL IN THE CRIMINAL JUSTICE SYSTEM.—Not later than 12 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report detailing the cost of imprisonment for individuals who have serious mental illness by the Federal Government or a State or unit of local government, which shall include—

(1) the number and type of crimes committed by individuals with serious mental illness each year; and

(2) detail strategies or ideas for preventing crimes by those individuals with serious mental illness from occurring.

(b) DEFINITION.—For purposes of this section, the Attorney General, in consultation with the Assistant Secretary of Mental Health and Substance Use Disorders, shall define "serious mental illness" based on the "Health Care Reform for Americans with Severe Mental Illnesses: Report" of the National Advisory Mental Health Council, American Journal of Psychiatry 1993; 150:1447–1465.

SEC. 14017. CODIFICATION OF DUE PROCESS FOR DETERMINATIONS BY SECRETARY OF VETERANS AFFAIRS OF MENTAL CAPACITY OF BENEFICIARIES.

38 USC 5501A.

(a) IN GENERAL.—Chapter 55 of title 38, United States Code, is amended by inserting after section 5501 the following new section:

"§ 5501A. Beneficiaries' rights in mental competence determinations

"The Secretary may not make an adverse determination concerning the mental capacity of a beneficiary to manage monetary benefits paid to or for the beneficiary by the Secretary under this title unless such beneficiary has been provided all of the following, subject to the procedures and timelines prescribed by the Secretary for determinations of incompetency:

"(1) Notice of the proposed adverse determination and the supporting evidence.

"(2) An opportunity to request a hearing.

"(3) An opportunity to present evidence, including an opinion from a medical professional or other person, on the capacity of the beneficiary to manage monetary benefits paid to or for the beneficiary by the Secretary under this title.

"(4) An opportunity to be represented at no expense to the Government (including by counsel) at any such hearing and to bring a medical professional or other person to provide relevant testimony at any such hearing.".

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter 55 is amended by inserting after the item relating to section 5501 the following new item:

38 USC 5501 prec.

"5501A. Beneficiaries' rights in mental competence determinations".

(c) EFFECTIVE DATE.—Section 5501A of title 38, United States Code, as added by subsection (a), shall apply to determinations made by the Secretary of Veterans Affairs on or after the date of the enactment of this Act.

38 USC 5501A note.

SEC. 14018. REAUTHORIZATION OF APPROPRIATIONS.

Subsection (o) of section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as redesignated by section 14006, is amended—

(1) in paragraph (1)(C), by striking "2009 through 2014" and inserting "2017 through 2021"; and

(2) by adding at the end the following:

"(3) LIMITATION.—Not more than 20 percent of the funds authorized to be appropriated under this section may be used for purposes described in subsection (i) (relating to veterans).".

Subtitle B—Comprehensive Justice and Mental Health

SEC. 14021. SEQUENTIAL INTERCEPT MODEL.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as amended by section 14005, is amended by inserting after subsection (j), the following:

"(k) SEQUENTIAL INTERCEPT GRANTS.—

"(1) DEFINITION.—In this subsection, the term 'eligible entity' means a State, unit of local government, Indian tribe, or tribal organization.

"(2) AUTHORIZATION.—The Attorney General may make grants under this subsection to an eligible entity for sequential intercept mapping and implementation in accordance with paragraph (3).

"(3) SEQUENTIAL INTERCEPT MAPPING; IMPLEMENTATION.—An eligible entity that receives a grant under this subsection may use funds for—

"(A) sequential intercept mapping, which—

"(i) shall consist of—

"(I) convening mental health and criminal justice stakeholders to—

"(aa) develop a shared understanding of the flow of justice-involved individuals with mental illnesses through the criminal justice system; and

"(bb) identify opportunities for improved collaborative responses to the risks and needs of individuals described in item (aa); and

"(II) developing strategies to address gaps in services and bring innovative and effective programs to scale along multiple intercepts, including—

"(aa) emergency and crisis services;

"(bb) specialized police-based responses;

"(cc) court hearings and disposition alternatives;

"(dd) reentry from jails and prisons; and

"(ee) community supervision, treatment and support services; and

"(ii) may serve as a starting point for the development of strategic plans to achieve positive public health and safety outcomes; and

"(B) implementation, which shall—

"(i) be derived from the strategic plans described in subparagraph (A)(ii); and

"(ii) consist of—

"(I) hiring and training personnel;

"(II) identifying the eligible entity's target population;

"(III) providing services and supports to reduce unnecessary penetration into the criminal justice system;

"(IV) reducing recidivism;

"(V) evaluating the impact of the eligible entity's approach; and

"(VI) planning for the sustainability of effective interventions.".

SEC. 14022. PRISON AND JAILS.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by inserting after subsection (k), as added by section 14021, the following:

"(l) CORRECTIONAL FACILITIES.—

"(1) DEFINITIONS.—

"(A) CORRECTIONAL FACILITY.—The term 'correctional facility' means a jail, prison, or other detention facility used to house people who have been arrested, detained, held, or convicted by a criminal justice agency or a court.

"(B) ELIGIBLE INMATE.—The term 'eligible inmate' means an individual who—

"(i) is being held, detained, or incarcerated in a correctional facility; and

"(ii) manifests obvious signs of a mental illness or has been diagnosed by a qualified mental health professional as having a mental illness.

"(2) CORRECTIONAL FACILITY GRANTS.—The Attorney General may award grants to applicants to enhance the capabilities of a correctional facility—

"(A) to identify and screen for eligible inmates;

"(B) to plan and provide—

"(i) initial and periodic assessments of the clinical, medical, and social needs of inmates; and

"(ii) appropriate treatment and services that address the mental health and substance abuse needs of inmates;

"(C) to develop, implement, and enhance—

"(i) post-release transition plans for eligible inmates that, in a comprehensive manner, coordinate health, housing, medical, employment, and other appropriate services and public benefits;

"(ii) the availability of mental health care services and substance abuse treatment services; and

"(iii) alternatives to solitary confinement and segregated housing and mental health screening and treatment for inmates placed in solitary confinement or segregated housing; and

"(D) to train each employee of the correctional facility to identify and appropriately respond to incidents involving inmates with mental health or co-occurring mental health and substance abuse disorders.".

SEC. 14023. ALLOWABLE USES.

Section 2991(b)(5)(I) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(b)(5)(I)) is amended by adding at the end the following:

"(v) TEAMS ADDRESSING FREQUENT USERS OF CRISIS SERVICES.—Multidisciplinary teams that—

"(I) coordinate, implement, and administer community-based crisis responses and long-term plans for frequent users of crisis services;

"(II) provide training on how to respond appropriately to the unique issues involving frequent users of crisis services for public service personnel,

including criminal justice, mental health, substance abuse, emergency room, healthcare, law enforcement, corrections, and housing personnel;

"(III) develop or support alternatives to hospital and jail admissions for frequent users of crisis services that provide treatment, stabilization, and other appropriate supports in the least restrictive, yet appropriate, environment; and

"(IV) develop protocols and systems among law enforcement, mental health, substance abuse, housing, corrections, and emergency medical service operations to provide coordinated assistance to frequent users of crisis services.".

SEC. 14024. LAW ENFORCEMENT TRAINING.

Section 2991(h) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(h)) is amended—

(1) in paragraph (1), by adding at the end the following:

"(F) ACADEMY TRAINING.—To provide support for academy curricula, law enforcement officer orientation programs, continuing education training, and other programs that teach law enforcement personnel how to identify and respond to incidents involving persons with mental health disorders or co-occurring mental health and substance abuse disorders."; and

(2) by adding at the end the following:

"(4) PRIORITY CONSIDERATION.—The Attorney General, in awarding grants under this subsection, shall give priority to programs that law enforcement personnel and members of the mental health and substance abuse professions develop and administer cooperatively.".

42 USC 3797aa–1 note.

SEC. 14025. FEDERAL LAW ENFORCEMENT TRAINING.

Not later than 1 year after the date of enactment of this Act, the Attorney General shall provide direction and guidance for the following:

(1) TRAINING PROGRAMS.—Programs that offer specialized and comprehensive training, in procedures to identify and appropriately respond to incidents in which the unique needs of individuals who have a mental illness are involved, to first responders and tactical units of—

(A) Federal law enforcement agencies; and

(B) other Federal criminal justice agencies such as the Bureau of Prisons, the Administrative Office of the United States Courts, and other agencies that the Attorney General determines appropriate.

(2) IMPROVED TECHNOLOGY.—The establishment of, or improvement of existing, computerized information systems to provide timely information to employees of Federal law enforcement agencies, and Federal criminal justice agencies to improve the response of such employees to situations involving individuals who have a mental illness.

SEC. 14026. GAO REPORT.

No later than 1 year after the date of enactment of this Act, the Comptroller General of the United States, in coordination with the Attorney General, shall submit to Congress a report on—

(1) the practices that Federal first responders, tactical units, and corrections officers are trained to use in responding to individuals with mental illness;

(2) procedures to identify and appropriately respond to incidents in which the unique needs of individuals who have a mental illness are involved, to Federal first responders and tactical units;

(3) the application of evidence-based practices in criminal justice settings to better address individuals with mental illnesses; and

(4) recommendations on how the Department of Justice can expand and improve information sharing and dissemination of best practices.

SEC. 14027. EVIDENCE BASED PRACTICES.

Section 2991(c) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(c)) is amended—

(1) in paragraph (3), by striking "or" at the end;

(2) by redesignating paragraph (4) as paragraph (6); and

(3) by inserting after paragraph (3), the following:

"(4) propose interventions that have been shown by empirical evidence to reduce recidivism;

"(5) when appropriate, use validated assessment tools to target preliminarily qualified offenders with a moderate or high risk of recidivism and a need for treatment and services; or".

SEC. 14028. TRANSPARENCY, PROGRAM ACCOUNTABILITY, AND ENHANCEMENT OF LOCAL AUTHORITY.

(a) IN GENERAL.—Section 2991(a) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(a)) is amended—

(1) in paragraph (7)—

(A) in the heading, by striking "MENTAL ILLNESS" and inserting "MENTAL ILLNESS; MENTAL HEALTH DISORDER"; and

(B) by striking "term 'mental illness' means" and inserting "terms 'mental illness' and 'mental health disorder' mean"; and

(2) by striking paragraph (9) and inserting the following:

"(9) PRELIMINARILY QUALIFIED OFFENDER.—

"(A) IN GENERAL.—The term 'preliminarily qualified offender' means an adult or juvenile accused of an offense who—

"(i)(I) previously or currently has been diagnosed by a qualified mental health professional as having a mental illness or co-occurring mental illness and substance abuse disorders;

"(II) manifests obvious signs of mental illness or co-occurring mental illness and substance abuse disorders during arrest or confinement or before any court; or

"(III) in the case of a veterans treatment court provided under subsection (i), has been diagnosed with, or manifests obvious signs of, mental illness or a substance abuse disorder or co-occurring mental illness and substance abuse disorder;

"(ii) has been unanimously approved for participation in a program funded under this section by, when appropriate—

"(I) the relevant—

"(aa) prosecuting attorney;

"(bb) defense attorney;

"(cc) probation or corrections official; and

"(dd) judge; and

"(II) a representative from the relevant mental health agency described in subsection (b)(5)(B)(i);

"(iii) has been determined, by each person described in clause (ii) who is involved in approving the adult or juvenile for participation in a program funded under this section, to not pose a risk of violence to any person in the program, or the public, if selected to participate in the program; and

"(iv) has not been charged with or convicted of—

"(I) any sex offense (as defined in section 111 of the Sex Offender Registration and Notification Act (42 U.S.C. 16911)) or any offense relating to the sexual exploitation of children; or

"(II) murder or assault with intent to commit murder.

"(B) DETERMINATION.—In determining whether to designate a defendant as a preliminarily qualified offender, the relevant prosecuting attorney, defense attorney, probation or corrections official, judge, and mental health or substance abuse agency representative shall take into account—

"(i) whether the participation of the defendant in the program would pose a substantial risk of violence to the community;

"(ii) the criminal history of the defendant and the nature and severity of the offense for which the defendant is charged;

"(iii) the views of any relevant victims to the offense;

"(iv) the extent to which the defendant would benefit from participation in the program;

"(v) the extent to which the community would realize cost savings because of the defendant's participation in the program; and

"(vi) whether the defendant satisfies the eligibility criteria for program participation unanimously established by the relevant prosecuting attorney, defense attorney, probation or corrections official, judge and mental health or substance abuse agency representative.".

(b) TECHNICAL AND CONFORMING AMENDMENT.—Section 2927(2) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797s–6(2)) is amended by striking "has the meaning given that term in section 2991(a)." and inserting "means an offense that—

"(A) does not have as an element the use, attempted use, or threatened use of physical force against the person or property of another; or

"(B) is not a felony that by its nature involves a substantial risk that physical force against the person or property of another may be used in the course of committing the offense.".

SEC. 14029. GRANT ACCOUNTABILITY.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by inserting after subsection (l), as added by section 14022, the following:

"(m) ACCOUNTABILITY.—All grants awarded by the Attorney General under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months from the date when the final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of recipients of grants under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) MANDATORY EXCLUSION.—A recipient of grant funds under this section that is found to have an unresolved audit finding shall not be eligible to receive grant funds under this section during the first 2 fiscal years beginning after the end of the 12-month period described in subparagraph (A).

"(D) PRIORITY.—In awarding grants under this section, the Attorney General shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(E) REIMBURSEMENT.—If an entity is awarded grant funds under this section during the 2-fiscal-year period during which the entity is barred from receiving grants under subparagraph (C), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

"(2) NONPROFIT ORGANIZATION REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant programs under this part, the term 'nonprofit organization' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

"(B) PROHIBITION.—The Attorney General may not award a grant under this part to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

"(C) DISCLOSURE.—Each nonprofit organization that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit, to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives, an annual certification—

"(A) indicating whether—

"(i) all audits issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(C) have been issued; and

"(iii) all reimbursements required under paragraph (1)(E) have been made; and

"(B) that includes a list of any grant recipients excluded under paragraph (1) from the previous year.

"(n) PREVENTING DUPLICATIVE GRANTS.—

"(1) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

"(2) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(A) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(B) the reason the Attorney General awarded the duplicate grants.".

DIVISION C—INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS

Increasing Choice, Access, and Quality in Health Care for Americans Act.

SEC. 15000. SHORT TITLE.

42 USC 1305 note.

This division may be cited as the "Increasing Choice, Access, and Quality in Health Care for Americans Act".

TITLE XV—PROVISIONS RELATING TO MEDICARE PART A

SEC. 15001. DEVELOPMENT OF MEDICARE HCPCS VERSION OF MS–DRG CODES FOR SIMILAR HOSPITAL SERVICES.

Section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended by adding at the end the following new subsection:

"(t) RELATING SIMILAR INPATIENT AND OUTPATIENT HOSPITAL SERVICES.—

"(1) DEVELOPMENT OF HCPCS VERSION OF MS–DRG CODES.—Not later than January 1, 2018, the Secretary shall develop HCPCS versions for MS–DRGs that are similar to the ICD–10–PCS for such MS–DRGs such that, to the extent possible, the MS–DRG assignment shall be similar for a claim coded with the HCPCS version as an identical claim coded with a ICD–10–PCS code.

"(2) COVERAGE OF SURGICAL MS–DRGS.—In carrying out paragraph (1), the Secretary shall develop HCPCS versions of MS–DRG codes for not fewer than 10 surgical MS–DRGs.

"(3) PUBLICATION AND DISSEMINATION OF THE HCPCS VERSIONS OF MS–DRGS.—

"(A) IN GENERAL.—The Secretary shall develop a HCPCS MS–DRG definitions manual and software that is similar to the definitions manual and software for ICD–10–PCS codes for such MS–DRGs. The Secretary shall post the HCPCS MS–DRG definitions manual and software on the Internet website of the Centers for Medicare & Medicaid Services. The HCPCS MS–DRG definitions

manual and software shall be in the public domain and available for use and redistribution without charge.

"(B) USE OF PREVIOUS ANALYSIS DONE BY MEDPAC.—In developing the HCPCS MS–DRG definitions manual and software under subparagraph (A), the Secretary shall consult with the Medicare Payment Advisory Commission and shall consider the analysis done by such Commission in translating outpatient surgical claims into inpatient surgical MS–DRGs in preparing chapter 7 (relating to hospital short-stay policy issues) of its 'Medicare and the Health Care Delivery System' report submitted to Congress in June 2015.

"(4) DEFINITION AND REFERENCE.—In this subsection:

"(A) HCPCS.—The term 'HCPCS' means, with respect to hospital items and services, the code under the Healthcare Common Procedure Coding System (HCPCS) (or a successor code) for such items and services.

"(B) ICD–10–PCS.—The term 'ICD–10–PCS' means the International Classification of Diseases, 10th Revision, Procedure Coding System, and includes any subsequent revision of such International Classification of Diseases, Procedure Coding System.".

SEC. 15002. ESTABLISHING BENEFICIARY EQUITY IN THE MEDICARE HOSPITAL READMISSION PROGRAM.

(a) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLE POPULATION.—Section 1886(q)(3) of the Social Security Act (42 U.S.C. 1395ww(q)(3)) is amended—

(1) in subparagraph (A), by inserting "subject to subparagraph (D)," after "purposes of paragraph (1),"; and

(2) by adding at the end the following new subparagraph:

"(D) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLES.—

"(i) IN GENERAL.—In determining a hospital's adjustment factor under this paragraph for purposes of making payments for discharges occurring during and after fiscal year 2019, and before the application of clause (i) of subparagraph (E), the Secretary shall assign hospitals to groups (as defined by the Secretary under clause (ii)) and apply the applicable provisions of this subsection using a methodology in a manner that allows for separate comparison of hospitals within each such group, as determined by the Secretary.

"(ii) DEFINING GROUPS.—For purposes of this subparagraph, the Secretary shall define groups of hospitals, based on their overall proportion, of the inpatients who are entitled to, or enrolled for, benefits under part A, and who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)). In defining groups, the Secretary shall consult the Medicare Payment Advisory Commission and may consider the analysis done by such Commission in preparing the portion of its report submitted to Congress in June 2013 relating to readmissions.

"(iii) MINIMIZING REPORTING BURDEN ON HOSPITALS.—In carrying out this subparagraph, the Secretary shall not impose any additional reporting requirements on hospitals.

"(iv) BUDGET NEUTRAL DESIGN METHODOLOGY.—The Secretary shall design the methodology to implement this subparagraph so that the estimated total amount of reductions in payments under this subsection equals the estimated total amount of reductions in payments that would otherwise occur under this subsection if this subparagraph did not apply.".

(b) CHANGES IN RISK ADJUSTMENT.—Section 1886(q)(3) of the Social Security Act (42 U.S.C. 1395ww(q)(3)), as amended by subsection (a), is further amended by adding at the end the following new subparagraph:

"(E) CHANGES IN RISK ADJUSTMENT.—

"(i) CONSIDERATION OF RECOMMENDATIONS IN IMPACT REPORTS.—The Secretary may take into account the studies conducted and the recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act of 2014 (Public Law 113–185; 42 U.S.C. 1395lll note) with respect to the application under this subsection of risk adjustment methodologies. Nothing in this clause shall be construed as precluding consideration of the use of groupings of hospitals.

"(ii) CONSIDERATION OF EXCLUSION OF PATIENT CASES BASED ON V OR OTHER APPROPRIATE CODES.—In promulgating regulations to carry out this subsection with respect to discharges occurring after fiscal year 2018, the Secretary may consider the use of V or other ICD-related codes for removal of a readmission. The Secretary may consider modifying measures under this subsection to incorporate V or other ICD-related codes at the same time as other changes are being made under this subparagraph.

"(iii) REMOVAL OF CERTAIN READMISSIONS.—In promulgating regulations to carry out this subsection, with respect to discharges occurring after fiscal year 2018, the Secretary may consider removal as a readmission of an admission that is classified within one or more of the following: transplants, end-stage renal disease, burns, trauma, psychosis, or substance abuse. The Secretary may consider modifying measures under this subsection to remove readmissions at the same time as other changes are being made under this subparagraph.".

(c) MEDPAC STUDY ON READMISSIONS PROGRAM.—The Medicare Payment Advisory Commission shall conduct a study to review overall hospital readmissions described in section 1886(q)(5)(E) of the Social Security Act (42 U.S.C. 1395ww(q)(5)(E)) and whether such readmissions are related to any changes in outpatient and emergency services furnished. The Commission shall submit to Congress a report on such study in its report to Congress in June 2018.

SEC. 15003. FIVE-YEAR EXTENSION OF THE RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) EXTENSION.—Section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 42 U.S.C. 1395ww note) is amended—

(1) in subsection (a)(5), by striking "5-year extension period" and inserting "10-year extension period"; and

(2) in subsection (g)—

(A) in the subsection heading, by striking "FIVE-YEAR" and inserting "TEN-YEAR";

(B) in paragraph (1), by striking "additional 5-year" and inserting "additional 10-year";

(C) by striking "5-year extension period" and inserting "10-year extension period" each place it appears;

(D) in paragraph (4)(B)—

(i) in the matter preceding clause (i), by inserting "each 5-year period in" after "hospital during"; and

(ii) in clause (i), by inserting "each applicable 5-year period in" after "the first day of"; and

(E) by adding at the end the following new paragraphs:

"(5) OTHER HOSPITALS IN DEMONSTRATION PROGRAM.—During the second 5 years of the 10-year extension period, the Secretary shall apply the provisions of paragraph (4) to rural community hospitals that are not described in paragraph (4) but are participating in the demonstration program under this section as of December 30, 2014, in a similar manner as such provisions apply to rural community hospitals described in paragraph (4).

"(6) EXPANSION OF DEMONSTRATION PROGRAM TO RURAL AREAS IN ANY STATE.—

"(A) IN GENERAL.—The Secretary shall, notwithstanding subsection (a)(2) or paragraph (2) of this subsection, not later than 120 days after the date of the enactment of this paragraph, issue a solicitation for applications to select up to the maximum number of additional rural community hospitals located in any State to participate in the demonstration program under this section for the second 5 years of the 10-year extension period without exceeding the limitation under paragraph (3) of this subsection.

"(B) PRIORITY.—In determining which rural community hospitals that submitted an application pursuant to the solicitation under subparagraph (A) to select for participation in the demonstration program, the Secretary—

"(i) shall give priority to rural community hospitals located in one of the 20 States with the lowest population densities (as determined by the Secretary using the 2015 Statistical Abstract of the United States); and

"(ii) may consider—

"(I) closures of hospitals located in rural areas in the State in which the rural community hospital is located during the 5-year period immediately preceding the date of the enactment of this paragraph; and

"(II) the population density of the State in which the rural community hospital is located.".

(b) CHANGE IN TIMING FOR REPORT.—Subsection (e) of such section 410A is amended—

(1) by striking "Not later than 6 months after the completion of the demonstration program under this section" and inserting "Not later than August 1, 2018"; and

(2) by striking "such program" and inserting "the demonstration program under this section".

SEC. 15004. REGULATORY RELIEF FOR LTCHS.

(a) TECHNICAL CHANGE TO THE MEDICARE LONG-TERM CARE HOSPITAL MORATORIUM EXCEPTION.—

(1) IN GENERAL.—Section 114(d)(7) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by sections 3106(b) and 10312(b) of Public Law 111–148, section 1206(b)(2) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67), and section 112 of the Protecting Access to Medicare Act of 2014 (Public Law 113–93), is amended by striking "The moratorium under paragraph (1)(A)" and inserting "Any moratorium under paragraph (1)".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as if included in the enactment of section 112 of the Protecting Access to Medicare Act of 2014. 42 USC 1395ww note.

(b) MODIFICATION TO MEDICARE LONG-TERM CARE HOSPITAL HIGH COST OUTLIER PAYMENTS.—Section 1886(m) of the Social Security Act (42 U.S.C. 1395ww(m)) is amended by adding at the end the following new paragraph:

"(7) TREATMENT OF HIGH COST OUTLIER PAYMENTS.—

"(A) ADJUSTMENT TO THE STANDARD FEDERAL PAYMENT RATE FOR ESTIMATED HIGH COST OUTLIER PAYMENTS.—Under the system described in paragraph (1), for fiscal years beginning on or after October 1, 2017, the Secretary shall reduce the standard Federal payment rate as if the estimated aggregate amount of high cost outlier payments for standard Federal payment rate discharges for each such fiscal year would be equal to 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

"(B) LIMITATION ON HIGH COST OUTLIER PAYMENT AMOUNTS.—Notwithstanding subparagraph (A), the Secretary shall set the fixed loss amount for high cost outlier payments such that the estimated aggregate amount of high cost outlier payments made for standard Federal payment rate discharges for fiscal years beginning on or after October 1, 2017, shall be equal to 99.6875 percent of 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

"(C) WAIVER OF BUDGET NEUTRALITY.—Any reduction in payments resulting from the application of subparagraph (B) shall not be taken into account in applying any budget neutrality provision under such system.

"(D) NO EFFECT ON SITE NEUTRAL HIGH COST OUTLIER PAYMENT RATE.—This paragraph shall not apply with respect to the computation of the applicable site neutral payment rate under paragraph (6).".

SEC. 15005. SAVINGS FROM IPPS MACRA PAY-FOR THROUGH NOT APPLYING DOCUMENTATION AND CODING ADJUSTMENTS.

Section 7(b)(1)(B) of the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (Public Law 110–90), as amended by section 631(b) of the American Taxpayer Relief Act of 2012 (Public Law 112–240) and section 414(1)(B)(iii) of the Medicare

Access and CHIP Reauthorization Act of 2015 (Public Law 114–10), is amended in clause (iii) by striking "an increase of 0.5 percentage points for discharges occurring during each of fiscal years 2018 through 2023" and inserting "an increase of 0.4588 percentage points for discharges occurring during fiscal year 2018 and 0.5 percentage points for discharges occurring during each of fiscal years 2019 through 2023".

SEC. 15006. EXTENSION OF CERTAIN LTCH MEDICARE PAYMENT RULES.

(a) 25–PERCENT PATIENT THRESHOLD PAYMENT ADJUSTMENT.—Section 114(c)(1)(A) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by section 4302(a) of division B of the American Recovery and Reinvestment Act (Public Law 111–5), sections 3106(a) and 10312(a) of Public Law 111–148, and section 1206(b)(1)(B) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67), is amended by striking "for a 9-year period" and inserting "through June 30, 2016, and for discharges occurring on or after October 1, 2016, and before October 1, 2017".

(b) PAYMENT FOR HOSPITALS-WITHIN-HOSPITALS.—Section 114(c)(2) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by section 4302(a) of division B of the American Recovery and Reinvestment Act (Public Law 111–5), sections 3106(a) and 10312(a) of Public Law 111–148, and section 1206(b)(1)(A) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67), is amended—

(1) in subparagraph (A), by inserting "or any similar provision," after "Regulations,";

(2) in subparagraph (B)—

(A) in clause (i), by inserting "or any similar provision," after "Regulations,"; and

(B) in clause (ii), by inserting ", or any similar provision," after "Regulations"; and

(3) in subparagraph (C), by striking "for a 9-year period" and inserting "through June 30, 2016, and for discharges occurring on or after October 1, 2016, and before October 1, 2017".

SEC. 15007. APPLICATION OF RULES ON THE CALCULATION OF HOSPITAL LENGTH OF STAY TO ALL LTCHS.

(a) IN GENERAL.—Section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67; 42 U.S.C. 1395ww note) is amended—

(1) by striking subparagraph (B);

(2) by striking "SITE NEUTRAL BASIS.—" and all that follows through "For discharges occurring" and inserting "SITE NEUTRAL BASIS.—For discharges occurring";

(3) by striking "subject to subparagraph (B),"; and

(4) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively, and moving each of such subparagraphs (as so redesignated) 2 ems to the left.

42 USC 1395ww note.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall be effective as if included in the enactment of section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113–67; 42 U.S.C. 1395ww note).

SEC. 15008. CHANGE IN MEDICARE CLASSIFICATION FOR CERTAIN HOSPITALS.

(a) IN GENERAL.—Subsection (d)(1)(B)(iv) of section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended—

(1) in subclause (I), by striking "or" at the end;

(2) in subclause (II)—

(A) by striking ", or" at the end and inserting a semicolon;

(B) by redesignating such subclause as clause (vi) and by moving it to immediately follow clause (v); and

(C) in clause (v), by striking the semicolon at the end and inserting ", or"; and

(3) by striking "(iv)(I) a hospital" and inserting "(iv) a hospital".

(b) CONFORMING PAYMENT REFERENCES.—The second sentence of subsection (d)(1)(B) of such section is amended—

(1) by inserting "(as in effect as of such date)" after "clause (iv)"; and

(2) by inserting "(or, in the case of a hospital described in clause (iv)(II), as so in effect, shall be classified under clause (vi) on and after the effective date of such clause (vi) and for cost reporting periods beginning on or after January 1, 2015, shall not be subject to subsection (m) as of the date of such classification)" after "so classified".

(c) APPLICATION.— 42 USC 1395ww note.

(1) IN GENERAL.—For cost reporting periods beginning on or after January 1, 2015, in the case of an applicable hospital (as defined in paragraph (3)), the following shall apply:

(A) Payment for inpatient operating costs shall be made on a reasonable cost basis in the manner provided in section 412.526(c)(3) of title 42, Code of Federal Regulations (as in effect on January 1, 2015) and in any subsequent modifications.

(B) Payment for capital costs shall be made in the manner provided by section 412.526(c)(4) of title 42, Code of Federal Regulations (as in effect on such date).

(C) Claims for payment for Medicare beneficiaries who are discharged on or after January 1, 2017, shall be processed as claims which are paid on a reasonable cost basis as described in section 412.526(c) of title 42, Code of Federal Regulations (as in effect on such date).

(2) APPLICABLE HOSPITAL DEFINED.—In this subsection, the term "applicable hospital" means a hospital that is classified under clause (iv)(II) of section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) on the day before the date of the enactment of this Act and which is classified under clause (vi) of such section, as redesignated and moved by subsection (a), on or after such date of enactment.

(d) CONFORMING TECHNICAL AMENDMENTS.—

(1) Section 1899B(a)(2)(A)(iv) of the Social Security Act (42 U.S.C. 1395lll(a)(2)(A)(iv)) is amended by striking "1886(d)(1)(B)(iv)(II)" and inserting "1886(d)(1)(B)(vi)".

(2) Section 1886(m)(5)(F) of such Act (42 U.S.C. 1395ww(m)(5)(F)) is amended in each of clauses (i) and (ii) by striking "(d)(1)(B)(iv)(II)" and inserting "(d)(1)(B)(vi)".

SEC. 15009. TEMPORARY EXCEPTION TO THE APPLICATION OF THE MEDICARE LTCH SITE NEUTRAL PROVISIONS FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS.

(a) EXCEPTION.—Section 1886(m)(6) of the Social Security Act (42 U.S.C. 1395ww(m)(6)) is amended—

(1) in subparagraph (A)(i), by striking "and (E)" and inserting ", (E), and (F)"; and

(2) by adding at the end the following new subparagraph:

"(F) TEMPORARY EXCEPTION FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS.—For discharges in cost reporting periods beginning during fiscal years 2018 and 2019, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge is from a long-term care hospital that meets each of the following requirements:

"(i) NOT-FOR-PROFIT.—The long-term care hospital was a not-for-profit long-term care hospital on June 1, 2014, as determined by cost report data.

"(ii) PRIMARILY PROVIDING TREATMENT FOR CATASTROPHIC SPINAL CORD OR ACQUIRED BRAIN INJURIES OR OTHER PARALYZING NEUROMUSCULAR CONDITIONS.—Of the discharges in calendar year 2013 from the long-term care hospital for which payment was made under this section, at least 50 percent were classified under MS–LTCH–DRGs 28, 29, 52, 57, 551, 573, and 963.

"(iii) SIGNIFICANT OUT-OF-STATE ADMISSIONS.—

"(I) IN GENERAL.—The long-term care hospital discharged inpatients (including both individuals entitled to, or enrolled for, benefits under this title and individuals not so entitled or enrolled) during fiscal year 2014 who had been admitted from at least 20 of the 50 States, determined by the States of residency of such inpatients and based on such data submitted by the hospital to the Secretary as the Secretary may require.

"(II) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement subclause (I) by program instruction or otherwise.

"(III) NON-APPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to data collected under this clause.".

(b) STUDY AND REPORT ON THE STATUS AND VIABILITY OF CERTAIN SPINAL CORD SPECIALTY LONG-TERM CARE HOSPITALS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on long-term care hospitals described in section 1886(m)(6)(F) of the Social Security Act, as added by subsection (a). Such report shall include an analysis of the following:

(A) The impact on such hospitals of the classification and facility licensure by State agencies of such hospitals.

(B) The Medicare payment rates for such hospitals.

(C) Data on the number and health care needs of Medicare beneficiaries who have been diagnosed with catastrophic spinal cord or acquired brain injuries or other paralyzing neuromuscular conditions (as described within

the discharge classifications specified in clause (ii) of such section) who are receiving services from such hospitals.

(2) REPORT.—Not later than October 1, 2018, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 15010. TEMPORARY EXTENSION TO THE APPLICATION OF THE MEDICARE LTCH SITE NEUTRAL PROVISIONS FOR CERTAIN DISCHARGES WITH SEVERE WOUNDS.

(a) IN GENERAL.—Section 1886(m)(6) of the Social Security Act (42 U.S.C. 1395ww(m)(6)), as amended by section 15009, is further amended—

(1) in subparagraph (A)(i) by striking "and (F)" and inserting "(F), and (G)";

(2) in subparagraph (E)(i)(I)(aa), by striking "the amendment made" and all that follows before the semicolon and inserting "the last sentence of subsection (d)(1)(B)"; and

(3) by adding at the end the following new subparagraph:

"(G) ADDITIONAL TEMPORARY EXCEPTION FOR CERTAIN SEVERE WOUND DISCHARGES FROM CERTAIN LONG-TERM CARE HOSPITALS.—

"(i) IN GENERAL.—For a discharge occurring in a cost reporting period beginning during fiscal year 2018, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge—

"(I) is from a long-term care hospital identified by the last sentence of subsection (d)(1)(B);

"(II) is classified under MS–LTCH–DRG 602, 603, 539, or 540; and

"(III) is with respect to an individual treated by a long-term care hospital for a severe wound.

"(ii) SEVERE WOUND DEFINED.—In this subparagraph, the term 'severe wound' means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, or fistula as identified in the claim from the long-term care hospital.

"(iii) WOUND DEFINED.—In this subparagraph, the term 'wound' means an injury involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.".

(c) STUDY AND REPORT TO CONGRESS.—

(1) STUDY.—The Comptroller General of the United States shall, in consultation with relevant stakeholders, conduct a study on the treatment needs of individuals entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title who require specialized wound care, and the cost, for such individuals and the Medicare program under such title, of treating severe wounds in rural and urban areas. Such study shall include an assessment of—

(A) access of such individuals to appropriate levels of care for such cases;

(B) the potential impact that section 1886(m)(6)(A)(i) of such Act (42 U.S.C. 1395ww(m)(6)(A)(i)) will have on

the access, quality, and cost of care for such individuals; and

(C) how to appropriately pay for such care under the Medicare program under such title.

(2) REPORT.—Not later than October 1, 2020, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

TITLE XVI—PROVISIONS RELATING TO MEDICARE PART B

SEC. 16001. CONTINUING MEDICARE PAYMENT UNDER HOPD PROSPECTIVE PAYMENT SYSTEM FOR SERVICES FURNISHED BY MID-BUILD OFF-CAMPUS OUTPATIENT DEPARTMENTS OF PROVIDERS.

(a) IN GENERAL.—Section 1833(t)(21) of the Social Security Act (42 U.S.C. 1395l(t)(21)) is amended—

(1) in subparagraph (B)—

(A) in clause (i), by striking "clause (ii)" and inserting "the subsequent provisions of this subparagraph"; and

(B) by adding at the end the following new clauses:

"(iii) DEEMED TREATMENT FOR 2017.—For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

"(iv) ALTERNATIVE EXCEPTION BEGINNING WITH 2018.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term 'off-campus outpatient department of a provider' also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

"(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after the date of the enactment of this clause), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

"(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(j); and

"(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after the date

of the enactment of this clause, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

"(v) MID-BUILD REQUIREMENT DESCRIBED.—The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

"(vii) AUDIT.—Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term 'off-campus outpatient department of a provider' under such clause.

"(viii) IMPLEMENTATION.—For purposes of implementing clauses (iii) through (vii):

"(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

"(II) Subchapter I of chapter 35 of title 44, United States Code, shall not apply.

"(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until December 31, 2018."; and

(2) in subparagraph (E), by adding at the end the following new clause:

"(iv) The determination of an audit under subparagraph (B)(vii).".

(b) EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114–74). 42 USC 1395*l* note.

SEC. 16002. TREATMENT OF CANCER HOSPITALS IN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER POLICY.

(a) IN GENERAL.—Section 1833(t)(21)(B) of the Social Security Act (42 U.S.C. 1395l(t)(21)(B)), as amended by section 16001(a), is amended—

(1) by inserting after clause (v) the following new clause:

"(vi) EXCLUSION FOR CERTAIN CANCER HOSPITALS.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term 'off-campus outpatient department of a provider' also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1886(d)(1)(B)(v) and—

"(I) in the case of a department that met the requirements of section 413.65 of title 42 of the

Code of Federal Regulations after November 1, 2015, and before the date of the enactment of this clause, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date of enactment; or

"(II) in the case of a department that meets such requirements after such date of enactment, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.";

(2) in clause (vii), by inserting after the first sentence the following: "Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department."; and

(3) in clause (viii)(III), by adding at the end the following: "For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until expended.".

(b) OFFSETTING SAVINGS.—Section 1833(t)(18) of the Social Security Act (42 U.S.C. 1395l(t)(18)) is amended—

(1) in subparagraph (B), by inserting ", subject to subparagraph (C)," after "shall"; and

(2) by adding at the end the following new subparagraph:

"(C) TARGET PCR ADJUSTMENT.—In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1886(d)(1)(B)(v). In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.".

42 USC 1395*l* note.

(c) EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114–74).

SEC. 16003. TREATMENT OF ELIGIBLE PROFESSIONALS IN AMBULATORY SURGICAL CENTERS FOR MEANINGFUL USE AND MIPS.

Section 1848(a)(7)(D) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)(D)) is amended—

(1) by striking "HOSPITAL-BASED ELIGIBLE PROFESSIONALS" and all that follows through "No payment" and inserting the following: "HOSPITAL-BASED AND AMBULATORY SURGICAL CENTER-BASED ELIGIBLE PROFESSIONALS.—

"(i) HOSPITAL-BASED.—No payment"; and

(2) by adding at the end the following new clauses:

"(ii) AMBULATORY SURGICAL CENTER-BASED.—Subject to clause (iv), no payment adjustment may be made under subparagraph (A) for 2017 and 2018 in the case of an eligible professional with respect to whom substantially all of the covered professional services furnished by such professional are furnished in an ambulatory surgical center.

"(iii) DETERMINATION.—The determination of whether an eligible professional is an eligible professional described in clause (ii) may be made on the basis of—

"(I) the site of service (as defined by the Secretary); or

"(II) an attestation submitted by the eligible professional.

Determinations made under subclauses (I) and (II) shall be made without regard to any employment or billing arrangement between the eligible professional and any other supplier or provider of services.

"(iv) SUNSET.—Clause (ii) shall no longer apply as of the first year that begins more than 3 years after the date on which the Secretary determines, through notice and comment rulemaking, that certified EHR technology applicable to the ambulatory surgical center setting is available.".

SEC. 16004. CONTINUING ACCESS TO HOSPITALS ACT OF 2016.

(a) EXTENSION OF ENFORCEMENT INSTRUCTION ON SUPERVISION REQUIREMENTS FOR OUTPATIENT THERAPEUTIC SERVICES IN CRITICAL ACCESS AND SMALL RURAL HOSPITALS THROUGH 2016.—Section 1 of Public Law 113–198, as amended by section 1 of Public Law 114–112, is amended—

(1) in the heading, by striking "**2014 AND 2015**" and inserting "**2016**"; and

(2) by striking "and 2015" and inserting ", 2015, and 2016".

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission (established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6)) shall submit to Congress a report analyzing the effect of the extension of the enforcement instruction under section 1 of Public Law 113–198, as amended by section 1 of Public Law 114–112 and subsection (a) of this section, on the access to health care by Medicare beneficiaries, on the economic impact and the impact upon hospital staffing needs, and on the quality of health care furnished to such beneficiaries.

SEC. 16005. DELAY OF IMPLEMENTATION OF MEDICARE FEE SCHEDULE ADJUSTMENTS FOR WHEELCHAIR ACCESSORIES AND SEATING SYSTEMS WHEN USED IN CONJUNCTION WITH COMPLEX REHABILITATION TECHNOLOGY (CRT) WHEELCHAIRS.

Section 2(a) of the Patient Access and Medicare Protection Act (42 U.S.C. 1305 note) is amended by striking "January 1, 2017" and inserting "July 1, 2017".

SEC. 16006. ALLOWING PHYSICAL THERAPISTS TO UTILIZE LOCUM TENENS ARRANGEMENTS UNDER MEDICARE.

(a) IN GENERAL.—The first sentence of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)), as amended by section 5012, is further amended—

(1) by striking "and" before "(I)"; and

(2) by inserting before the period at the end the following: ", and (J) in the case of outpatient physical therapy services furnished by physical therapists in a health professional shortage area (as defined in section 332(a)(1)(A) of the Public Health Service Act), a medically underserved area (as designated pursuant to section 330(b)(3)(A) of such Act), or a rural area (as defined in section 1886(d)(2)(D)), subparagraph (D) of this sentence shall apply to such services and therapists in the same manner as such subparagraph applies to physicians' services furnished by physicians".

42 USC 1395u note.

(b) EFFECTIVE DATE; IMPLEMENTATION.—

(1) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to services furnished beginning not later than six months after the date of the enactment of this Act.

(2) IMPLEMENTATION.—The Secretary of Health and Human Services may implement subparagraph (J) of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)), as added by subsection (a)(2), by program instruction or otherwise.

SEC. 16007. EXTENSION OF THE TRANSITION TO NEW PAYMENT RATES FOR DURABLE MEDICAL EQUIPMENT UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services shall extend the transition period described in clause (i) of section 414.210(g)(9) of title 42, Code of Federal Regulations, from June 30, 2016, to December 31, 2016 (with the full implementation described in clause (ii) of such section applying to items and services furnished with dates of service on or after January 1, 2017).

(b) STUDY AND REPORT.—

(1) STUDY.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study that examines the impact of applicable payment adjustments upon—

(i) the number of suppliers of durable medical equipment that, on a date that is not before January 1, 2016, and not later than December 31, 2016, ceased to conduct business as such suppliers; and

(ii) the availability of durable medical equipment, during the period beginning on January 1, 2016, and ending on December 31, 2016, to individuals entitled to benefits under part A of title XVIII of the Social

Security Act (42 U.S.C. 1395 et seq.) or enrolled under part B of such title.

(B) DEFINITIONS.—For purposes of this subsection, the following definitions apply:

(i) SUPPLIER; DURABLE MEDICAL EQUIPMENT.—The terms "supplier" and "durable medical equipment" have the meanings given such terms by section 1861 of the Social Security Act (42 U.S.C. 1395x).

(ii) APPLICABLE PAYMENT ADJUSTMENT.—The term "applicable payment adjustment" means a payment adjustment described in section 414.210(g) of title 42, Code of Federal Regulations, that is phased in by paragraph (9)(i) of such section. For purposes of the preceding sentence, a payment adjustment that is phased in pursuant to the extension under subsection (a) shall be considered a payment adjustment that is phased in by such paragraph (9)(i).

(2) REPORT.—The Secretary of Health and Human Services shall, not later than January 12, 2017, submit to the Committees on Ways and Means and on Energy and Commerce of the House of Representatives, and to the Committee on Finance of the Senate, a report on the findings of the study conducted under paragraph (1).

SEC. 16008. REQUIREMENTS IN DETERMINING ADJUSTMENTS USING INFORMATION FROM COMPETITIVE BIDDING PROGRAMS.

(a) IN GENERAL.—Section 1834(a)(1)(G) of the Social Security Act (42 U.S.C. 1395m(a)(1)(G)) is amended by adding at the end the following new sentence: "In the case of items and services furnished on or after January 1, 2019, in making any adjustments under clause (ii) or (iii) of subparagraph (F), under subsection (h)(1)(H)(ii), or under section 1842(s)(3)(B), the Secretary shall—

"(i) solicit and take into account stakeholder input; and

"(ii) take into account the highest amount bid by a winning supplier in a competitive acquisition area and a comparison of each of the following with respect to non-competitive acquisition areas and competitive acquisition areas:

"(I) The average travel distance and cost associated with furnishing items and services in the area.

"(II) The average volume of items and services furnished by suppliers in the area.

"(III) The number of suppliers in the area.".

(b) CONFORMING AMENDMENTS.—(1) Section 1834(h)(1)(H)(ii) of the Social Security Act (42 U.S.C. 1395m(h)(1)(H)(ii)) is amended by striking "the Secretary" and inserting "subject to subsection (a)(1)(G), the Secretary".

(2) Section 1842(s)(3)(B) of the Social Security Act (42 U.S.C. 1395m(s)(3)(B)) is amended by striking "the Secretary" and inserting "subject to section 1834(a)(1)(G), the Secretary".

TITLE XVII—OTHER MEDICARE PROVISIONS

SEC. 17001. DELAY IN AUTHORITY TO TERMINATE CONTRACTS FOR MEDICARE ADVANTAGE PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATINGS.

42 USC 1395w–27 note.

(a) FINDINGS.—Consistent with the studies provided under the IMPACT Act of 2014 (Public Law 113–185), it is the intent of Congress—

(1) to continue to study and request input on the effects of socioeconomic status and dual-eligible populations on the Medicare Advantage STARS rating system before reforming such system with the input of stakeholders; and

(2) pending the results of such studies and input, to provide for a temporary delay in authority of the Centers for Medicare & Medicaid Services (CMS) to terminate Medicare Advantage plan contracts solely on the basis of performance of plans under the STARS rating system.

(b) DELAY IN MA CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATINGS.—Section 1857(h) of the Social Security Act (42 U.S.C. 1395w–27(h)) is amended by adding at the end the following new paragraph:

"(3) DELAY IN CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATING.—During the period beginning on the date of the enactment of this paragraph and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1853(o)(4).".

SEC. 17002. REQUIREMENT FOR ENROLLMENT DATA REPORTING FOR MEDICARE.

Section 1874 of the Social Security Act (42 U.S.C. 1395kk) is amended by adding at the end the following new subsection:

"(g) REQUIREMENT FOR ENROLLMENT DATA REPORTING.—

"(1) IN GENERAL.—Each year (beginning with 2016), the Secretary shall submit to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on Medicare enrollment data (and, in the case of part A, on data on individuals receiving benefits under such part) as of a date in such year specified by the Secretary. Such data shall be presented—

"(A) by Congressional district and State; and

"(B) in a manner that provides for such data based on—

"(i) fee-for-service enrollment (as defined in paragraph (2));

"(ii) enrollment under part C (including separate for aggregate enrollment in MA–PD plans and aggregate enrollment in MA plans that are not MA–PD plans); and

"(iii) enrollment under part D.

"(2) FEE-FOR-SERVICE ENROLLMENT DEFINED.—For purpose of paragraph (1)(B)(i), the term 'fee-for-service enrollment' means aggregate enrollment (including receipt of benefits other than through enrollment) under—

"(A) part A only;

"(B) part B only; and

"(C) both part A and part B.".

SEC. 17003. UPDATING THE WELCOME TO MEDICARE PACKAGE.

42 USC 1395a note.

(a) IN GENERAL.—Not later than 12 months after the last day of the period for the request of information described in subsection (b), the Secretary of Health and Human Services shall, taking into consideration information collected pursuant to subsection (b), update the information included in the Welcome to Medicare package to include information, presented in a clear and simple manner, about options for receiving benefits under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including through the original medicare fee-for-service program under parts A and B of such title (42 U.S.C. 1395c et seq., 42 U.S.C. 1395j et seq.), Medicare Advantage plans under part C of such title (42 U.S.C. 1395w–21 et seq.), and prescription drug plans under part D of such title (42 U.S.C. 1395w–101 et seq.)). The Secretary shall make subsequent updates to the information included in the Welcome to Medicare package as appropriate.

(b) REQUEST FOR INFORMATION.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall request information, including recommendations, from stakeholders (including patient advocates, issuers, and employers) on information included in the Welcome to Medicare package, including pertinent data and information regarding enrollment and coverage for Medicare eligible individuals.

SEC. 17004. NO PAYMENT FOR ITEMS AND SERVICES FURNISHED BY NEWLY ENROLLED PROVIDERS OR SUPPLIERS WITHIN A TEMPORARY MORATORIUM AREA.

(a) MEDICARE.—Section 1866(j)(7) of the Social Security Act (42 U.S.C. 1395cc(j)(7)) is amended—

(1) in the paragraph heading, by inserting "; NONPAYMENT" before the period; and

(2) by adding at the end the following new subparagraph:

"(C) NONPAYMENT.—

"(i) IN GENERAL.—No payment may be made under this title or under a program described in subparagraph (A) with respect to an item or service described in clause (ii) furnished on or after October 1, 2017.

"(ii) ITEM OR SERVICE DESCRIBED.—An item or service described in this clause is an item or service furnished—

"(I) within a geographic area with respect to which a temporary moratorium imposed under subparagraph (A) is in effect; and

"(II) by a provider of services or supplier that meets the requirements of clause (iii).

"(iii) REQUIREMENTS.—For purposes of clause (ii), the requirements of this clause are that a provider of services or supplier—

"(I) enrolls under this title on or after the effective date of such temporary moratorium; and

"(II) is within a category of providers of services and suppliers (as described in subparagraph (A)) subject to such temporary moratorium.

"(iv) PROHIBITION ON CHARGES FOR SPECIFIED ITEMS OR SERVICES.—In no case shall a provider of services or supplier described in clause (ii)(II) charge an individual or other person for an item or service described in clause (ii) furnished on or after October 1, 2017, to an individual entitled to benefits under part A or enrolled under part B or an individual under a program specified in subparagraph (A).".

(b) CONFORMING AMENDMENTS.—

(1) MEDICAID.—

(A) IN GENERAL.—Section 1903(i)(2) of the Social Security Act (42 U.S.C. 1396b(i)(2)), as amended by section 5005(a)(4), is further amended—

(i) in subparagraph (C), by striking "or" at the end; and

(ii) by adding at the end the following new subparagraph:

"(E) with respect to any amount expended for such an item or service furnished during calendar quarters beginning on or after October 1, 2017, subject to section 1902(kk)(4)(A)(ii)(II), within a geographic area that is subject to a moratorium imposed under section 1866(j)(7) by a provider or supplier that meets the requirements specified in subparagraph (C)(iii) of such section, during the period of such moratorium; or".

(B) EXCEPTION WITH RESPECT TO ACCESS.—Section 1902(kk)(4)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(kk)(4)(A)(ii)) is amended to read as follows:

"(ii) EXCEPTIONS.—

"(I) COMPLIANCE WITH MORATORIUM.—A State shall not be required to comply with a temporary moratorium described in clause (i) if the State determines that the imposition of such temporary moratorium would adversely impact beneficiaries' access to medical assistance.

"(II) FFP AVAILABLE.—Notwithstanding section 1903(i)(2)(E), payment may be made to a State under this title with respect to amounts expended for items and services described in such section if the Secretary, in consultation with the State agency administering the State plan under this title (or a waiver of the plan), determines that denying payment to the State pursuant to such section would adversely impact beneficiaries' access to medical assistance. ".

(C) STATE PLAN REQUIREMENT WITH RESPECT TO LIMITATION ON CHARGES TO BENEFICIARIES.—Section 1902(kk)(4)(A) of the Social Security Act (42 U.S.C. 1396a(kk)(4)(A)) is amended by adding at the end the following new clause:

"(iii) LIMITATION ON CHARGES TO BENEFICIARIES.—With respect to any amount expended for items or services furnished during calendar quarters beginning on or after October 1, 2017, the State prohibits, during

the period of a temporary moratorium described in clause (i), a provider meeting the requirements specified in subparagraph (C)(iii) of section 1866(j)(7) from charging an individual or other person eligible to receive medical assistance under the State plan under this title (or a waiver of the plan) for an item or service described in section 1903(i)(2)(E) furnished to such an individual.".

(2) CORRECTING AMENDMENTS TO RELATED PROVISIONS.—

(A) SECTION 1866(J).—Section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)) is amended—

(i) in paragraph (1)(A)—

(I) by striking "paragraph (4)" and inserting "paragraph (5)";

(II) by striking "moratoria in accordance with paragraph (5)" and inserting "moratoria in accordance with paragraph (7)"; and

(III) by striking "paragraph (6)" and inserting "paragraph (9)"; and

(ii) by redesignating the second paragraph (8) (redesignated by section 1304(1) of Public Law 111–152) as paragraph (9).

(B) SECTION 1902(KK).—Section 1902(kk) of such Act (42 U.S.C. 1396a(kk)) is amended—

(i) in paragraph (1), by striking "section 1886(j)(2)" and inserting "section 1866(j)(2)";

(ii) in paragraph (2), by striking "section 1886(j)(3)" and inserting "section 1866(j)(3)";

(iii) in paragraph (3), by striking "section 1886(j)(4)" and inserting "section 1866(j)(5)"; and

(iv) in paragraph (4)(A), by striking "section 1886(j)(6)" and inserting "section 1866(j)(7)".

SEC. 17005. PRESERVATION OF MEDICARE BENEFICIARY CHOICE UNDER MEDICARE ADVANTAGE.

Section 1851(e)(2) of the Social Security Act (42 U.S.C. 1395w–21(e)(2)) is amended—

(1) in subparagraph (C)—

(A) in the heading, by inserting "FROM 2011 THROUGH 2018" after "45-DAY PERIOD"; and

(B) by inserting "and ending with 2018" after "beginning with 2011"; and

(2) by adding at the end the following new subparagraph:

"(G) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 3 MONTHS IN 2016 AND SUBSEQUENT YEARS.—

"(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D)—

"(I) in the case of an MA eligible individual who is enrolled in an MA plan, at any time during the first 3 months of a year (beginning with 2019); or

"(II) in the case of an individual who first becomes an MA eligible individual during a year (beginning with 2019) and enrolls in an MA plan, during the first 3 months during such year in which the individual is an MA eligible individual;

such MA eligible individual may change the election under subsection (a)(1).

"(ii) LIMITATION OF ONE CHANGE DURING OPEN ENROLLMENT PERIOD EACH YEAR.—An individual may change the election pursuant to clause (i) only once during the applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

"(iii) LIMITED APPLICATION TO PART D.—Clauses (i) and (ii) of this subparagraph shall only apply with respect to changes in enrollment in a prescription drug plan under part D in the case of an individual who, previous to such change in enrollment, is enrolled in a Medicare Advantage plan.

"(iv) LIMITATIONS ON MARKETING.— Pursuant to subsection (j), no unsolicited marketing or marketing materials may be sent to an individual described in clause (i) during the continuous open enrollment and disenrollment period established for the individual under such clause, notwithstanding marketing guidelines established by the Centers for Medicare & Medicaid Services.".

SEC. 17006. ALLOWING END-STAGE RENAL DISEASE BENEFICIARIES TO CHOOSE A MEDICARE ADVANTAGE PLAN.

(a) REMOVING PROHIBITION.—

(1) IN GENERAL.—Section 1851(a)(3) of the Social Security Act (42 U.S.C. 1395w–21(a)(3)) is amended—

(A) by striking subparagraph (B); and

(B) by striking "ELIGIBLE INDIVIDUAL" and all that follows through "In this title, subject to subparagraph (B)," and inserting "ELIGIBLE INDIVIDUAL.—In this title,".

(2) CONFORMING AMENDMENTS.—

(A) Section 1852(b)(1) of the Social Security Act (42 U.S.C. 1395w–22(b)(1)) is amended—

(i) by striking subparagraph (B); and

(ii) by striking "BENEFICIARIES" and all that follows through "A Medicare+Choice organization" and inserting "BENEFICIARIES.—A Medicare Advantage organization".

(B) Section 1859(b)(6) of the Social Security Act (42 U.S.C. 1395w–28(b)(6)) is amended, in the last sentence, by striking "may waive" and all that follows through "subparagraph and".

42 USC 1395w–21 note.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after January 1, 2021.

(b) EXCLUDING COSTS FOR KIDNEY ACQUISITIONS FROM MA BENCHMARK.—Section 1853 of the Social Security Act (42 U.S.C. 1395w–23) is amended—

(1) in subsection (k)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "paragraphs (2) and (4)" and inserting "paragraphs (2), (4), and (5)"; and

(ii) in subparagraph (B)(i), by striking "paragraphs (2) and (4)" and inserting "paragraphs (2), (4), and (5)"; and

(B) by adding at the end the following new paragraph:

"(5) EXCLUSION OF COSTS FOR KIDNEY ACQUISITIONS FROM CAPITATION RATES.—After determining the applicable amount for an area for a year under paragraph (1) (beginning with 2021), the Secretary shall adjust such applicable amount to exclude from such applicable amount the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d)) in the area for the year."; and

(2) in subsection (n)(2)—

(A) in subparagraph (A)(i), by inserting "and, for 2021 and subsequent years, the exclusion of payments for organ acquisitions for kidney transplants from the capitation rate as described in subsection (k)(5)" before the semicolon at the end;

(B) in subparagraph (E), in the matter preceding clause (i), by striking "subparagraph (F)" and inserting "subparagraphs (F) and (G)"; and

(C) by adding at the end the following new subparagraph:

"(G) APPLICATION OF KIDNEY ACQUISITIONS ADJUSTMENT.—The base payment amount specified in subparagraph (E) for a year (beginning with 2021) shall be adjusted in the same manner under paragraph (5) of subsection (k) as the applicable amount is adjusted under such subsection.".

(c) FFS COVERAGE OF KIDNEY ACQUISITIONS.—

(1) IN GENERAL.—Section 1852(a)(1)(B)(i) of the Social Security Act (42 U.S.C. 1395w–22(a)(1)(B)(i)) is amended by inserting "or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)" after "hospice care".

(2) CONFORMING AMENDMENT.—Section 1851(i) of the Social Security Act (42 U.S.C. 1395w–21(i)) is amended by adding at the end the following new paragraph:

"(3) FFS PAYMENT FOR EXPENSES FOR KIDNEY ACQUISITIONS.—Paragraphs (1) and (2) shall not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i).".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after January 1, 2021. 42 USC 1395w–21 note.

(d) EVALUATION OF QUALITY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall conduct an evaluation of whether the 5-star rating system based on the data collected under section 1852(e) of the Social Security Act (42 U.S.C. 1395w–22(e)) should include a quality measure specifically related to care for enrollees in Medicare

Advantage plans under part C of title XVIII of such Act determined to have end-stage renal disease.

(2) PUBLIC AVAILABILITY.—Not later than April 1, 2020, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the results of the evaluation under paragraph (1).

(e) REPORT.—Not later than December 31, 2023, the Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall submit to Congress a report on the impact of the provisions of, and amendments made by, this section with respect to the following:

(1) Spending under—

(A) the original Medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act; and

(B) the Medicare Advantage program under part C of such title.

(2) The number of enrollees determined to have end-stage renal disease—

(A) in the original Medicare fee-for-service program; and

(B) in the Medicare Advantage program.

(3) The sufficiency of the amount of data under the original Medicare fee-for-service program for individuals determined to have end-stage renal disease for purposes of determining payment rates for end-stage renal disease under the Medicare Advantage program.

(f) IMPROVEMENTS TO RISK ADJUSTMENT UNDER MEDICARE ADVANTAGE.—

(1) IN GENERAL.—Section 1853(a)(1) of the Social Security Act (42 U.S.C. 1395w–23(a)(1)) is amended—

(A) in subparagraph (C)(i), by striking "The Secretary" and inserting "Subject to subparagraph (I), the Secretary"; and

(B) by adding at the end the following new subparagraph:

"(I) IMPROVEMENTS TO RISK ADJUSTMENT FOR 2019 AND SUBSEQUENT YEARS.—

"(i) IN GENERAL.—In order to determine the appropriate adjustment for health status under subparagraph (C)(i), the following shall apply:

"(I) TAKING INTO ACCOUNT TOTAL NUMBER OF DISEASES OR CONDITIONS.—The Secretary shall take into account the total number of diseases or conditions of an individual enrolled in an MA plan. The Secretary shall make an additional adjustment under such subparagraph as the number of diseases or conditions of an individual increases.

"(II) USING AT LEAST 2 YEARS OF DIAGNOSTIC DATA.—The Secretary may use at least 2 years of diagnosis data.

"(III) PROVIDING SEPARATE ADJUSTMENTS FOR DUAL ELIGIBLE INDIVIDUALS.—With respect to individuals who are dually eligible for benefits under this title and title XIX, the Secretary shall

make separate adjustments for each of the following:

"(aa) Full-benefit dual eligible individuals (as defined in section 1935(c)(6)).

"(bb) Such individuals not described in item (aa).

"(IV) EVALUATION OF MENTAL HEALTH AND SUBSTANCE USE DISORDERS.—The Secretary shall evaluate the impact of including additional diagnosis codes related to mental health and substance use disorders in the risk adjustment model.

"(V) EVALUATION OF CHRONIC KIDNEY DISEASE.—The Secretary shall evaluate the impact of including the severity of chronic kidney disease in the risk adjustment model.

"(VI) EVALUATION OF PAYMENT RATES FOR END-STAGE RENAL DISEASE.—The Secretary shall evaluate whether other factors (in addition to those described in subparagraph (H)) should be taken into consideration when computing payment rates under such subparagraph.

"(ii) PHASED-IN IMPLEMENTATION.—The Secretary shall phase-in any changes to risk adjustment payment amounts under subparagraph (C)(i) under this subparagraph over a 3-year period, beginning with 2019, with such changes being fully implemented for 2022 and subsequent years.

"(iii) OPPORTUNITY FOR REVIEW AND PUBLIC COMMENT.—The Secretary shall provide an opportunity for review of the proposed changes to such risk adjustment payment amounts under this subparagraph and a public comment period of not less than 60 days before implementing such changes.".

(2) STUDIES AND REPORTS.—

(A) REPORTS ON THE RISK ADJUSTMENT SYSTEM.—

(i) MEDPAC EVALUATION AND REPORT.—

(I) EVALUATION.—The Medicare Payment Advisory Commission shall conduct an evaluation of the impact of the provisions of, and amendments made by, this section on risk scores for enrollees in Medicare Advantage plans under part C of title XVIII of the Social Security Act and payments to Medicare Advantage plans under such part, including the impact of such provisions and amendments on the overall accuracy of risk scores under the Medicare Advantage program.

(II) REPORT.—Not later than July 1, 2020, the Medicare Payment Advisory Commission shall submit to Congress a report on the evaluation under subclause (I), together with recommendations for such legislation and administrative action as the Commission determines appropriate.

(ii) REPORTS BY SECRETARY OF HEALTH AND HUMAN SERVICES.—Not later than December 31, 2018, and every 3 years thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the risk adjustment model and the ESRD risk

42 USC 1395w–23 note.

adjustment model under the Medicare Advantage program under part C of title XVIII of the Social Security Act, including any revisions to either such model since the previous report. Such report shall include information on how such revisions impact the predictive ratios under either such model for groups of enrollees in Medicare Advantage plans, including very high and very low cost enrollees, and groups defined by the number of chronic conditions of enrollees.

(B) STUDY AND REPORT ON FUNCTIONAL STATUS.—

(i) STUDY.—The Comptroller General of the United States (in this subparagraph referred to as the "Comptroller General") shall conduct a study on how to most accurately measure the functional status of enrollees in Medicare Advantage plans and whether the use of such functional status would improve the accuracy of risk adjustment payments under the Medicare Advantage program under part C of title XVIII of the Social Security Act. Such study shall include an analysis of the challenges in collecting and reporting functional status information for Medicare Advantage plans under such part, providers of services and suppliers under the Medicare program, and the Centers for Medicare & Medicaid Services.

(ii) REPORT.—Not later than June 30, 2018, the Comptroller General shall submit to Congress a report containing the results of the study under clause (i), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 17007. IMPROVEMENTS TO THE ASSIGNMENT OF BENEFICIARIES UNDER THE MEDICARE SHARED SAVINGS PROGRAM.

Section 1899(c) of the Social Security Act (42 U.S.C. 1395jjj(c)) is amended—

(1) by striking "utilization of primary" and inserting "utilization of—

"(1) in the case of performance years beginning on or after April 1, 2012, primary";

(2) in paragraph (1), as added by paragraph (1) of this section, by striking the period at the end and inserting "; and";

(3) by adding at the end the following new paragraph:

"(2) in the case of performance years beginning on or after January 1, 2019, services provided under this title by a Federally qualified health center or rural health clinic (as those terms are defined in section 1861(aa)), as may be determined by the Secretary.".

TITLE XVIII—OTHER PROVISIONS

SEC. 18001. EXCEPTION FROM GROUP HEALTH PLAN REQUIREMENTS FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.

(a) AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986 AND THE PATIENT PROTECTION AND AFFORDABLE CARE ACT.—

(1) IN GENERAL.—Section 9831 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

"(d) EXCEPTION FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—

"(1) IN GENERAL.—For purposes of this title (except as provided in section 4980I(f)(4) and notwithstanding any other provision of this title), the term 'group health plan' shall not include any qualified small employer health reimbursement arrangement.

"(2) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this subsection—

"(A) IN GENERAL.—The term 'qualified small employer health reimbursement arrangement' means an arrangement which—

"(i) is described in subparagraph (B), and

"(ii) is provided on the same terms to all eligible employees of the eligible employer.

"(B) ARRANGEMENT DESCRIBED.—An arrangement is described in this subparagraph if—

"(i) such arrangement is funded solely by an eligible employer and no salary reduction contributions may be made under such arrangement,

"(ii) such arrangement provides, after the employee provides proof of coverage, for the payment of, or reimbursement of, an eligible employee for expenses for medical care (as defined in section 213(d)) incurred by the eligible employee or the eligible employee's family members (as determined under the terms of the arrangement), and

"(iii) the amount of payments and reimbursements described in clause (ii) for any year do not exceed $4,950 ($10,000 in the case of an arrangement that also provides for payments or reimbursements for family members of the employee).

"(C) CERTAIN VARIATION PERMITTED.—For purposes of subparagraph (A)(ii), an arrangement shall not fail to be treated as provided on the same terms to each eligible employee merely because the employee's permitted benefit under such arrangement varies in accordance with the variation in the price of an insurance policy in the relevant individual health insurance market based on—

"(i) the age of the eligible employee (and, in the case of an arrangement which covers medical expenses of the eligible employee's family members, the age of such family members), or

"(ii) the number of family members of the eligible employee the medical expenses of which are covered under such arrangement.

The variation permitted under the preceding sentence shall be determined by reference to the same insurance policy with respect to all eligible employees.

"(D) RULES RELATING TO MAXIMUM DOLLAR LIMITATION.—

"(i) AMOUNT PRORATED IN CERTAIN CASES.—In the case of an individual who is not covered by an arrangement for the entire year, the limitation under subparagraph (B)(iii) for such year shall be an amount which bears the same ratio to the amount which would (but for this clause) be in effect for such individual for such year under subparagraph (B)(iii) as the number of months for which such individual is covered by the arrangement for such year bears to 12.

"(ii) INFLATION ADJUSTMENT.—In the case of any year beginning after 2016, each of the dollar amounts in subparagraph (B)(iii) shall be increased by an amount equal to—

"(I) such dollar amount, multiplied by

"(II) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins, determined by substituting 'calendar year 2015' for 'calendar year 1992' in subparagraph (B) thereof.

If any dollar amount increased under the preceding sentence is not a multiple of $50, such dollar amount shall be rounded to the next lowest multiple of $50.

"(3) OTHER DEFINITIONS.—For purposes of this subsection—

"(A) ELIGIBLE EMPLOYEE.—The term 'eligible employee' means any employee of an eligible employer, except that the terms of the arrangement may exclude from consideration employees described in any clause of section 105(h)(3)(B) (applied by substituting '90 days' for '3 years' in clause (i) thereof).

"(B) ELIGIBLE EMPLOYER.—The term 'eligible employer' means an employer that—

"(i) is not an applicable large employer as defined in section 4980H(c)(2), and

"(ii) does not offer a group health plan to any of its employees.

"(C) PERMITTED BENEFIT.—The term 'permitted benefit' means, with respect to any eligible employee, the maximum dollar amount of payments and reimbursements which may be made under the terms of the qualified small employer health reimbursement arrangement for the year with respect to such employee.

"(4) NOTICE.—

"(A) IN GENERAL.—An employer funding a qualified small employer health reimbursement arrangement for any year shall, not later than 90 days before the beginning of such year (or, in the case of an employee who is not eligible to participate in the arrangement as of the beginning of such year, the date on which such employee is first so eligible), provide a written notice to each eligible employee which includes the information described in subparagraph (B).

"(B) CONTENTS OF NOTICE.—The notice required under subparagraph (A) shall include each of the following:

"(i) A statement of the amount which would be such eligible employee's permitted benefit under the arrangement for the year.

"(ii) A statement that the eligible employee should provide the information described in clause (i) to any health insurance exchange to which the employee applies for advance payment of the premium assistance tax credit.

"(iii) A statement that if the employee is not covered under minimum essential coverage for any month the employee may be subject to tax under section 5000A for such month and reimbursements under the arrangement may be includible in gross income.".

(2) LIMITATION ON EXCLUSION FROM GROSS INCOME.—Section 106 of such Code is amended by adding at the end the following:

"(g) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this section and section 105, payments or reimbursements from a qualified small employer health reimbursement arrangement (as defined in section 9831(d)) of an individual for medical care (as defined in section 213(d)) shall not be treated as paid or reimbursed under employer-provided coverage for medical expenses under an accident or health plan if for the month in which such medical care is provided the individual does not have minimum essential coverage (within the meaning of section 5000A(f)).".

(3) COORDINATION WITH HEALTH INSURANCE PREMIUM CREDIT.—Section 36B(c) of such Code is amended by adding at the end the following new paragraph:

"(4) SPECIAL RULES FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—

"(A) IN GENERAL.—The term 'coverage month' shall not include any month with respect to an employee (or any spouse or dependent of such employee) if for such month the employee is provided a qualified small employer health reimbursement arrangement which constitutes affordable coverage.

"(B) DENIAL OF DOUBLE BENEFIT.—In the case of any employee who is provided a qualified small employer health reimbursement arrangement for any coverage month (determined without regard to subparagraph (A)), the credit otherwise allowable under subsection (a) to the taxpayer for such month shall be reduced (but not below zero) by the amount described in subparagraph (C)(i)(II) for such month.

"(C) AFFORDABLE COVERAGE.—For purposes of subparagraph (A), a qualified small employer health reimbursement arrangement shall be treated as constituting affordable coverage for a month if—

"(i) the excess of—

"(I) the amount that would be paid by the employee as the premium for such month for self-only coverage under the second lowest cost silver plan offered in the relevant individual health insurance market, over

"(II) 1/12 of the employee's permitted benefit (as defined in section 9831(d)(3)(C)) under such arrangement, does not exceed—

"(ii) 1/12 of 9.5 percent of the employee's household income.

"(D) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this paragraph, the term 'qualified small employer health reimbursement arrangement' has the meaning given such term by section 9831(d)(2).

"(E) COVERAGE FOR LESS THAN ENTIRE YEAR.—In the case of an employee who is provided a qualified small employer health reimbursement arrangement for less than an entire year, subparagraph (C)(i)(II) shall be applied by substituting 'the number of months during the year for which such arrangement was provided' for '12'.

"(F) INDEXING.—In the case of plan years beginning in any calendar year after 2014, the Secretary shall adjust the 9.5 percent amount under subparagraph (C)(ii) in the same manner as the percentages are adjusted under subsection (b)(3)(A)(ii).".

(4) APPLICATION OF EXCISE TAX ON HIGH COST EMPLOYER-SPONSORED HEALTH COVERAGE.—

(A) IN GENERAL.—Section 4980I(f)(4) of such Code is amended by adding at the end the following: "Section 9831(d)(1) shall not apply for purposes of this section.".

(B) DETERMINATION OF COST OF COVERAGE.—Section 4980I(d)(2) of such Code is amended by redesignating subparagraph (D) as subparagraph (E) and by inserting after subparagraph (C) the following new subparagraph:

"(D) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—In the case of applicable employer-sponsored coverage consisting of coverage under any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2)), the cost of coverage shall be equal to the amount described in section 6051(a)(15).".

(5) ENFORCEMENT OF NOTICE REQUIREMENT.—Section 6652 of such Code is amended by adding at the end the following new subsection:

"(o) FAILURE TO PROVIDE NOTICES WITH RESPECT TO QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—In the case of each failure to provide a written notice as required by section 9831(d)(4), unless it is shown that such failure is due to reasonable cause and not willful neglect, there shall be paid, on notice and demand of the Secretary and in the same manner as tax, by the person failing to provide such written notice, an amount equal to $50 per employee per incident of failure to provide such notice, but the total amount imposed on such person for all such failures during any calendar year shall not exceed $2,500.".

(6) REPORTING.—

(A) W–2 REPORTING.—Section 6051(a) of such Code is amended by striking "and" at the end of paragraph (13), by striking the period at the end of paragraph (14) and inserting ", and", and by inserting after paragraph (14) the following new paragraph:

"(15) the total amount of permitted benefit (as defined in section 9831(d)(3)(C)) for the year under a qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2)) with respect to the employee.".

(B) INFORMATION REQUIRED TO BE PROVIDED BY EXCHANGE SUBSIDY APPLICANTS.—Section 1411(b)(3) of the Patient Protection and Affordable Care Act is amended

by redesignating subparagraph (B) as subparagraph (C) and by inserting after subparagraph (A) the following new subparagraph:

"(B) CERTAIN INDIVIDUAL HEALTH INSURANCE POLICIES OBTAINED THROUGH SMALL EMPLOYERS.—The amount of the enrollee's permitted benefit (as defined in section 9831(d)(3)(C) of the Internal Revenue Code of 1986) under a qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of such Code).".

(7) EFFECTIVE DATES.— 26 USC 36B note.

(A) IN GENERAL.—Except as otherwise provided in this paragraph, the amendments made by this subsection shall apply to years beginning after December 31, 2016.

(B) TRANSITION RELIEF.—The relief under Treasury Notice 2015–17 shall be treated as applying to any plan year beginning on or before December 31, 2016.

(C) COORDINATION WITH HEALTH INSURANCE PREMIUM CREDIT.—The amendments made by paragraph (3) shall apply to taxable years beginning after December 31, 2016.

(D) EMPLOYEE NOTICE.—

(i) IN GENERAL.—The amendments made by paragraph (5) shall apply to notices with respect to years beginning after December 31, 2016.

(ii) TRANSITION RELIEF.—For purposes of section 6652(o) of the Internal Revenue Code of 1986 (as added by this Act), a person shall not be treated as failing to provide a written notice as required by section 9831(d)(4) of such Code if such notice is so provided not later than 90 days after the date of the enactment of this Act.

(E) W–2 REPORTING.—The amendments made by paragraph (6)(A) shall apply to calendar years beginning after December 31, 2016.

(F) INFORMATION PROVIDED BY EXCHANGE SUBSIDY APPLICANTS.—

(i) IN GENERAL.—The amendments made by paragraph (6)(B) shall apply to applications for enrollment made after December 31, 2016.

(ii) VERIFICATION.—Verification under section 1411 of the Patient Protection and Affordable Care Act of information provided under section 1411(b)(3)(B) of such Act shall apply with respect to months beginning after October 2016.

(iii) TRANSITIONAL RELIEF.—In the case of an application for enrollment under section 1411(b) of the Patient Protection and Affordable Care Act made before April 1, 2017, the requirement of section 1411(b)(3)(B) of such Act shall be treated as met if the information described therein is provided not later than 30 days after the date on which the applicant receives the notice described in section 9831(d)(4) of the Internal Revenue Code of 1986.

(8) SUBSTANTIATION REQUIREMENTS.—The Secretary of the Treasury (or his designee) may issue substantiation requirements as necessary to carry out this subsection. 26 USC 36B note.

(b) AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(1) IN GENERAL.—Section 733(a)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(a)(1)) is amended by adding at the end the following: "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

(2) EXCEPTION FROM CONTINUATION COVERAGE REQUIREMENTS, ETC.—Section 607(1) of such Act (29 U.S.C. 1167(1)) is amended by adding at the end the following: "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

29 USC 1167 note.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning after December 31, 2016.

(c) AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.—

(1) IN GENERAL.—Section 2791(a)(1) of the Public Health Service Act (42 U.S.C. 300gg–91(a)(1)) is amended by adding at the end the following: "Except for purposes of part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.), such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

(2) EXCEPTION FROM CONTINUATION COVERAGE REQUIREMENTS.—Section 2208(1) of the Public Health Service Act (42 U.S.C. 300bb–8(1)) is amended by adding at the end the following: "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

42 USC 300bb–8 note.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning after December 31, 2016.

Approved December 13, 2016.

LEGISLATIVE HISTORY—H.R. 34:

SENATE REPORTS: No. 114–146 (Comm. on Commerce, Science, and Transportation).

CONGRESSIONAL RECORD:

Vol. 161 (2015): Jan. 7, considered and passed House.
Oct. 6, considered and passed Senate, amended.

Vol. 162 (2016): Nov. 30, House concurred in Senate amendment with an amendment.
Dec. 1, 5–7, Senate considered and concurred in House amendment.

DAILY COMPILATION OF PRESIDENTIAL DOCUMENTS (2016):
Dec. 13, Presidential remarks.

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Guidance for Industry and FDA Staff

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Document issued on: May 11, 2005

This document supersedes Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 29, 1998, and Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software, issued January 13, 1997.

For questions regarding this document concerning devices regulated by CDRH contact Linda Ricci at (301) 796-6325. For questions regarding this document concerning devices regulated by CBER contact Linda Weir at (301) 827-6136.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation
Office of In Vitro Diagnostics

Center for Biologics Evaluation and Research
Office of Blood Research and Review

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089543.htm,
You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (337) to identify the guidance you are requesting.

CBER

Additional copies of this guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Rockville, MD 20852-1448 or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm.

Table of Contents

Guidance for Industry and FDA Staff

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This guidance document is intended to provide information to industry regarding the documentation that we recommend you include in premarket submissions for software devices, including stand-alone software applications and hardware-based devices that incorporate software. This document is a result of ongoing efforts to state our recommendations more clearly and ensure they remain current as technology advances. This document also combines into one guidance recommendations previously included in two guidance documents.[i]

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe should be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the guidance, **A Suggested Approach to Resolving Least Burdensome Issues,** http://www.fda.gov/cdrh/modact/leastburdensome.html.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Scope

For the purposes of this document, we refer to devices that contain one or more software components, parts, or accessories, or are composed solely of software as "software devices," including:

- firmware and other means for software-based control of medical devices
- stand-alone software applications
- software intended for installation in general-purpose computers
- dedicated hardware/software medical devices.
- accessories to medical devices when those accessories contain or are composed of software.

This guidance applies to software devices regardless of the means by which the software is delivered to the end user, whether factory-installed, installed by a third-party vendor, or field-installed or -upgraded.

Software not covered by this guidance includes software designed for manufacturing or other process-control functions but not intended for use as a device. For further information or to clarify the requirements for your device, please contact the responsible FDA review division.

This guidance document applies to all types of premarket submissions for software devices, including:

- Premarket Notification (510(k)) including Traditional, Special, and Abbreviated submissions
- Premarket Approval Application (PMA)
- Investigational Device Exemption (IDE)
- Humanitarian Device Exemption (HDE), including amendments and supplements.

Relationship to Other Documents

FDA Guidance Documents

We intend this document to complement other existing guidance documents that provide recommendations related to software. For example, we recommend that you also refer to the guidance "General Principles of Software Validation"[ii] for recommendations on software related to a device (including software that is a stand-alone device or that is a component, part, or accessory of a device). We recommend that you refer to the "Guidance for Off-the-Shelf Software Use in Medical Devices"[iii] in cases where your device uses off-the-shelf software.

Manufacturers of Software Devices should create and maintain software-related documentation in accordance with the requirements of the Quality System Regulation[iv] (QS regulation) (21 CFR part 820). As with other FDA guidance documents that provide recommendations, please note that following the recommendations of this guidance is not a substitute for compliance with the QS regulation.

Software-Related Consensus Standards

The emergence of consensus standards related to software has helped to improve the consistency and quality of software development and documentation, particularly with respect to critical activities such as risk assessment and management. When possible, we harmonized the terminology and recommendations in this guidance with software-related consensus standards such as ISO 14971[v] and AAMI SW68.[vi]

Terminology

Verification and Validation

This document uses the terms "verification" and "validation" (also referred to as "V&V") as they are defined in the QS regulation.[iv]

Verification "means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled." 21 CFR 820.3(aa). In a software development environment, software verification is confirmation that the output of a particular phase of development meets all of the input requirements for that phase. Software testing is one of several verification activities intended to confirm that the software development output meets its input requirements. Other verification activities include:

- walk-throughs
- various static and dynamic analyses
- code and document inspections

- module level testing
- integration testing.

Design validation "means establishing by objective evidence that device specifications conform with user needs and intended use(s)." 21 CFR 820.3(z)(2). Use of the term validation in this document is limited to design validation and does not include process validation as defined in 21 CFR 820.3(z)(1).

One component of design validation is software validation. Software validation refers to establishing, by objective evidence, that the software conforms with the user needs and intended uses of the device. Software validation is a part of design validation of the finished device. It involves checking for proper operation of the software in its actual or simulated use environment, including integration into the final device where appropriate. Software validation is highly dependent upon comprehensive software testing and other verification tasks previously completed at each stage of the software development life cycle. Planning, verification, traceability, configuration management, and many other aspects of good software engineering are important activities that together help to support a conclusion that software is validated.

Minor and Serious Injuries

For the purposes of this document, we use the term minor injury to mean any injury that does not meet the definition of a serious injury as defined in 21 CFR 803.3(bb)(1). This regulation defines serious injury as an injury or illness that:

i. is life threatening;

ii. results in permanent impairment of a body function or permanent damage to a body structure; or

iii. necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

For the purposes of this document, the term permanent is defined as "irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage." 21 CFR 803.3(bb)(2).

Level of Concern

Introduction

The documentation that we recommend you include in a premarket submission generally depends on the device's Level of Concern. For the purposes of this guidance document, Level of Concern refers to an estimate of the severity of injury that a device could permit or inflict, either directly or indirectly, on a patient or operator as a result of device failures, design flaws,

or simply by virtue of employing the device for its intended use. We recommend that you describe the role of the software in causing, controlling, and/or mitigating hazards that could result in injury to the patient or the operator, because this is also a factor in determining the appropriate Level of Concern for your device.

The extent of documentation that we recommend you submit for your Software Device is proportional to the Level of Concern associated with the device. Level of Concern is defined only for use in this context and is not related to device classification (Class I, II or III) or to hazard or risk analysis *per se*.

Major, Moderate, or Minor Level of Concern

The following sections provide recommendations for determining the Level of Concern that may be appropriate for your Software Device and recommendations for documentation that you should submit for each Level of Concern. We recommend that you determine the Level of Concern before any mitigation of relevant hazards. In other words, the Level of Concern should be driven by the hazard analysis in the absence of mitigations, regardless of the effects of the mitigations on the individual hazards.

FDA recommends that you state in your submission the Level of Concern you have determined for your Software Device. It may be Major, Moderate or Minor as defined below. We also recommend that you describe how you arrived at that Level of Concern. The Level of Concern is based on how the operation of the software associated with device function affects the patient or operator. The effect may be direct or indirect.

Major

We believe the level of concern is Major if a failure or latent flaw could directly result in death or serious injury to the patient or operator. The level of concern is also Major if a failure or latent flaw could indirectly result in death or serious injury of the patient or operator through incorrect or delayed information or through the action of a care provider.

Moderate

We believe the level of concern is Moderate if a failure or latent design flaw could directly result in minor injury to the patient or operator. The level of concern is also Moderate if a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Minor

We believe the level of concern is Minor if failures or latent design flaws are unlikely to cause any injury to the patient or operator.

Determining Level of Concern

We have provided the following key questions to assist you in determining the Level of Concern. We recommend that you assess the Level of Concern before mitigating any hazard; that is, you should assess your software device against these questions as though you have not implemented hazard mitigations.

If the answer to any question is No, continue on to the next question. As discussed in more detail later, we recommend that you include the basis for your conclusion as to the Level of Concern in your submission. In all cases, we recommend that you assess the Level of Concern within the context of the worst possible, reasonably foreseeable, clinical consequences of failure of the Software Device.

Table 1 Major Level of Concern

If the answer to any <u>one</u> question below is Yes, the Level of Concern for the Software Device is likely to be Major.
1. Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)
2. Is the Software Device intended to be used in combination with a drug or biologic?
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:
a. Does the Software Device control a life supporting or life sustaining function?

b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

Table 2 Moderate Level of Concern

If the Software Device is not Major Level of Concern and the answer to any <u>one</u> question below is Yes, the Level of Concern is likely to be Moderate.
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.

The review divisions at FDA are available to discuss any questions you may have about the Level of Concern for your Software Device. If you believe the Level of Concern for your device is Major and you have not previously filed a premarket submission for this type of Software Device, we recommend that you contact the appropriate division at FDA to discuss your Software Device before filing your submission.

Software-related Documentation

Software-related documentation that you provide in your premarket submission should be consistent with the intended use of the Software Device, the Level of Concern, and the type of submission. This section describes the documentation that we recommend you include in your premarket submission based on the Level of Concern (see Table 3). However, you should follow the recommendations in device-specific guidance, if available for your device. In general, the documentation provided in your submission should:

- describe the design of your device
- document how your design was implemented
- demonstrate how the device produced by your design implementation was tested
- show that you identified hazards appropriately and managed risks effectively
- provide traceability to link together design, implementation, testing, and risk management.

The type and extent of documentation that we recommend you submit is summarized in Table 3. Our recommendations are keyed to the Level of Concern of your device. These recommendations are predicated on your effective implementation and management of the QSR, including Design Controls.[iv]

We believe the documents that we recommend submitting will generally be the same documents that you would normally generate during the development of a Software Device. Therefore, in a properly managed and documented medical device software development environment, the documents that you submit in response to the recommendations in this guidance may be copies of your product development documents.

We explain the documents that we recommend submitting in the sections following Table 3. In some instances, the recommended documentation for the Level of Concern may take the form of statements in the body of the submission; other documents, such as the Software Requirements Specification, will likely be stand-alone documents copied into the submission.

Table 3. Documentation Based on Level of Concern

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.		
Software Description	A summary overview of the features and software operating environment.		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	The complete SRS document.	
Architecture Design Chart	No documentation is necessary in the submission.	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	
Software Design Specification (SDS)	No documentation is necessary in the submission.	Software design specification document.	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		
Software Development Environment Description	No documentation is necessary in the submission.	Summary of software life cycle development plan, including a summary of the configuration management and	Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
		maintenance activities.	configuration management and maintenance plan documents.
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.	Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.
Revision Level History	Revision history log, including release version number and date.		
Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the submission.	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.	

Level of Concern

We recommend that you indicate the Level of Concern for your Software Device, determined before the effects of any mitigations. We recommend that you clearly state which one of the three levels of concern is appropriate for your device and include documentation of the rationale for your decision. We also recommend that your documentation make your decision-making process apparent to FDA.

Software Description

We recommend that you provide a comprehensive overview of the device features that are controlled by software, and describe the intended operational environment. Generally, we

recommend that you provide the information in paragraph format and highlight major or operationally significant software features. The software description should include information on the following:

- programming language
- hardware platform
- operating system (if applicable)
- use of Off-the-Shelf software (if applicable).

If your device uses Off-the Shelf software, please refer to the FDA guidance document "Guidance for Off-the-Shelf Software Use in Medical Devices."[iii]

If this information is included in another document, such as the Software Requirements Specification, your submission should contain an annotation and a reference to the document in the submission where this information is located.

Device Hazard Analysis

We recommend that you submit a Device Hazard Analysis for all Software Devices. The Device Hazard Analysis should take into account all device hazards associated with the device's intended use, including both hardware and software hazards. We recommend that you present the information in tabular form with a line item for each identified hazard. This document can be in the form of an extract of the software-related items from a comprehensive risk management document, such as the Risk Management Summary described in ISO 14971.[v] In this format, each line item should include:

- identification of the hazardous event
- severity of the hazard
- cause(s) of the hazard
- method of control (e.g., alarm, hardware design)
- corrective measures taken, including an explanation of the aspects of the device design/requirements, that eliminate, reduce, or warn of a hazardous event; and
- verification that the method of control was implemented correctly.

When performing a hazard analysis, we recommend that you address all foreseeable hazards, including those resulting from intentional or inadvertent misuse of the device.

Software Requirements Specification

The Software Requirements Specification (SRS) documents the requirements for the software. This typically includes functional, performance, interface, design, developmental, and other requirements for the software. In effect, this document describes what the Software Device is supposed to do. Examples of some typical requirements that would be included in a SRS are

described below. For Software Devices that are identified as Minor Level of Concern, we recommend that you provide only the summary functional requirements section from the SRS, including identification of off-the-shelf software. For Software Devices that are identified as Major or Moderate Level of Concern, we recommend that you provide the complete SRS document.

Hardware Requirements

Hardware requirements generally include:

- microprocessors
- memory devices
- sensors
- energy sources
- safety features
- communications.

Programming Language Requirements

Programming language requirements include program size requirements or restrictions, and information on management of memory leaks.

Interface Requirements

Interface requirements generally include both communication between system components and communication with the user such as:

- printers
- monitors
- keyboard
- mouse.

Software Performance and Functional Requirements

Software performance and functional requirements include algorithms or control characteristics for therapy, diagnosis, monitoring, alarms, analysis, and interpretation with full text references or supporting clinical data, if necessary. Software performance and functional requirements may also include:

- device limitations due to software
- internal software tests and checks
- error and interrupt handling
- fault detection, tolerance, and recovery characteristics

- safety requirements
- timing and memory requirements
- identification of off-the-shelf software, if appropriate.

Architecture Design Chart

This document is typically a flowchart or similar depiction of the relationships among the major functional units in the Software Device, including relationships to hardware and to data flows such as networking. It is usually not necessary to include every function call and module in this document; however, there should be sufficient information to allow for review of the organization of the software relative to the functionality and to the intended use of the Software Device. For Moderate and Major Level of Concern devices, detailed information such as state diagrams may be useful to clearly depict the relationships among the software functional units. If the Architecture Design Chart is included in another document such as the SRS then you should include in your submission a statement to that effect and a reference to the location of the Architecture Design Chart in the submission.

Software Design Specification

The Software Design Specification (SDS) describes the implementation of the requirements for the Software Device. In terms of the relationship between the SRS and the SDS, the SRS describes what the Software Device will do and the SDS describes how the requirements in the SRS are implemented. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the Software Device was clear and unambiguous, with minimal ad hoc design decisions. The SDS may contain references to other documents, such as detailed software specifications. However, the document you submit should, in and of itself, provide adequate information to allow for review of the implementation plan for the software requirements in terms of intended use, functionality, safety, and effectiveness.

Traceability Analysis

A Traceability Analysis links together your product design requirements, design specifications, and testing requirements. It also provides a means of tying together identified hazards with the implementation and testing of the mitigations. We recommend that you submit for review explicit traceability among these activities and associated documentation because they are essential to effective product development and to our understanding of product design, development and testing, and hazard mitigations. The Traceability Analysis commonly consists of a matrix with line items for requirements, specifications and tests, and pointers to hazard mitigations. It is possible to document traceability simply through a shared organizational

structure with a common numbering scheme; however, we recommend that you include some mechanism, such as a matrix for guiding the reviewer through the information you submit.

Software Development Environment Description

For Moderate and Major Level of Concern Software Devices, the submission should include a summary of the software development life cycle plan. This summary should describe the sponsor's software development life cycle and the processes that are in place to manage the various life cycle activities. For Major Level of Concern Software Devices, this document should also include an annotated list of the control/baseline documents generated during the software development process and a list or description of software coding standards.

As mentioned elsewhere, configuration or change management is a crucial aspect of software development. Changes to the Software Device after initial market release should be subject to positive control, with definitive specification and test plans including well-defined regression testing where appropriate. The description of the development environment should provide information on your configuration management and maintenance plan that addresses these aspects of the software development life cycle. For a Major Level of Concern device, we recommend that you provide sufficient detail to allow for a thorough understanding of the configuration management and maintenance plan. For a Moderate Level of Concern device, we recommend that you provide only a summary of the configuration management and maintenance plans.

Verification and Validation Documentation

The terms "verification" and "validation" described earlier in this document refer to two phases of Software Device testing. This section recommends the type of testing documentation you should include in a premarket submission for a Software Device, based on the Level of Concern.

Minor Level of Concern Devices

For Minor Level of Concern devices, we recommend that you submit documentation of system or device level testing, and, where appropriate, integration testing. The documentation submitted should include system or device level test pass/fail criteria and a summary of the test results.

Moderate Level of Concern Devices

For Moderate Level of Concern devices, we recommend that you submit a summary list of validation and verification activities and the results of these activities. We also recommend that you submit your pass/fail criteria. You should ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications.

Major Level of Concern Devices

For Major Level of Concern devices, we recommend that you submit the information recommended above for Moderate Level of Concern devices and a description of any tests that were not passed. We also recommend that you include any modifications made in response to failed tests and documentation of results demonstrating that the modifications were effective. Documentation provided in your submission should include examples of unit integration testing and a summary of the results.

Revision Level History

Your submission should include the history of software revisions generated during the course of product development. This typically takes the form of a line-item tabulation of the major changes to the software during the development cycle, including date, version number, and a brief description of the changes in the version relative to the previous version. The last entry in the list should be the final version to be incorporated in the released device. This entry should also include any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

Unresolved Anomalies (Bugs or Defects)

For Moderate and Major Level of Concern Software Devices, the submission should include a list of all unresolved software anomalies. For each anomaly, we recommend that you indicate the:

- problem
- impact on device performance
- any plans or timeframes for correcting the problem (where appropriate).

We recommend that you annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. Typically, this list can be generated as an output of a change control board or similar mechanism for evaluation and disposition of unresolved software anomalies. We recommend that you communicate this list to the end user as appropriate to assist in the proper operation of the device. In all instances where it is practical to do so, you should include any mitigations or possible work-arounds for unresolved anomalies; this recommendation applies to Blood Establishment Computer Software in particular.

The Special 510(k) Program

For a premarket submission to qualify for review under the Special 510(k) Program, the device should be a modification of your 510(k) cleared device that you own, where the modification does

not alter the intended use or the fundamental scientific technology of the device[vii]. In a Special 510(k), you should follow the recommendations in this guidance on the documentation to submit, but submit only the documentation related to the modification that prompted the submission. For example, when submitting the documentation of requirements and specifications in a Special 510(k), the documentation should focus on the modifications and may not necessarily include all of the requirements and specifications of the entire device.

We recommend that you submit the regression testing performed to verify and validate the modifications. We recommend that you submit your test plans, pass/fail criteria, and summary results rather than test data. In all cases, the type of software-related documentation and the level of detail you provide should be appropriate to the Level of Concern associated with your device in the context of the modifications. Since a Special 510(k) submission relies on your declaration of conformance to design controls, we believe you cannot properly submit a Special 510(k) until you have completed testing or other activities relied on by your declaration (see section 514(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. 360d(c)(1)(B)).

The Abbreviated 510(k) Program

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87. In an Abbreviated 510(k), FDA may consider the contents of the documentation recommended in this guidance to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g). Therefore, we recommend that you submit the documentation described in this guidance.[viii]

If you choose to rely on an FDA-recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the product is marketed; or
- declaration of conformity to the standard.[ix]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance, "Use of Standards in Substantial Equivalence Determinations."[x]

If you declare conformance to a standard that recommends specific tests or testing methods for your Software Device, we recommend that you submit documentation of pass/fail criteria and associated test results along with your declaration of conformance. We also recommend that you list deviations from the tests and test methods specified in the standard and explain these deviations in terms of the impact on the safety and effectiveness of the Software Device. A list of FDA recognized consensus standards is available on the CDRH web site.[xi]

Additional Topics

Risk Assessment and Management

Background

Inadequate or inappropriate software development life cycle and risk management activities, inappropriate use of a Software Device, or operational errors can result in a variety of potential failures or design flaws. Among these are unsafe or ineffective delivery of energy, drugs, and life-supporting or life-sustaining functions. The delivery of incorrect or incomplete information causing a misdiagnosis or selection of the wrong treatment or therapy is also a potential failure associated with certain Software Devices. Therefore, the risks associated with potential failures or design flaws are a concern during the review of Software Devices.

Risk Assessment and Level of Concern

As mentioned earlier, your assessment of the risks associated with your Software Device should assist you in determining an appropriate Level of Concern. We also recommend that you consider the Level of Concern for other devices of the same generic type or intended use. If you believe a different Level of Concern is appropriate for your device, we recommend that you submit a detailed explanation of your rationale.

Risk Management

The risk associated with Software Devices varies over a continuum from negligible to very severe. In general, FDA considers risk as the product of the severity of injury and the probability of its occurrence. However, software failures are systemic in nature and therefore the probability of occurrence cannot be determined using traditional statistical methods. Therefore, we recommend that you base your estimation of risk for your Software Device on the severity of the hazard resulting from failure, assuming that the failure will occur. We also recommend that you use risk identification and control techniques described in consensus standards such as ISO 14971.[v]

Software Change Management

Design, development, testing, and version control of revisions to the software are as important as development and testing of the software that was reviewed in the premarket submission. We believe the majority of software-related device problems that occur in the field, including software-related device recalls, happen to devices that are running software that has been revised since premarket review. In some instances, revisions that did not require FDA review were implicated in adverse events and recalls.[xii] We believe this indicates the need for careful control of software revisions.

Blood Establishment Computer Software

In premarket submissions for Blood Establishment Computer Software, you should submit a complete copy of the User's Manual as it will be provided to the user, including, but not limited to, a description of all limitations. Additionally, you should submit the documentation you will provide to the user to describe all outstanding anomalies or software defects with corresponding workarounds, where applicable, if these issues are not addressed in the User's Manual.

Software of Unknown Pedigree (SOUP)

Some or all of the software contained in a Software Device may have been obtained by the submitter from a third party. The type and quality of documentation that accompanies this software can vary considerably. Software for which adequate documentation may be difficult to obtain is referred to as Software of Unknown Pedigree or "SOUP."

It may be difficult for you to obtain, generate, or reconstruct appropriate design documentation as described in this guidance for SOUP. Therefore, we recommend that you explain the origin of the software and the circumstances surrounding the software documentation. Additionally, your Hazard Analysis should encompass the risks associated with the SOUP regarding missing or incomplete documentation or lack of documentation of prior testing. Nonetheless, the responsibility for adequate testing of the device and for providing appropriate documentation of software test plans and results remains with you.

Virus Protection Software

Software applications designed to protect information systems, including Software Devices, from harmful or malicious code ("viruses," "worms," etc.) are becoming more commonplace as devices become increasingly interconnected and therefore exposed to the external information environment. Issues related to installation and testing of virus protection software are beyond the scope of this document. You may contact the CDRH Office of Compliance for more information on this topic.

Interfaces, Networking, and Network Infrastructure

As mentioned above, Software Devices are increasingly interconnected, both through point-to-point interfaces for exchange of specific data with specific devices and by connection to local and wide area networks and the Internet. While data exchange and communication infrastructure such as telephone lines, local area networks, and broadband connections are not regulated as medical devices, connection to these carriers affects the operation of Software Devices, sometimes adversely. An example is a Software Device that is connected to a local area network and ceases to operate properly when a problem occurs with the network interface. We recommend that your software design should take into account both the capabilities and liabilities of the interfaces provided with your device, and in particular that your hazard analysis and mitigations encompass these issues.

Combination Products

Generally, the recommendations of this guidance will apply to the device component of combination products (such as drug-device and biologics-device combinations) when the device component meets the definition of a Software Device. For more information, you may contact the Office of Combination Products or the FDA review division that will have the lead review for your combination product.

References

[i] This document combines the recommendations in "Guidance for FDA Reviewers and Industry: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 29, 1998, and "Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software" issued on January 13, 1997.

[ii] "General Principles of Software Validation," http://www.fda.gov/cdrh/comp/guidance/938.html.

[iii] "Guidance for Off-the-Shelf Software Use in Medical Devices" http://www.fda.gov/cdrh/ode/guidance/585.pdf.

[iv] 21 CFR 820.30 Subpart C – Design Controls of the Quality System Regulation.

[v] ISO 14971-1; Medical devices - Risk management - Part 1: Application of risk analysis.

[vi] AAMI SW68:2001; Medical device software - Software life cycle processes.

[vii] See "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance," available on the FDA Web site at http://www.fda.gov/cdrh/ode/parad510.html.

[viii] For more information see Device Advice, "How to Prepare an Abbreviated 510(k)," http://www.fda.gov/cdrh/devadvice/3145.html, in particular the section titled "Information Required in an Abbreviated 510(k)."

[ix] See "Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions)," http://www.fda.gov/cdrh/ode/reqrecstand.html.

[x] See "Use of Standards in Substantial Equivalence Determinations," http://www.fda.gov/cdrh/ode/guidance/1131.html.

[xi] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

[xii] For information on determining when revisions to software should result in a new premarket submission, you should consult the relevant FDA guidances such as "Deciding When to Submit

a 510(k) for a Change to an Existing Device," http://www.fda.gov/cdrh/ode/510kmod.html. See also 21 CFR 807.81(a)(3).

Contains Nonbinding Recommendations

Deciding When to Submit a 510(k) for a Software Change to an Existing Device

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Guidance for Industry and Food and Drug Administration Staff

Document issued on October 25, 2017.

The draft of this document was issued on August 8, 2016.

For questions about this document, contact (CDRH) Linda Ricci, Office of Device Evaluation, 301-796-6325, Linda.Ricci@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2016-D-2021. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1500055 to identify the guidance you are requesting.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835 4709 or 240-402-8010, by email, ocod@fda.hhs.gov or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Table of Contents

Deciding When to Submit a 510(k) for a Software Change to an Existing Device

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance will assist industry and Agency staff in determining when a software (including firmware) change to a medical device may require a manufacturer to submit and obtain FDA clearance of a new premarket notification (510(k)). This guidance is not intended to implement significant policy changes to FDA's current thinking on when submission of a new 510(k) is required for a software change to a 510(k)-cleared device (or group of devices) or other device subject to 510(k) requirements, such as a preamendments device or a device that was granted marketing authorization via the De Novo classification process under section 513(f)(2) of the Food, Drug, and Cosmetic Act (FD&C Act) (also referred to together as "existing devices"). Rather, the intent of this guidance is to enhance the predictability, consistency, and transparency of the "when to submit" decision-making process by providing a least burdensome approach, and describing in greater detail the regulatory framework, policies, and practices underlying such a decision, specifically as it relates to software changes.

For the current edition of the FDA-recognized standards referenced in this document, see the FDA Recognized Consensus Standards Database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

The regulatory criteria in 21 CFR 807.81(a)(3) state that a premarket notification must be submitted when:

> *(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:*
>
> > *(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.*
> >
> > *(ii) A major change or modification in the intended use of the device.*

FDA issued the original guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)* on January 10, 1997 to provide guidance on this regulatory language. As stated in that guidance, the key issue in the interpretation of 21 CFR 807.81(a)(3) is that the phrase "could significantly affect the safety or effectiveness of the device" and the use of the adjectives "major" and "significant" sometimes lead FDA and device manufacturers to different interpretations. The original guidance provided the Agency's interpretation of these terms, with principles and points for manufacturers to consider in analyzing how changes in devices may affect safety or effectiveness and determining whether a new 510(k) must be submitted for a particular type of change. The current guidance preserves the basic format and content of the original, with updates to add clarity. The added clarity is intended to increase consistent interpretations of the guidance by FDA staff and manufacturers and provide a more transparent framework for determining when submission of a new 510(k) is required.

The 510(k) Process and the Quality System Regulation

Any guidance on 510(k)s for changes to a legally marketed device should consider the role the Quality System (QS) regulation, 21 CFR Part 820, plays in changes to devices. For some types of changes to a device, the Agency believes that submission of a new 510(k) is not required and that reliance on existing QS requirements is the least burdensome approach to reasonably assure the safety and effectiveness of the changed device.

Regardless of whether a change requires premarket review, the QS regulation requires manufacturers of finished medical devices to review and approve changes to device design and production (21 CFR 820.30 and 820.70) and document changes and approvals in the device master record (21 CFR 820.181). Any process whose results cannot be fully verified by subsequent inspection and testing must be validated (21 CFR 820.75), and changes to the process require review, evaluation, and revalidation of the process where appropriate (21 CFR 820.75(c)).

The net effect of the QS regulation is to require that, when manufacturers of a finished medical device make a change in the design of a device, there is a process in place to demonstrate that the manufactured device meets the change in design specifications (or the original specifications, if no change was intended). They must keep records, and these records must be made available to an FDA investigator upon request (see Section 704(e) of the FD&C Act). For many changes to a device, submission of a new 510(k) may not be required. In these cases, including many software design changes, compliance with the QS regulation can reasonably assure the safety and effectiveness of the changed device.

Least Burdensome Principles

The least burdensome provision concerning 510(k)s states that FDA "shall only request information that is necessary…" and "shall consider the least burdensome means of demonstrating substantial equivalence…" (see section 513(i)(1)(D)(i) of the FD&C Act). While not changing the standard for substantial equivalence, this provision states that FDA shall only request the "minimum required information" necessary to support a determination of substantial equivalence (see sections 513(i)(1)(D)(ii)-(iii) of the FD&C Act). The recommendations discussed in this guidance for evaluating when a change in a medical device would trigger the requirement that a manufacturer submit a new 510(k) to the Agency are consistent with least burdensome principles, and applies them in discussing the considerations that may affect the decision-making about when to submit a new 510(k) for a device change or modification.

III. Scope

As used in this guidance, "software" is the set of electronic instructions used to control the actions or output of a medical device, to provide input to or output from a medical device, or to provide the actions of a medical device. This definition includes software that is embedded within or a component of a medical device, software that is an accessory to another medical device, or software that is intended to be used for one or more medical purposes that performs these purposes without being part of a hardware medical device.[1]

This guidance will aid manufacturers of medical devices subject to premarket notification requirements who intend to modify a 510(k)-cleared device (or group of devices) or other device subject to 510(k) requirements, such as a preamendments device or a device that was granted marketing authorization via the De Novo classification process[2] under section 513(f)(2) of the FD&C Act (also referred to together as "existing devices"), during the process of deciding whether the change exceeds the regulatory threshold of 21 CFR 807.81(a)(3) for submission and clearance of a new 510(k). Note that any person required to register under 21 CFR 807.20 who plans to introduce a device into commercial distribution for the first time must, per 21 CFR

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[1] IMDRF/SaMD WG/N10: *Software as a Medical Device (SaMD): Key Definitions* (http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf).

[2] This guidance applies to devices granted marketing authorization via the De Novo classification process and that are not exempt from premarket notification requirements.

807.81(a)(2), submit a 510(k) if that device is not exempt from premarket notification requirements. Also note that devices with changes requiring submission of a new 510(k) may not be legally commercially distributed before FDA clears the changed device (21 CFR 807.100(a) and sections 513(f)(1) and 513(i) of the FD&C Act). Private label distributors and repackagers are exempt from submitting a 510(k) if they satisfy the requirements of 21 CFR 807.85(b). This guidance is not intended to address changes to devices that are 510(k)-exempt or that require premarket approval (PMA).

This guidance specifically addresses software modifications and is intended as a companion to *Deciding When to Submit a 510(k) for a Change to an Existing Device* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf). Any modifications that are not modifications to software are not within the scope of this guidance; such changes (e.g., labeling changes) should be evaluated using *Deciding When to Submit a 510(k) for a Change to an Existing Device*. Both guidance documents explain FDA's current thinking on 21 CFR 807.81(a)(3), and as such, the threshold for submission of a new 510(k) in response to a change to an existing device is not different between the two guidances; however the terminology used may differ due to the nature of the technology and the assessment of the risks associated with the change. In addition, it may be necessary to refer to other relevant FDA guidance documents that aid in the evaluation of non-software device modifications. It is the manufacturer's responsibility to collectively evaluate the combination of both software and non-software changes to evaluate the impact of a change to a device. For those circumstances where the proposed change is not addressed in this guidance, in *Deciding When to Submit a 510(k) for a Change to an Existing Device*, or in a device-specific guidance, manufacturers are encouraged to contact the appropriate office in CDRH or CBER.

When there are multiple changes that affect labeling or hardware in addition to software, the manufacturer should assess the changes using both the general and software-specific modifications guidances. If use of either guidance leads to a "New 510(k)" conclusion, submission of a new 510(k) is likely required.

This guidance does not apply to software for which the Agency has stated in guidance that it does not intend to enforce compliance with applicable regulatory controls (see, e.g., *Mobile Medical Applications Guidance for Industry and FDA Staff* https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263366.pdf. Further, this guidance does not address the software lifecycle (covered in AAMI/ANSI/IEC 62304: *Medical device software - software life cycle processes*), what documentation should be included in a 510(k) for a software modification (covered in *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf)) or the principles that are applicable to the validation of medical device software (covered in *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf)).

This guidance is also intended to apply to situations when a legally marketed existing device is the subject of a recall, correction, or removal, and a change in the device or its labeling is necessary. For more information on recommended procedures in a recall situation, please see Blue Book Memorandum K95-1, *510(k) Requirements During Firm-Initiated Recalls* (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080297.htm). As stated in that guidance, if a correction alters a device rather than simply restoring it to its original specifications, submission of a new 510(k) may be required. FDA may use this guidance in determining whether submission of a new 510(k) is warranted in cases where the correction does alter the device.

This guidance does not specifically address combination products, such as drug/device or biologic/device combinations; however, the general principles and concepts described herein may be helpful to manufacturers in determining whether submission of a 510(k) is required for changes to software-containing device constituent parts of combination products.

Software modifications may be identified by many names, including, but not limited to: bug fix, hot fix, patch, software change, code change, or tweak. Regardless of name or form, these are considered design changes under the Quality System regulation, 21 CFR Part 820.

This guidance is not intended to supersede final device-specific guidance (such as the *Infusion Pumps Total Product Life Cycle* https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm209337.pdf), but may cover areas not addressed in any final device-specific guidance.

IV. Guiding Principles

In using this guidance for deciding whether to submit a new 510(k) for a change to an existing device, a number of guiding principles should be followed. Some derive from existing FDA 510(k) policy and are widely known, and others are necessary for using the logic scheme contained in this guidance. Thus, anyone using this guidance should bear in mind the following Guiding Principles:

1. **Changes made with intent to significantly affect safety or effectiveness of a device –** If a manufacturer modifies their device with the intent to significantly affect the safety or effectiveness of the device (for example, to significantly improve clinical outcomes, to mitigate a known risk, in response to adverse events, etc.), submission of a new 510(k) is likely required. A change *intended* to significantly affect the safety or effectiveness of the device is considered to be a change that "*could* significantly affect the safety or effectiveness of the device" and thus requires submission of a new 510(k) regardless of the considerations outlined below. Changes that are not intended to significantly affect the safety or effectiveness of a device, however, should still be evaluated to determine whether the change could significantly affect device safety or effectiveness.

   If a manufacturer modifies their device to address a violation or recall, they should refer to FDA guidances Blue Book Memorandum K95-1, *510(k) Requirements During Firm-Initiated Recalls*

(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080297.htm) and *Distinguishing Medical Device Recalls from Medical Device Enhancements* (https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm418469.pdf).

2. **Initial risk-based assessment –** To determine whether a change or modification could significantly affect the safety or effectiveness of a device, the manufacturer should first conduct a risk-based assessment, using the guidance below, of whether the change could significantly affect the device's safety or effectiveness, either positively or negatively. This risk-based assessment should identify and analyze all new risks and changes in existing risks resulting from the device change, and lead to an initial decision whether or not submission of a new 510(k) is required.

   For the purposes of this guidance, we have chosen the term "risk-based assessment" to describe the analysis that should be completed to assist in the determination of whether or not a change could significantly affect safety or effectiveness of the device. Although common risk analysis methods define risk in terms of device harms and their effects on safety, it is important to note that whether submission of a new 510(k) is required depends on whether the change could significantly affect the safety *or effectiveness* of the device. Therefore, manufacturers should also consider the possible effects a device change may have on device effectiveness. As such, we have chosen to use the distinct terminology of "risk-based assessment."

3. **Unintended consequences of changes** – After a manufacturer considers whether the change was made with the intent to significantly affect safety or effectiveness, the manufacturer should also consider whether the change could have unintended consequences. Software modifications may trigger additional unintended or unplanned consequences which should be assessed using the flowchart (and its companion text) to determine if submission of a new 510(k) is needed. For example, an intended operating system (OS) upgrade may trigger unintended effects in device drivers and software code embedded in the device and/or may require an update to other components for compatibility purposes. Manufacturers should consider all consequences of changes to fully assess whether submission of a new 510(k) is required.

4. **Use of risk management –** A risk-based assessment as referred to throughout this document is based on the combination of multiple risk concepts that are important for managing the risks of medical devices. Hazards and hazardous situations, risk estimation, risk acceptability, risk control, risk/benefit analysis and overall risk evaluation are all concepts that can be applied during the design and development of a medical device. The concept of risk, as defined in ISO 14971: *Medical devices – Application of risk management to medical devices*, is the combination of the probability of occurrence of harm and the severity of that harm. Although the risk terminology used in this document is primarily derived from ISO 14971, we recognize that an individual manufacturer's terminology may differ. Because 21 CFR 807.81(a)(3)(i) requires submission of a new 510(k) when a change "could significantly affect safety or effectiveness," both safety and

effectiveness should be considered in evaluating a device's risk profile and performing a risk-based assessment. The risk terminology from the currently FDA-recognized version of IEC TR 80002-1: *Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software* is also used in this guidance. For software, failures tend to be systematic in nature and therefore the probability of occurrence of a software failure cannot be determined using traditional statistical methods. While it may be possible to estimate the probability for other events in the sequence, if the overall probability of occurrence of harm cannot be estimated, the estimation of risk should be based on the severity of harm alone.

5. **The role of testing (i.e., verification and validation activities) in evaluating whether a change could significantly affect safety and effectiveness** – If the initial decision following the risk-based assessment is that submission of a new 510(k) is not required, this decision should be confirmed by successful, routine verification and validation activities. If routine verification and validation activities produce any unexpected results, any prior decision that submission of a new 510(k) is not required should be reconsidered in light of these issues (i.e., go through the flowchart again). Because 21 CFR 807.81(a)(3) requires submission of a new 510(k) for a change that "*could* significantly affect safety or effectiveness," if the result of a risk-based assessment is that a change could significantly affect safety or effectiveness, submission of a new 510(k) is required even if routine verification and validation activities are conducted successfully without any unexpected results. Note that verification and validation requirements apply for all devices subject to 21 CFR 820.30, and must be conducted regardless of whether submission of a new 510(k) is required.

6. **Evaluating simultaneous changes to determine whether submission of a new 510(k) is required –** Because many simultaneous changes may be considered at once, each change should be assessed separately, as well as in aggregate. Note that, for software, each individual line change in the code may not constitute an individual change in the device.

7. **Appropriate comparative device and cumulative effect of changes –** In using this guidance to help determine whether a particular change requires submission of a new 510(k), a manufacturer should conduct a risk-based assessment that compares the changed device to their device as previously found to be substantially equivalent in their most recently cleared 510(k), to their preamendments device (if the device was in commercial distribution before May 28, 1976 and there have not been changes to it subsequently cleared in a 510(k)), or to their device that FDA granted marketing authorization via the De Novo classification process (if there have not been changes to it subsequently cleared in a 510(k)). The appropriate comparative device is referred to as the "original device" throughout this guidance document. Of note, this comparison is different from a substantial equivalence comparison between the modified device and a legally marketed predicate device. Manufacturers may make a number of changes without having to submit a new 510(k), but each time they make a change, the modified device should be compared to the original device (i.e., the device described in their most recently cleared 510(k) for the device, to their legally marketed preamendments device,

or to their device that was granted marketing authorization via the De Novo classification process). When the cumulative effect of individual changes triggers the regulatory threshold for submission, the manufacturer should submit a new 510(k). When it does not, the manufacturer must document the change(s) (see 21 CFR Part 820.30).

8. **Documentation requirement –** Whenever manufacturers change their device, they must take certain actions to comply with the QS regulation, 21 CFR Part 820, unless the device in question is exempt by regulation from the QS regulation. The QS regulation requires, among other things, that device changes be documented. The scope and type of documentation may vary, but the process of documenting the decisions described in this guidance should be established as part of the manufacturer's own quality system.

9. **510(k) submissions for modified devices –** When a new 510(k) is submitted for a device with multiple changes, that 510(k) should describe all changes that trigger the requirement for submission of a new 510(k). To help ensure that FDA has a complete understanding of the device under review, that 510(k) should also describe other changes since the most recently cleared 510(k) (i.e., those that did not require submission of a new 510(k)) that would have been documented as part of the first 510(k) for that device. For instance, 510(k)s typically include a listing of device warnings in the labeling, so if a warning in the device's labeling had been changed, that change should be described in the new 510(k) for the software modification even if that labeling change did not itself trigger the requirement for submission of a new 510(k) and the 510(k) is being triggered by a software modification only. A 510(k) would not typically identify or describe individual components of a circuit board, such as resistors, or identify the specific version of a printer driver, and therefore FDA would not expect changes to the resistors or the printer driver to be listed in the new 510(k) for a modified device because the first 510(k) would have not included information about the resistors or printer drivers. Please note that manufacturers should know which versions of off-the-shelf software and/or firmware are included in their device even if that level of detail is not included in a 510(k).

   If a manufacturer makes multiple changes to a device, but only one change triggers the requirement for submission of a new 510(k), the changes that do not require submission of a new 510(k) may be immediately implemented, so long as those changes can be implemented independently of changes that do require submission of a new 510(k). Any immediately implemented change should still be documented in accordance with applicable QS regulations and the manufacturer's documentation procedures. Those changes should, however, also be described in the new 510(k) for the change that does require submission.

10. **Substantial equivalence determinations –** Manufacturers should understand that, even though they may follow this guidance and submit a new 510(k), a substantially equivalent determination is not assured. See FDA's guidance *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (510(k))* (https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm284443.pdf) for more information on the decision-making process FDA uses to determine substantial equivalence.

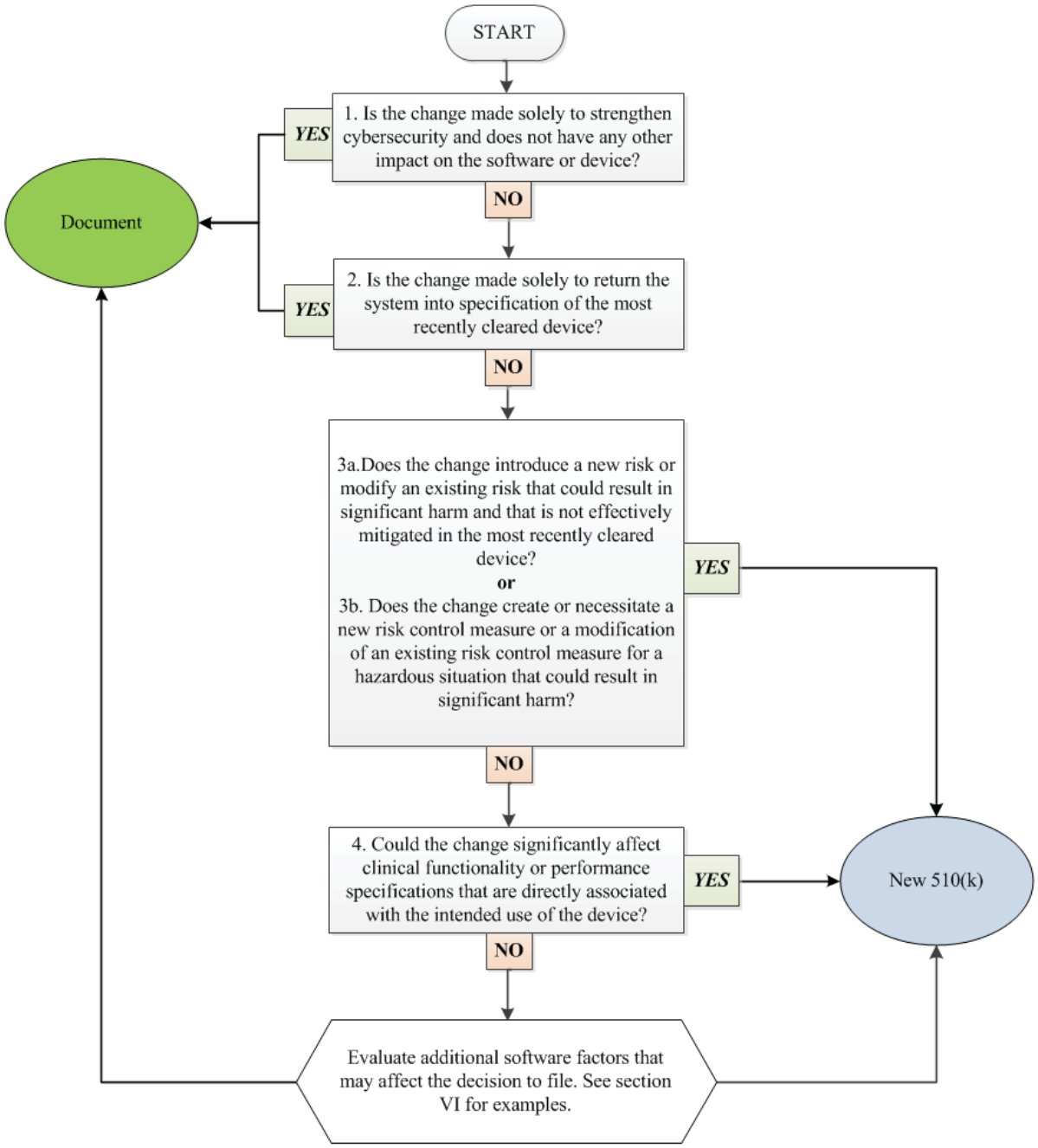
V. How to Use This Guidance

This guidance uses a flowchart and text with considerations and examples to guide manufacturers through the logic scheme we recommend to arrive at a decision on whether to submit a new 510(k) for a software change to an existing device. A single logic scheme covering all the intricacies in software modifications and their impact on the decision to submit a new 510(k) would be impractical to develop. Rather, for ease of use, a flowchart and text expected to cover the most common software modifications has been created.

Manufacturers should use the flowchart in concert with the Guiding Principles above, the text below, and additional factors in section VI. Manufacturers should answer the questions posed for each individual type of change (e.g., performance specification change, OS driver change) until a decision is made either to submit a new 510(k) or to document the basis for concluding that submission of a new 510(k) is not required. As mentioned above, when making the decision on whether to submit a new 510(k) for changes, the manufacturer's basis for comparison of any changed device should be the original device. Manufacturers are required to submit a new 510(k) when a change (or changes) exceeds the 21 CFR 807.81(a)(3) threshold, "could significantly affect the safety or effectiveness of the device," or constitutes a "major change or modification in the intended use of the device." This significant effect could be positive or negative. One must keep in mind that what may on the surface appear to be one discrete change to a device may involve multiple changes of various types. Appendix A provides a number of examples with rationale that can be helpful in working through this guidance.

In cases with multiple changes, manufacturers should use all applicable parts of the flowchart and companion text, including the Guiding Principles in Section IV of this guidance.

Note that the flowchart entries, "new 510(k)" and "document," are written in this way only for conciseness. The reader should interpret "new 510(k)" as **submission of a new 510(k) is likely required** and "document" as **a new 510(k) is likely not required, document your analysis, and file it for future reference.** The goal of the flowchart is to provide guidance in answering a manufacturer's questions on whether submission of a new 510(k) is likely required for a software change and to minimize the number of instances where the answer would be uncertain.



This flowchart is not intended to be used as a 'stand-alone' document and should only be considered in conjunction with the accompanying text in this guidance.

Figure 1. When to Submit a New 510(k) For a Software Change to an Existing Device.

1. Is the change made solely to strengthen cybersecurity and does not have any other impact on the software or device?

In many cases, a change made solely to strengthen cybersecurity is not likely to require submission of a new 510(k). Cybersecurity updates are considered a subset of software changes that are implemented to strengthen the security of a system, protect information, and reduce disruption in service. FDA expects manufacturers to ensure that such changes do not impact the safety or effectiveness of the device by performing necessary analysis, verification, and/or validation. If a manufacturer becomes aware of any incidental or unintended impacts of the change on other aspects of the software or device, the manufacturer should continue through the remaining questions in this guidance. The manufacturer should also refer to FDA's guidance *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm356190.pdf) and *Postmarket Management of Cybersecurity in Medical Devices* (https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm482022.pdf).

2. Is the change made solely to return the system into specification of the most recently cleared device?

When a change to the software only restores the device to the specifications of the most recently cleared device, then submission of a new 510(k) is likely not required. Generally, it is unlikely that modifications to software solely to restore the device to the most recently cleared device's specifications could significantly impact safety, effectiveness, or intended use of the device; however, manufacturers should evaluate the impact of the software changes. Manufacturers should conduct an analysis that involves determining the overall impact of the change to the device in terms of risk assessment and performance. The concepts expressed in Questions 3 and 4 below could be helpful in this analysis. In addition, this analysis is important for evaluating any modification that adds new features that appeared in the specification of the most recently cleared device but were not yet implemented.

Missing, incomplete, ambiguous, or conflicting software requirements may lead to a software modification that involves updating specifications, resulting in additional software code changes. In these situations, the answer to this question is likely "no" and the manufacturer should proceed to Question 3.

Generally, manufacturers are not required to submit a new 510(k) for changes to a specification document to clarify to an existing software requirement or to capture a missing software requirement, provided that this does not necessitate any changes to software code or product performance specifications. However, manufacturers should still assess the impact of the changes on other software documentation when applying appropriate design controls.

3. What are the impacts of any changes to risks associated with use of the device and the impacts of any changes to the risk

controls for the device?

a) Does the change introduce a new risk or modify an existing risk that could result in significant harm and that is not effectively mitigated in the most recently cleared device?

The purpose of this question is to determine whether a new risk is created or has been identified, or if an existing risk is modified, as a result of the software change. The term "risk" is meant to broadly include hazard, hazardous situation, or cause of an existing hazard or hazardous situation. A "hazardous situation" exists when there is exposure to a hazard (i.e., a potential source of harm) that can lead to physical injury or damage to the health of people. The term "cause" refers to one possible component in the "sequence of events," that can lead to a hazardous situation and possible harm, as described in ISO 14971. These are identified and defined by the manufacturer in the risk management file for the device. Significant harm refers to situations where the risk level is serious or more severe, e.g., the risk could result in injury or impairment requiring professional medical intervention, permanent impairment, or death.

Submission of a new 510(k) is likely required if **all** of the following criteria are met:

1. The change creates a new or modifies a hazard, hazardous situation, or cause in the risk management file.

2. The level of harm associated with the new or modified hazard, hazardous situation, or cause is considered serious or more severe, e.g., the hazard, hazardous situation, or cause of the hazardous situation could result in injury or impairment requiring professional medical intervention, permanent impairment, or death. The pre-mitigation risk score should be assessed in order to focus on the effects of the change.

3. The hazard, hazardous situation, or cause is not already effectively mitigated in the most recently cleared device.

    - **Note:** This criterion is met if there are no existing risk control measures in the most recently cleared device that reduce the risk associated with this hazard, hazardous situation, or cause to an acceptable level.

    - **Note:** New hazards, hazardous situations, or causes of hazardous situations may be effectively mitigated by risk controls that were already included in the device for other hazards, hazardous situations, or causes.

If all of the above criteria are not met, proceed to Question 3b.

b) Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?

It is possible that introducing new risk control measures or implementing changes to existing risk control measures could significantly affect the safety or effectiveness of the product, and thus such changes should be evaluated. It may be that the change is directly tied to the risk control measures or the software change may necessitate a new or modified risk control measure. Changes to or additions of risk control measures may be necessary due to new, modified, or previously unknown hazardous situations or causes thereof. If the changes to risk controls are necessary to prevent significant harm, submission of a new 510(k) is likely required. Conversely, submission of a new 510(k) is likely not required when implementing redundant risk control measures or enhancing existing risk control measures if the risk control measures in the most recently cleared device effectively mitigated the hazardous situation.

If the answer to this question is no, proceed to Question 4.

4. Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?

Changes in performance specifications encompass everything from routine specification changes necessary to improve device performance to significant product redesigns. For the purpose of this question, specifications include elements that could influence the device's ability to clinically perform as intended. These specifications may address attributes such as speed, strength, response times, throughput, limits of operation, reliability, delivery rate, or assay performance.

If the software change could significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device, then submission of a new 510(k) is likely required. For *in vitro* diagnostic devices (IVDs), this includes a change that could have clinically significant impact in terms of clinical decision-making. This question does not address direct changes to the indications for use and/or intended use of the device. If there is a change in the indications for use and/or intended use of the device, refer to FDA's guidance, *Deciding When to Submit a 510(k) for a Change to an Existing Device* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf).

For IVDs, performance generally refers to the analytical and clinical specifications established as part of the most recent 510(k) clearance. Analytical performance refers to the documented ability of an IVD test or test system to measure or detect a target analyte or substance that the IVD test or test system is represented or purported to identify or measure. Clinical performance refers to the documented ability of an IVD test or test system to identify, measure, monitor, or predict the presence or absence of, or the future development of, a clinical condition or predisposition, for

which the device is intended.

Depending on the assay, analytical performance specifications may be defined by:

- Analytical Sensitivity: limit of detection, reactivity (inclusivity);
- Analytical Specificity: exclusivity, cross-reactivity, interference;
- Cut-off and equivocal zone; and/or
- Precision: site-to-site reproducibility, within-laboratory precision/repeatability.

There are also times when IVD functionality or performance specifications could be changed but the change is not related to the IVD's intended use and the performance of the modified device could not be significantly affected when compared to previously cleared performance claims, and thus submission of a new 510(k) would not be required.

VI. Additional Factors to Consider When Determining When to Submit a New 510(k) for a Software Change to an Existing Device

In addition to the questions above, the common issues below should also be considered when determining if submission of a new 510(k) is required.

Medical device software is used in a wide variety of applications and is subject to a wide variety of changes. This guidance, therefore, cannot address every type of software change. Nonetheless, the questions in the flowchart and the associated recommendations in the text provide a guide for manufacturers' decision-making and associated documentation. The goal of the guidance is to provide examples of software changes that clearly could have a significant impact on the safety or effectiveness of the device based on functional changes to the device's operation (Note: modifications in the intended use of the device are covered in *Deciding When to Submit a 510(k) for a Change to an Existing Device* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf)). The impact of software changes on safety and effectiveness may not always be clear. This is often the case when making general code changes to software that are not necessarily intended to change function, but rather to perform what could be described as "code maintenance" or "infrastructure" modifications. These types of changes can, if not controlled properly, create unexpected changes to how the device functions. These types of changes, as well as others described in this section, should therefore involve a careful evaluation of their potential impact on device safety and effectiveness.

In addition to change management, these types of changes should also involve careful consideration of the overall architecture of the software. If the software architecture was developed in a planned, modular format, the likelihood of unintended impact to other areas of the code may be significantly reduced. On the other hand, if the software code was developed in a

looser construct, without a clear architectural plan, the ability to clearly delineate between functional modules in the code may be reduced. The potential impact to device safety and effectiveness increases in code with looser construct, due to the inherent risk of unintended changes in code without clear boundaries in the functional modules.

The purpose of this section is to provide guidance regarding evaluation of certain types of software changes, such as "code maintenance" and "infrastructure" changes. Manufacturers are encouraged to discuss these "gray areas" with the relevant CDRH or CBER Office and Division if there are questions about whether to submit a new 510(k) for these or other types of software changes. In most cases, this will be the Division under which the device was originally cleared.

Common Software Change Types

The following list of common change types are intended to help manufacturers consider additional factors that may affect a decision to submit a new 510(k). Note that this list is not exhaustive. Any questions should be discussed with the respective CDRH Offices and/or CBER Offices and/or Divisions responsible for the device being modified.

Some of the common software change types include:

- **"Infrastructure"** changes are modifications made to the software support system. Examples include but are not limited to: switching compilers, changing programming languages (C to C++, C++ to Java), or changing software drivers or libraries.

  The complexity of the change should be taken into consideration while determining whether the change requires submission of a new 510(k). For example, when changing programming languages, the similarity of the programming syntax between the two languages, as well as other factors (such as the coding paradigm associated with the old and new code), should be considered. A change from C to C++ may not entail significant code writing if the syntax is similar. On the other hand, moving from a functional or logical coding paradigm to an Object Oriented Programming paradigm, in conjunction with the change from C to C++, could involve significant software re-write, and submission of a new 510(k) is likely required.

  Similar analysis generally applies to software driver changes, OS changes, etc. It should be noted that significant changes to verification and validation scripts might be a signal that significant infrastructure changes have taken place and should be examined. Updates to scripts alone do not indicate that submission of a new 510(k) is required; however, it is important to understand why the scripts are being updated.

- **"Architecture**" changes are modifications to the overall structure of the software. Examples include but are not limited to: porting to a new OS, software changes to support a new hardware platform, and new middleware.

  These changes may impact the overall performance of the device or extend the environment in which the device can operate. The extent of the changes and the impact

that they have on the device should be considered in determining whether submission of a new 510(k) is required.

- **"Core algorithm"** changes are modifications made to an algorithm that directly impact or contribute to the device's intended use. Examples include: alarm algorithms on a monitor, a motor control algorithm for an infusion pump, and a detection module and measurement engine algorithm for an IVD.

  Changes to the core algorithm that impact performance are addressed by the preceding section and flowchart. However, it is important to understand that a complete rewrite of the algorithm, even with the same performance claims and risk profile, may be significant enough to require submission of a new 510(k) because the rewrite may impact performance indirectly.

- **"Clarification of Requirements – No Change to Functionality"** are changes made to clarify software requirements after a product has received premarket clearance. This clarification may be revised phrasing of an existing requirement or creation of a new requirement altogether, without changing or adding functionality. Changes made to clarify the requirements as discussed here likely do not require submission of a new 510(k).

- **"Cosmetic Changes – No Change to Functionality"** are changes made to the appearance of the device that do not impact the clinical use of the device. For example, changing the company logo that is displayed on the background of every screen could involve modifying multiple software modules; while the number of modules impacted may be large, it is unlikely that the intended change could significantly impact the device's safety and effectiveness or intended use, and submission of a new 510(k) is likely not required.

- **"Reengineering" and "refactoring"** are two common software maintenance techniques. "Reengineering" is defined as the examination and alteration of software to reconstitute it in a new form, and includes the subsequent implementation of the new form. It is often undertaken to replace aging legacy software. "Refactoring" is a disciplined technique for restructuring a software program's internal structure without changing its clinical performance specification. Refactoring seeks to improve a program structure and its maintainability. In general, reengineering often results in broader and more complex changes, while refactoring is often narrower in scope and less complex. The complexity of the change and the impact on risk controls or performance should be considered to determine whether the change requires submission of a new 510(k). Changes that are minor modifications to enhance the maintainability of the device within its specification context are unlikely to require submission of a new 510(k). Changes involving significant software re-write likely require submission of a new 510(k) because of the impact on the performance and on the risk controls.

Appendix A. Software Modification Examples

The following are hypothetical examples of software changes with explanations as to why they likely would or would not require submission of a new 510(k). Note that these generalized examples do not necessarily account for every possible detail, risk, or consideration a manufacturer should evaluate, and should not be taken to mean that the changes described definitely do or do not require submission of a new 510(k). Real-world device modification decisions will depend on the particular details of the change and the specific device in question.

The examples below are only intended to illustrate the principles and recommendations discussed above with regard to a particular question. As such, the examples each contain only the response to the question that is being highlighted; this does not necessarily mean that an earlier question would not have appropriately led to a decision to submit a new 510(k).

1. Flowchart Question 1 Examples

1.1. Proactive software security patch

Description: A device manufacturer finds a security vulnerability as part of an ongoing security evaluation of their device. The manufacturer modifies the software solely to remove this vulnerability. The manufacturer's analysis determined that the change does not have any other impact on the software or the device.

#	Question	Yes/No	Rationale
1	**Is the change made solely to strengthen cybersecurity and does not have any other impact on the software or device?**	Yes	The change is made solely to address cybersecurity vulnerabilities or to strengthen cybersecurity. The manufacturer's analysis determined that the change does not impact any other aspects of the software or device.

Outcome: Document the change to file.

1.2. Adding encryption and additional access control for remote users

Description: A manufacturer makes a software modification to add encryption to the configuration file of the device, and add passcode requirements for remote users, in addition to the password needed to access the device. A timeout is also added for remote users. The manufacturer's analysis determined that the change does not have any other impact on the software or the device.

#	Question	Yes/No	Rationale

1	**Is the change made solely to strengthen cybersecurity and does not have any other impact on the software or device?**	Yes	The change is made to restrict user/customer access to appropriate levels and provide protection to the device configuration information, in order to strengthen the cybersecurity of the device. The manufacturer's analysis determined that the change does not have any other impact on the software or the device.

Outcome: Document the change to file.

2. Flowchart Question 2 Examples

2.1. Modify system to meet specification

Description: A manufacturer makes a software modification to prevent system software from truncating Specimen Identification (ID) barcode information. Without the change, the software system would truncate the Specimen ID from the point of an inserted invalid character. For instance, if the invalid character was "%" and the Specimen ID barcode was "12345%678," the system software would read and assign a Specimen ID of "12345." This defect could lead to mis-association of patient data. Incorrect software collation of patient information with patient results could lead to incorrect reports. The specification of the most recently cleared device indicated what constituted an invalid character and how invalid characters were to be handled. However, the software did not handle this one particular invalid character in line with the specification. A change is made to the software to prevent the truncation of Specimen ID barcode information where an invalid character has been inserted.

#	Question	Yes/No	Rationale
2	**Is the change made solely to return the system into specification of the most recently cleared device?**	Yes	The software change disallowed use of the specific invalid character in Specimen IDs as defined in the instrument host interface specification. The original specification indicated how all illegal characters were to be handled. The existing device handled all but one as indicated in the specification. The change is made solely to ensure the software meets the original specification.

Outcome: Document the change to file.

2.2. Correcting DICOM retrieve parameter error

Description: A PACS (Picture Archiving and Communication System) is able to automatically retrieve prior studies from a radiology information system to allow comparison with the current study. A software error resulted in a non DICOM-compliant (Digital Imaging and Communications in Medicine standard; http://dicom.nema.org/) sending of query parameters that prevented the automatic fetching of prior studies. A manual workaround existed, allowing the user to open these prior studies as needed. The

manufacturer implements a software change to bring the product back to specification regarding DICOM conformance (send and retrieve).

#	Question	Yes/No	Rationale
2	**Is the change made solely to return the system into specification of the most recently cleared device?**	Yes	The software change is implemented solely to return the system into specification of the most recently cleared device regarding DICOM conformance (send and retrieve) by automatically opening prior studies as expected in a routing reading workflow.

Outcome: Document the change to file.

2.3. Error during maintenance procedure

Description: A manufacturer makes a software modification to fix an automated scheduled daily maintenance procedure. The defect concerned the cleaning solution bottle size parameter used in a maintenance procedure. The defect impacted the system's ability to detect fluid on the bottle septum and caused intermittent fluid detection errors during the maintenance procedure. The user may need to repeat the procedure 2-3 times to complete the procedure without error. A software change is made to update the size parameter as was originally documented in the software specifications.

#	Question	Yes/No	Rationale
2	**Is the change made solely to return the system into specification of the most recently cleared device?**	Yes	The change is to correct the software error to change the bottle size parameter back to the specified bottle size to bring system back into specification.

Outcome: Document the change to file.

2.4. Data error

Description: An issue was observed in IVD analyzer software that collects reagent administrative records (e.g., material number, lot number, expiration date). The records are to be written by the software into a database table. After enough records are collected to fill the table, newly-collected records are then to be written in the first row of the table, overwriting previous records. Because of a software bug, the system mistakenly merges the new data with the existing data in the first row of the table. The cause of the anomaly was determined to be a coding error that did not affect any of the software requirements. A change was made to correct the software code in the control unit of the analyzer to ensure that data written to a row in the table is not merged with any existing data. The change to the software involved modification of a table within the analyzer software to add new columns to track the administrative data stored for reagents to prevent data from being merged.

#	Question	Yes/No	Rationale

2	**Is the change made solely to return the system into specification of the most recently cleared device?**	Yes	The change was only to address a software anomaly and was not a change in specification or functionality of the most recently cleared device.

Outcome: Document the change to file.

2.5. Database error

Description: An issue was observed for an IVD analyzer in the field. The IVD analyzer software collects reagent administrative records (e.g., material number, lot number, expiration date). The records are to be written by the software into a database table. After enough records are collected to fill the table, newly-collected records are then to be written in the first row of the table, overwriting previous records. Under certain conditions, the software system mistakenly merges the new data with the existing data in the first row of the table in the database, which may lead to an incorrect result. The cause of the bug was found to be an incorrectly worded software requirement that led to an error in the software code. The requirement was rewritten. An additional software change was made to correct the software code in the control unit of the analyzer. Code was modified to ensure that data written to a database is not merged with any existing data. The change to the software involved creating an entirely separate database within the instrument software, specifically for the administrative records stored for reagents to prevent records from being merged. This change required a specification change at the unit level to describe the new database.

#	Question	Yes/No	Rationale
2	**Is the change made solely to return the system into specification of the most recently cleared device?**	No	A change was made to correct a coding error by adding a new database. This caused a change to the design specifications of the software.

Outcome: Continue to question 3.

3. Flowchart Question 3a Examples

3.1. Adding a new diagnostic parameter

Description: An electroencephalogram (EEG) diagnostic monitor was cleared with spectral edge frequency (SEF) and peak power (PP) as quantitative parameters. The device's intended use is to monitor brain electrical activity through electrodes placed on the surface of the head. A software modification is made to add Amplitude Integrated EEG (aEEG) as an additional quantitative parameter that was not included in the original premarket notification.

#	Question	Yes/No	Rationale

3a	**Does the change introduce a new risk or modify an existing risk that could result in significant harm and that is not effectively mitigated in the most recently cleared device?**	Yes	The hazardous situation most commonly associated with quantitative diagnostic parameters is the risk of incorrect or confusing information to the physician leading to a misdiagnosis, which could result in significant harm. While the causes of incorrect information for SEF and PP would be included in the original risk files, aEEG introduces a new cause related to an error in the aEEG calculation. Submission of a new 510(k) is required because the new cause is not effectively mitigated in the most recently cleared device and the hazardous situation, as discussed above, could result in significant harm.

Outcome: Submit the change in a new 510(k).

3.2. Removing a diagnostic parameter

Description: An electroencephalogram (EEG) diagnostic monitor was cleared with Spectral Edge Frequency (SEF) and Peak Power (PP). SEF and PP are used by neurologists as quantitative parameters along with the raw EEG trace and other clinical metrics to arrive at a clinical decision. The device's intended use is to monitor brain electrical activity through electrodes placed on the surface of the head. A modification is made to remove PP from the displayed quantitative parameters based on a marketing-conducted survey that indicated customers did not use PP in their clinical decisions.

#	Question	Yes/No	Rationale
3a	**Does the change introduce a new risk or modify an existing risk that could result in significant harm and that is not effectively mitigated in the most recently cleared device?**	No	Removal of PP does not introduce a new risk or modify any of the existing risks for the device.

Outcome: Continue to question 3b.

3.3. Customer maintenance procedure

Description: The manufacturer makes a software modification to prevent a patient sample probe motor from overheating during a customer maintenance procedure. Power is applied to the sample probe motor to keep the sample probe assembly in a locked position during the user maintenance procedure. In the field, it was reported that applying power to the sample probe motor for more than 20 minutes causes the motor to overheat and creates a potential minor burn hazard (i.e., it becomes too hot to touch safely). The software change applies a timeout to power being applied to the sample probe motor during the maintenance procedure; after ten minutes, power to the sample probe motor is turned off. An additional software change adds a message window at the beginning of the procedure to alert the user that the procedure must be completed within a ten-minute window or the system will cut power to the motor. A limit of ten minutes was determined to keep the motor from overheating to the point of creating a potential minor burn hazard.

#	Question	Yes/No	Rationale

3a	**Does the change introduce a new risk or modify an existing risk that could result in significant harm and that is not effectively mitigated in the most recently cleared device?**	No	The change provides a mitigation to an existing hazardous situation that was not appropriately mitigated in the cleared device. However, the hazardous situation could not cause significant harm.

Outcome: Continue to question 3b.

3.4. Adding new programming mode to a cardiac monitor

Description: The device is an implantable, automatically activated monitoring system that records subcutaneous electrocardiograms designed to record the arrhythmias in a patient. The manufacturer has made a software modification to add an alternative programming mode to change the way the device interacts with the programmer. This new programming mode provided different capabilities for data programming, interrogating, and managing the device data and function. The mode introduces new technology that impacts the safety profile of the device as a result of the energy transfer that occurs during programming.

#	Question	Yes/No	Rationale
3a	**Does the change introduce a new risk or modify an existing risk that could result in significant harm and that is not effectively mitigated in the most recently cleared device?**	Yes	This feature introduces new risks based on the new programming mode that could cause significant harm as a result of energy transfer to the patient.

Outcome: Submit the change in a new 510(k).

3.5. Imaging catheters – new optical module and new laser

Description: The device is an imaging catheter for coronary arteries that includes lasers and optical components. The manufacturer modifies the device software to integrate new optical modules and a new advanced laser method. The integration of the new components and function pose new risks to patients as a result of the new control parameters for the laser which could result in patient injury if not integrated appropriately.

#	Question	Yes/No	Rationale
3a	**Does the change introduce a new risk or modify an existing risk that could result in significant harm and that is not effectively mitigated in the most recently cleared device?**	Yes	The change introduces new hazardous situations associated with interoperability. This change introduces a new hazardous situation as a result of the optical module not recognizing the new catheter and therefore not providing the correct laser settings, which could result in significant harm.

Outcome: Submit the change in a new 510(k).

4. Flowchart Question 3b Examples

4.1. Modification of a risk control

Description: The device is a robotically assisted surgical system that utilizes position sensors. The system incorporates primary and secondary sensors to monitor the movement of actuators to prevent uncontrolled motion of the instrument in the event of a component failure. The system goes into a fault state and halts motion if the position information between the sensors does not match within a certain threshold. The threshold for each actuator is programmed in the software and there is a specification for how much overall movement is acceptable at the tip of the instrument before movement stops. The manufacturer makes a software change to the threshold settings for the position sensors; specifically, the software specification that defines the tip movement was widened and the software was changed to allow the wider tolerance. The change was made to minimize false assertion of the safety system, and the change in the specification for movement at the tip of the instrument was still within an appropriate safety tolerance for the device, as determined by analysis done by the manufacturer. However, the change modified an existing risk control (distance that can be traveled under fault conditions) that could significantly affect safety or effectiveness.

#	Question	Yes/No	Rationale
3b	**Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?**	Yes	The modified threshold values do not meet the specification for overall tip movement, which was required in the most recently cleared device to effectively mitigate the hazardous situation that could result in significant harm. Thus, the change necessitated modification of an existing risk control in the most recently cleared device and submission of a new 510(k) is required.

Outcome: Submit the change in a new 510(k).

4.2. Modification of threshold settings

Description: The device is a robotically assisted surgical system that utilizes position sensors. The system incorporates primary and secondary sensors to monitor the movement of actuators to prevent uncontrolled motion of the instrument in the event of a component failure. The system goes into a fault state and halts motion if the position information between the sensors does not match within a certain threshold. The threshold for each actuator is programmed in the software and there is a specification for how much overall movement is acceptable at the tip of the instrument before movement stops. The manufacturer makes a software change to the threshold settings for the position sensors; specifically, the software was modified to better calculate overall movement. The change was made to minimize false assertion of the safety system, which required the surgeon to hit an override button to continue. This requirement can be a nuisance and distract from surgery. The modified software continued to meet the specification for movement at the tip of the instrument after a component failure.

#	Question	Yes/No	Rationale
3b	**Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?**	No	This change modifies sensor threshold parameters so that transient conditions that can be present during normal operation do not cause unnecessary activation of the risk control measure. The change makes the system more noise-tolerant without impacting true positive detection for the risk control measure. The overall movement criteria are met under all fault conditions.

Outcome: Continue to Question 4.

4.3. Adding user interface alerts and controls

Description: An IVD analyzer manufacturer makes software modifications to replace existing modes of controls for handling samples having invalid characters in specimen IDs (specimen identification mis-association) received from Laboratory Information System or middleware vendors. Existing manual modes of control were adequate, but required operator interaction to evaluate whether a result record for a sample had an invalid specimen ID. The new modes of control include additional automation through a design improvement that will not generate results for a sample having an invalid specimen ID. Instead, the system software will: (1) generate a warning message to the operator that an invalid specimen ID was detected; (2) not generate or report results for a sample having an invalid specimen ID; and (3) create a system log entry.

#	Question	Yes/No	Rationale
3b	**Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?**	Yes	This software change modifies the risk control that identifies invalid characters by automating a previously manual process. If the invalid characters are not identified appropriately, then patient laboratory test results could be lost or replaced by incorrect results. Loss or replacement of results could influence treatment decisions, which could cause significant harm.

Outcome: Submit the change in a new 510(k).

4.4. Print patient information on PACS report

Description: A PACS provides the option to print images along with a copy of the diagnostic findings from the radiologist. There is data on each page allowing the user to match each page to the corresponding information (e.g., patient ID, Study Identifier). This data helps to address the known risk of pages being mixed-up after printout. Based on customer preference, the manufacturer decided to enhance this existing risk control and have actual patient information and demographics printed on each page. This is intended to be easier for the user to identify which pages belong together and, as a result, further decrease the risk of mixing up printed pages.

#	Question	Yes/No	Rationale

3b	**Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?**	No	The risk is already sufficiently mitigated with the original risk controls (that is, to have patient identification related information on each printed page). This software modification is a redundant risk control that was not made in response to a new, modified, or previously unknown hazardous situation or cause thereof.

Outcome: Continue to Question 4.

4.5. Infusion pump alarm

Description: A general purpose infusion pump has one alarm to alert the user when an occlusion has been detected. The software change modifies the existing alarm to provide two alarms related to occlusion: occlusion downstream and occlusion upstream. These alarms provide specific information to help resolve the occlusion.

#	Question	Yes/No	Rationale
3b	**Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?**	Yes	The change modifies the risk control, i.e., the alarm, which is already present for occlusion. This risk control is necessary to improve safety by effectively mitigating specific occlusion events that could result in significant harm if not resolved correctly.

Outcome: Submit the change in a new 510(k).

5. Flowchart Question 4 Examples

5.1. Improve sample throughput 1

Description: A manufacturer makes a software performance enhancement to improve sample throughput time by 20%. Software modifications include changes to decrease assay cycle times by allowing for shorter sample reaction incubation times. Decreasing sample assay times could have an impact on run performance and/or assay performance in a manner that could have a negative impact on diagnosis or therapy delivered to patients.

#	Question	Yes/No	Rationale
4	**Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?**	Yes	The change is to increase the throughput performance specification, but has a significant impact on the performance of the device. There is a shorter reaction incubation time and therefore a potential significant impact on diagnostic utility and effectiveness.

Outcome: Submit the change in a new 510(k).

5.2. Improve sample throughput 2

Description: A manufacturer makes a software modification to improve sample throughput by 5% by decreasing pre-analytic processing time. Software modifications include a change to decrease sample delivery time from the sample load area to the sample aspiration area. As described here, decreasing sample delivery times do not have an impact on assay performance.

#	Question	Yes/No	Rationale
4	**Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?**	No	The modifications do not impact assay performance as it relates to intended use. Improvement resulted from technical analysis of the sample delivery algorithm to optimize timing and remove unnecessary timing delays.

Outcome: If the factors identified in Section VI are not relevant for this change, document the change to file.

5.3. Software change to modify summary window

Description: A manufacturer makes a software modification to increase the number of images that can be viewed in a summary view for an ingestible telemetric gastrointestinal capsule imaging system. The new software allows for four images to be viewed simultaneously instead of two while a user reviews the images. The specifications for the image quality are not impacted by this change.

#	Question	Yes/No	Rationale
4	**Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?**	No	The change does not significantly impact functionality or performance specifications that are directly associated with the intended use of the device. Having more images in the window allows for the physician to review more images without increasing software loading time.

Outcome: If the factors identified in Section VI are not relevant for this change, document the change to file.

5.4. OEM module

Description: A multi-parameter monitor device was originally cleared with version A of an original equipment manufacturer (OEM) module for blood oxygen saturation (SpO_2). The OEM makes a change to version A of the SpO_2 sensor. The change to the SpO_2 sensor did not require submission of a new 510(k) and the change did not impact the specifications for the SpO_2 in terms of data acquisition or processing. However, the SpO_2 does identify itself to the multi-parameter monitor using a new version number. This

requires a software change on the multi-parameter monitor to allow for successful interoperability with the new version of the sensor.

#	Question	Yes/No	Rationale
4	**Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?**	No	The clinical functionality is not affected. The software modification allows for successful integration of this version of the sensor.

Outcome: If the factors identified in Section VI are not relevant for this change, document the change to file.

5.5. Sterilizer user interface change

Description: A sterilizer display provides vital information on the temperature, the pressure, and the remaining cycle time. Software changes are made to increase the font size of these parameters on the display due to customer feedback (not related to any adverse events). The items are all in the same location and the appearance is unchanged aside from the larger font size.

#	Question	Yes/No	Rationale
4	**Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?**	No	Since the information was previously displayed, the change has no significant effect on the functionality or the performance of the device.

Outcome: If the factors identified in Section VI are not relevant for this change, document the change to file.

5.6. Modify device algorithms

Description: A manufacturer makes a software modification to enhance an arrhythmia detection algorithm. The device is intended to provide detection alarms for life-threatening arrhythmias in an intensive care unit (ICU) environment. The change impacts sensitivity and specificity and therefore the detection of arrhythmias, which are critical to the clinical performance of the device.

#	Question	Yes/No	Rationale
4	**Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?**	Yes	The modification has direct impact on diagnostic performance of the device in that the performance of the arrhythmia detection was changed.

Outcome: Submit the change in a new 510(k).

5.7. Modification to alarm duration

Description: A manufacturer makes a software modification to allow users to silence a low-risk alarm on a dialysis system. The change consists of a "snooze" button that silences the alarm for a set amount of time before resounding.

#	Question	Yes/No	Rationale
4	**Could the change significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device?**	No	The silencing of a non-critical alarm does not impact the clinical functionality. The criteria for the alarm are unchanged from the most recently cleared device.

Outcome: If the factors identified in section VI are not relevant for this change, document the change to file.

The 21st Century Cures Act (12/13/2016) amended the definition of "device" in the Food, Drug and Cosmetic Act to exclude certain software functions, including some described in this guidance document. FDA is assessing how to revise this guidance to represent our current thinking on this topic. For additional information, contact digitalhealth@fda.hhs.gov or refer to https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm.

Contains Nonbinding Recommendations

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on February 9, 2015.

This document supersedes "Mobile Medical Applications: Guidance for Food and Drug Administration Staff" issued on September 25, 2013.

This document was updated to be consistent with the guidance document "Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices" issued on February 9, 2015.

For questions about this document regarding CDRH-regulated devices, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov or contact the Office of the Center Director at 301-796-5900.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Identify all comments with the docket number FDA-2011-D-0530. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number (1741) to identify the guidance you are requesting.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20903, or by calling 1-800-835-4709 or 240-402-7800, by e-mail, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Table of Contents

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) recognizes the extensive variety of actual and potential functions of mobile apps, the rapid pace of innovation in mobile apps, and the potential benefits and risks to public health represented by these apps. The FDA is issuing this guidance document to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or "mobile apps"). Given the rapid expansion and broad applicability of mobile apps, the FDA is issuing this guidance document to clarify the subset of mobile apps to which the FDA intends to apply its authority.

Many mobile apps are not medical devices (meaning such mobile apps do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them. Some mobile apps may meet the definition of a medical device but because they pose a lower risk to the public, FDA intends to exercise enforcement discretion over these devices (meaning it will not enforce requirements under the FD&C Act). The majority of mobile apps on the market at this time fit into these two categories.

Consistent with the FDA's existing oversight approach that considers functionality rather than platform, the FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended. This subset of mobile apps the FDA refers to as mobile medical apps.

FDA is issuing this guidance to provide clarity and predictability for manufacturers of mobile medical apps. This document has been updated to be consistent with the guidance document entitled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices" issued on February 9, 2015.

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf. Examples on the Mobile Medical Apps Web site http://www.fda.gov/medicaldevices/productsandmedicalprocedures/connectedhealth/mobilemedicalapplications/default.htm which were added after September 25, 2013, were incorporated into the appropriate appendices of this document for consistency.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

As mobile platforms become more user friendly, computationally powerful, and readily available, innovators have begun to develop mobile apps of increasing complexity to leverage the portability mobile platforms can offer. Some of these new mobile apps are specifically targeted to assisting individuals in their own health and wellness management. Other mobile apps are targeted to healthcare providers as tools to improve and facilitate the delivery of patient care.

In 1989, FDA prepared a general policy statement on how it planned to determine whether a computer-based product and/or software-based product is a device, and, if so, how the FDA intended to regulate it. The document, "FDA Policy for the Regulation of Computer Products," became known as the "Draft Software Policy." After 1989, however, the use of computer and software products as medical devices grew exponentially and the types of products diversified and grew more complex (and that trend has continued). As a result, the FDA determined that the draft policy did not adequately address all of the issues related to the regulation of all medical devices containing software. Therefore, in 2005, the Draft Software Policy was withdrawn.[1]

Although the FDA has not issued an overarching software policy, the Agency has formally classified certain types of software applications that meet the definition of a device and, through classification, identified specific regulatory requirements that apply to these devices and their manufacturers. These software devices include products that feature one or more software components, parts, or accessories (such as electrocardiographic (ECG) systems used to monitor cardiac rhythms), as well as devices that are composed solely of software (such as laboratory information management systems). On February 15, 2011, the FDA issued a regulation down-classifying certain computer- or software-based devices intended to be used for the electronic transfer, storage, display, and/or format conversion of medical device data – called Medical Device Data Systems (MDDSs) – from Class III (high-risk) to Class I (low-risk).[2]

The FDA has previously clarified that when stand-alone software is used to analyze medical device data, it has traditionally been regulated as an accessory to a medical device[3] or as medical device software.

As is the case with traditional medical devices, certain mobile medical apps can pose potential risks to public health. Moreover, certain mobile medical apps may pose risks that are unique to the characteristics of the platform on which the mobile medical app is run. For example, the

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[1] Annual Comprehensive List of Guidance Documents at the Food and Drug Administration (70 FR 824 at 890) (January 5, 2005).

[2] Medical Devices; Medical Device Data Systems Final Rule (76 FR 8637) (Feb. 15, 2011).

[3] See, for example, Content of a 510(k) -- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm ("Accessories to classified devices take on the same classification as the "parent" device. An accessory such as software that accepts input from multiple devices usually takes on the classification of the "parent" device with the highest risk, i.e., class."); See also final Rule, Medical Devices, Medical Device Data Systems, 76 FR 8637 at 8643-8644 – comment 16 and FDA's response (Feb. 15, 2011).

interpretation of radiological images on a mobile device could be adversely affected by the smaller screen size, lower contrast ratio, and uncontrolled ambient light of the mobile platform. FDA intends to take these risks into account in assessing the appropriate regulatory oversight for these products.

This guidance clarifies and outlines the FDA's current thinking. The Agency will continue to evaluate the potential impact these technologies might have on improving health care, reducing potential medical mistakes, and protecting patients.

III. Definitions

A. Mobile Platform

For purposes of this guidance, "mobile platforms" are defined as commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as smart phones, tablet computers, or other portable computers.

B. Mobile Application (Mobile App)

For purposes of this guidance, a mobile application or "mobile app" is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server.

C. Mobile Medical Application (Mobile Medical App)

For purposes of this guidance, a "mobile medical app" is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[4]; and either is intended:

- to be used as an accessory to a regulated medical device; or
- to transform a mobile platform into a regulated medical device.

[4] Products that are built with or consist of computer and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act. That provision defines a device as "…an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory", that is "… intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man …" or "… intended to affect the structure or any function of the body of man or other animals …." Thus, software applications that run on a desktop computer, laptop computer, remotely on a website or "cloud," or on a handheld computer may be subject to device regulation if they are intended for use in the diagnosis or the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man. The level of regulatory control necessary to assure safety and effectiveness varies based upon the risk the device presents to public health. (See Appendix D for examples).

The intended use of a mobile app determines whether it meets the definition of a "device." As stated in 21 CFR 801.4,[5] intended use may be shown by labeling[6] claims, advertising materials, or oral or written statements by manufacturers or their representatives. When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device.

One example is a mobile app that makes a light emitting diode (LED) operate. If the manufacturer intends the system to illuminate objects generally (i.e., without a specific medical device intended use), the mobile app would not be considered a medical device. If, however, through marketing, labeling, and the circumstances surrounding the distribution, the mobile app is promoted by the manufacturer for use as a light source for doctors to examine patients, then the intended use of the light source would be similar to a conventional device such as an ophthalmoscope.

In general, if a mobile app is intended for use in performing a medical device function (i.e. for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease) it is a medical device, regardless of the platform on which it is run. For example, mobile apps intended to run on smart phones to analyze and interpret EKG waveforms to detect heart function irregularities would be considered similar to software running on a desktop computer that serves the same function, which is regulated under 21 CFR 870.2340 ("Electrocardiograph"). FDA's oversight approach to mobile apps is focused on their functionality, just as we focus on the functionality of conventional devices. Our oversight is not determined by the platform. Under this guidance, FDA would **not** regulate the sale or general/conventional consumer use of smartphones or tablets. FDA's oversight applies to mobile apps performing medical device functions, such as when a mobile medical app transforms a mobile platform into a medical device. However, as previously noted, we intend to apply this oversight authority only to those mobile apps whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended.

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[5] "The words 'intended uses' or words of similar import … refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put." 21 CFR 801.4.

[6] "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Section 201(m) of the FD&C Act, 21 U.S.C. 321(m).

D. Regulated Medical Device

For purposes of this guidance, a "regulated medical device" is defined as a product that meets the definition of device in section 201(h) of the FD&C Act and that has been cleared or approved by the FDA review of a premarket submission or otherwise classified by the FDA.

This definition can include novel devices, whether or not on a mobile platform, that the FDA will clear or approve by the review of a premarket submission or otherwise classify. Examples of regulated medical devices are identified in Appendix D.

E. Mobile Medical App Manufacturer

For purposes of this guidance, a "mobile medical app manufacturer" is any person or entity that manufactures mobile medical apps in accordance with the definitions of manufacturer in 21 CFR Parts 803, 806, 807, and 820.[7] A mobile medical app manufacturer may include anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components. This term does not include persons who exclusively distribute mobile medical apps without engaging in manufacturing functions; examples of such distributors may include owners and operators of "Google play," "iTunes App store," and "BlackBerry App World." Examples of mobile medical app manufacturers include any person or entity that:

- Creates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a mobile medical app software system from multiple components. This could include a person or entity that creates a mobile medical app by using commercial off the shelf (COTS) software components and markets the product to perform as a mobile medical app;
- Initiates specifications or requirements for mobile medical apps or procures product development/manufacturing services from other individuals or entities (second party) for subsequent commercial distribution. For example, when a "developer" (i.e., an entity that provides engineering, design, and development services) creates a mobile medical app from the specifications that were initiated by the "author," the "author" who initiated and developed specifications for the mobile medical app is considered a "manufacturer" of the mobile medical app under 21 CFR 803.3. For purposes of this guidance, manufacturers of a mobile medical app would include persons or entities who are the creators of the original idea (initial specifications) for a mobile medical

[7] Regulatory definitions of the term "manufacturer" or "manufacture" appear in 21 CFR Parts 803, 806, 807, and 820. For example -- under FDA's 21 CFR 807.3(d)-- establishment registration and device listing for manufacturers and initial importers of devices-- ,"*Manufacture, preparation, propagation, compounding, assembly, or processing of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act." These terms include the following activities: (1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer; (2) Initial importation of devices manufactured in foreign establishments; or (3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.*"

app, unless another entity assumes all responsibility for manufacturing and distributing the mobile medical app, in which case that other entity would be the "manufacturer."[8] Software "developers" of a mobile medical app that are only responsible for performing design and development activities to transform the author's specifications into a mobile medical app would not constitute manufacturers, and instead the author would be considered the manufacturer;

- Creates a mobile medical app and hardware attachments for a mobile platform that are intended to be used as a medical device by any combination of the mobile medical app, hardware attachments, and the mobile platform;
- Creates a mobile medical app or a software system that provides users access to the medical device function through a website subscription, software as a service,[9] or other similar means.

In contrast, the following are examples of persons or entities that are NOT considered to be mobile medical app manufacturers (i.e., persons *not* within the definition of manufacturer in 21 CFR Parts 803, 806, 807, and 820). Because they are not manufacturers, none of the persons or entities in these examples would have to register their establishments, list their products with the FDA[10] or submit a premarket application:

- Manufacturers or distributors of mobile platforms who solely distribute or market their platform and do not intend (by marketing claims -- e.g., labeling claims or advertising material) the platform to be used for medical device functions. When mobile medical apps are run on a mobile platform, the mobile platform is treated as a component of the mobile medical app's intended use. [11] Therefore the mobile platform manufacturer is exempt from the Quality System regulation and registration and listing requirements. [12] For example, if it is possible to run mobile medical apps on BrandNamePhone but BrandNamePhone is not marketed by BrandNameCompany as intended for use as a medical device, then BrandNameCompany would not be considered a mobile medical app manufacturer or a medical device manufacturer. Also, in this example, the BrandName Phone sold to consumers would not be regulated by FDA as a medical device. FDA does **not** consider entities that exclusively distribute mobile medical apps, such as the owners and operators of the "iTunes App store" or the "Android market," to be medical device manufacturers. FDA also does not consider mobile platform manufacturers to be medical device manufacturer just because their mobile platform could be used to run a mobile medical app regulated by FDA.
- Third parties who solely provide market access to mobile medical apps (i.e. solely distribute mobile apps), but do not engage in any manufacturing functions as defined in

[8] See 21 CFR 803.3 (definition of manufacturer) and 21 CFR 807.20(a)(2).
[9] By this we mean to include any "server software application" that provides a service to a client software application on a mobile platform.
[10] 21 CFR 807.65 and 21 CFR 807.85
[11] See 21 CFR 820.3(c) which defines a component as "any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.".
[12] 21 CFR 807.65(a) and 21 CFR 820.1(a).

21 CFR Parts 803, 806, 807, and 820. Examples of such third parties may include owners and operators that are only engaged in providing an online market place that allow mobile medical app manufacturers to commercially distribute their mobile medical apps. Specific examples of such online market places include "Google play," "iTunes store," and "BlackBerry App World";

- Providers of tools, services or infrastructure used in the development, distribution, or use of a mobile medical app. Examples include providers of internet connectivity (i.e., internet service), providers of general purpose computer or information technology, providers that host the web service for content or software application. Other examples of providers of tools, services, or infrastructure include customer support services, data center hosting services, cloud hosting services, application hosting services, wireless carriers, or providers of software development kits. However, a creator of a mobile medical app or a software system that provides users access to the medical device function through a website subscription, software as a service,[13] or other similar means *is* considered a mobile medical app manufacturer;

- Licensed practitioners, including physicians, dentists, and optometrists, who manufacture a mobile medical app or alter a mobile medical app solely for use in their professional practice and do not label or promote their mobile medical apps to be generally used by other licensed practitioners or other individuals.[14,15] For example, if Dr. XYZ, a licensed practitioner, creates a mobile medical app called the "XYZ-recorder" which enables attaching an ECG electrode to a smartphone, and provides the "XYZ-recorder" to his/her patient to use it to record the patient's electrocardiographic readings for 24 hours, Dr. XYZ is not considered a mobile medical app manufacturer. If Dr. XYZ is in a group practice (including a telehealth network) and permits other physicians in the practice to provide the XYZ-recorder to their patients, Dr. XYZ is not considered a mobile medical apps manufacturer. However, if Dr. XYZ, the licensed practitioner, distributes the "XYZ-recorder" and, through labeling or promotion intends to make it generally available to or to be generally used by other physicians (or other specially qualified persons), Dr. XYZ would be considered a mobile medical app manufacturer;

- Persons who manufacture mobile medical apps solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution. We note that while persons conducting research using mobile medical apps involving human subjects are exempt from registration and listing, they may instead be subject to investigational device exemption regulations.[16,17]

[13] See footnote 9.
[14] Section 510(g)(2) of the FD&C Act: - *Registration of producers of drugs or devices – Exclusions from application of section*: "practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice."
[15] See 21 CFR 807.65(d).
[16] See 21 CFR 807.65(f).
[17] See 21 CFR 812.1.

IV. Scope

This guidance explains the FDA's intentions to focus its oversight on a subset of mobile apps. Mobile medical apps as defined in section III include only those mobile apps that meet the statutory definition of a device and either are intended:

- to be used as an accessory to a regulated medical device; or
- to transform a mobile platform into a regulated medical device.

Appendix A provides examples of mobile apps that FDA does **NOT** consider to meet the definition of medical device and, therefore, are NOT mobile medical apps for the purposes of this guidance.

Section V-B and Appendix B provide examples of mobile apps that MAY meet the definition of a medical device but for which the FDA intends to exercise enforcement discretion because they pose a low risk to patients.[18]

This guidance does not address the approach for software that performs patient-specific analysis to aid or support clinical decision-making.

FDA's policies regarding accessories to medical devices are not unique to mobile medical apps and go beyond the scope of this guidance. Specifically this guidance does not address FDA's general approach for accessories to medical devices.

If you are developing a mobile medical app with an entirely new intended use, we encourage you to contact FDA to discuss what regulatory requirements may apply.

[18] This indicates that for certain mobile medical app devices, such as those in Appendix B, the FDA intends not to pursue enforcement action for violations of the FD&C Act and applicable regulations by a manufacturer of a mobile app that meets the definition of a device in section 201(h) of the FD&C Act as specified in this guidance. This does not constitute a change in the requirements of the FD&C Act or any applicable regulation.

V. Regulatory approach for mobile medical apps

As described in this guidance, FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended. This approach to overseeing mobile medical apps is consistent with our existing approach to overseeing medical device functionality of a product and the risks it poses to patients regardless of the shape, size or the platform. The FDA believes that this subset of mobile medical apps poses the same or similar potential risks to the public health as currently regulated devices if they fail to function as intended.

The FDA strongly recommends that manufacturers of all mobile apps that may meet the definition of a device follow the Quality System[19] regulation (which includes good manufacturing practices) in the design and development[20] of their mobile medical apps and initiate prompt corrections to their mobile medical apps, when appropriate, to prevent patient and user harm.

For mobile medical apps, manufacturers must meet the requirements associated with the applicable device classification. If the mobile medical app, on its own, falls within a medical device classification, its manufacturer is subject to the requirements associated with that classification. A mobile medical app, like other devices, may be classified as class I (general controls), class II (special controls in addition to general controls), or class III (premarket approval).[21]

A. Mobile medical apps: Subset of mobile apps that are the focus of FDA's regulatory oversight

Mobile apps may take a number of forms, but it is important to note that the FDA intends to apply its regulatory oversight to only the subset of mobile apps identified below and in Appendix C. These mobile apps can transform a mobile platform into a regulated medical device by using attachments, display screens, sensors, or other such methods. Regardless of the mechanism behind the transformation, FDA considers such mobile apps to be mobile medical apps.

The following are mobile apps that FDA considers to be mobile medical apps subject to regulatory oversight:

[19] See 21 CFR part 820.
[20] The FDA has found that the majority of software-related device failures are due to design errors. In one study, the most common problem was failure to validate software prior to routine production. See Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule); Quality System Regulation (61 FR 52602) (October 7, 1996).
[21] See footnotes 3 and 4.

1. **Mobile apps that are an extension of one or more medical devices by connecting[22] to such device(s) for purposes of controlling[23] the device(s) or for use in active patient monitoring or analyzing medical device data.**

    - *Examples of displays of patient-specific medical device data include:* display of medical images directly from a Picture Archiving and Communication System (PACS) server and remote display of data from bedside monitors (note that mobile medical apps that display medical device data to perform active patient monitoring such as bedside monitors are subject to regulations associated with such devices) ..
    - *Examples of mobile apps that control medical devices include:* apps that provide the ability to control inflation and deflation of a blood pressure cuff through a mobile platform and mobile apps that control the delivery of insulin on an insulin pump by transmitting control signals to the pumps from the mobile platform.

      Mobile medical apps of this type are considered an accessory to the connected device and are required to comply with the controls applicable to that connected device. The FDA considers such mobile medical apps to extend the intended use and functionality of the connected medical device. As a result, the mobile medical app would be required to comply with the regulations applicable to the connected medical device in order to address any associated risks.

2. **Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. Mobile apps that use attachments, display screens, sensors or other such similar components to transform a mobile platform into a regulated medical device are required to comply with the device classification associated with the transformed platform.**

    - *Examples of these types of mobile apps include:* a mobile app that uses a mobile platform for medical device functions, such as attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter; or attachment of electrocardiograph (ECG) electrodes to a mobile platform to measure, store, and display ECG signals; a mobile app that uses the built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea; a mobile app that uses sensors (internal or external) on a mobile platform for creating electronic stethoscope function is considered to transform the mobile platform into an electronic stethoscope; manufacturers of such a mobile app are required to follow the requirements of 21 CFR 870.1875(b) (Electronic Stethoscope); and similarly a mobile app that displays radiological images for diagnosis transforms the mobile platform into a class II Picture Archiving and Communications System (PACS) under 21 CFR 892.2050.

[22] To meet this criterion, the mobile medical apps need not be physically connected to the regulated medical device (i.e. the connection can be wired or wireless).
[23] Controlling the intended use, function, modes, or energy source of the connected medical device.

The FDA has cleared several mobile medical apps with attachments to a mobile platform. Specifically, patient monitoring mobile apps that monitors a patient for heart rate variability from a signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor are classified as cardiac monitoring software under 21 CFR 870.2300 (Cardiac monitor). Other mobile medical apps that use a hardware attachment or interface to a monitoring system that have been cleared include an automatic electronic blood pressure monitor under 21 CFR 870.1130 and a perinatal monitoring system under 21 CFR 884.2740.

3. **Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations. These types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved.**

    - *Examples of mobile apps that perform sophisticated analysis or interpret data (electronically collected or manually entered) from another medical device include:* apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; Computer Aided Detection software (CAD) image processing software[24]; and radiation therapy treatment planning software [25]. We believe that these types of software present the same level of risk to patients regardless of the platform on which they run.

The FDA encourages manufacturers of such mobile medical apps that perform patient-specific analysis to contact FDA to discuss what, if any, regulatory requirements may apply to their mobile app. For additional examples see 0.

B. Mobile Apps for which FDA intends to exercise enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act)

FDA intends to exercise enforcement discretion for mobile apps that:

- Help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions;
- Provide patients with simple tools to organize and track their health information;
- Provide easy access to information related to patients' health conditions or treatments;
- Help patients document, show, or communicate potential medical conditions to health care providers;
- Automate simple tasks for health care providers;

[24] 21 CFR 892.2050.
[25] 21 CFR 892.5050.

- Enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems; or
- Intended to transfer, store, convert format, and display medical device data in its original format from a medical device (as defined by MDDS regulation 880.6310 OUG).

Some mobile apps in the above categories and listed below may be considered mobile medical apps, and others might not. For those mobile apps listed below that are devices, FDA intends to exercise enforcement discretion because they pose a low risk to patients.

The following examples represent mobile apps for which the FDA intends to exercise enforcement discretion:

1. **Mobile apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.** – These are apps that supplement[26] professional clinical care by facilitating behavioral change or coaching patients with specific diseases or identifiable health conditions in their daily environment. Examples include:
    - Apps that coach patients with conditions such as cardiovascular disease, hypertension, diabetes or obesity, and promote strategies for maintaining a healthy weight, getting optimal nutrition, exercising and staying fit, managing salt intake, or adhering to pre-determined medication dosing schedules[27] by simple prompting.

2. **Mobile apps that provide patients with simple tools to organize and track their health information** – These are apps that provide patients with tools[28] to organize and track health information without providing recommendations to alter or change a previously prescribed treatment or therapy. Examples include:
    - Apps that provide simple tools for patients with specific conditions or chronic disease (e.g., obesity, anorexia, arthritis, diabetes, heart disease) to log, track, or trend their events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their health care provider as part of a disease-management plan.

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[26] By this we mean that the app can be safely used by a patient without active oversight by a medical professional and, when used for serious conditions necessitating professional medical care, use of the app is not intended to replace or discourage seeking treatment from a health care provider.

[27] We consider these mobile medical apps as "medication reminders – Product code NXQ" currently defined as "*A medication reminder is a device intended for medical purposes to provide alerts to patients or healthcare providers for pre-determined medication dosing schedules. The device may incorporate wireless communication.*" The FDA intends to exercise enforcement discretion for this specific product code (NXQ) identified under 21 CFR 890.5050 – Daily activity assist device.

[28] We consider these mobile apps to be simple tools which are not intended to provide specific treatment recommendations. For such simple tools, even when exceeding the limitations of 510(k) exemptions referred to in 21 CFR 8XX.9, FDA does not intend to enforce compliance with the regulatory controls. For example, to the extent that these limitations apply, FDA does not intend to enforce compliance with regulatory controls for these simple tools, in vitro devices that are intended to be used in diabetes management (21 CFR 8xx.9(c)(5)) or for assessing cardiovascular disease (21 CFR 8xx.9(c)(4)).

3. **Mobile apps that provide easy access to information related to patients' health conditions or treatments (beyond providing an electronic "copy" of a medical reference)** – These are apps that provide contextually-relevant information to users by matching patient-specific information (e.g., diagnosis, treatments, allergies, signs or symptoms) to reference information routinely used in clinical practice[29] (e.g., practice guidelines) to facilitate a user's assessment of a specific patient. Examples include:
    - Apps that use a patient's diagnosis to provide a clinician with best practice treatment guidelines for common illnesses or conditions such as influenza;
    - Apps that are drug-drug interaction or drug-allergy look-up tools.

4. **Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions** – These are apps that in their labeling or promotional materials are not promoted for medical uses but which, by virtue of other circumstances surrounding their distribution, may meet the definition of a medical device. These products either pose little or no risk, or are the sole responsibility of the health care providers who have used them in medical applications. Examples include:
    - Apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications between patients, healthcare providers, and caregivers;
    - Apps specifically intended for medical uses that utilize the mobile device's built-in camera or a connected camera for purposes of documenting or transmitting pictures (e.g., photos of a patient's skin lesions or wounds) to supplement or augment what would otherwise be a verbal description in a consultation between healthcare providers or between healthcare providers and patients/caregivers.

5. **Mobile apps that perform simple calculations routinely used in clinical practice** – These are apps that are intended to provide a convenient way for clinicians to perform various simple medical calculations taught in medical schools[30] and are routinely used in clinical practice. These apps are generally tailored for clinical use, but retain functionality that is similar to simple general purpose tools such as paper charts, spread sheets, timers or generic mathematical calculators. Examples of such general purpose tools include medical calculators for:
    - Body Mass Index (BMI)
    - Total Body Water / Urea Volume of Distribution
    - Mean arterial pressure
    - Glascow Coma Scale score
    - APGAR score
    - NIH Stroke Scale
    - Delivery date estimator

[29] The type of information provided in these apps is from authoritative medical sources, as recognized by the field or discipline that is the subject of the app.

[30] The types of information in these calculators are available in medical sources which includes medical textbooks used in the curriculum of accredited medical schools.

6. **Mobile apps that enable individuals to interact with PHR systems or EHR systems --** These are apps that provide patients and providers with mobile access to health record systems or enables them to gain electronic access to health information stored within a PHR system or EHR system. Applications that only allow individuals to view or download EHR data are also included in this category. These mobile apps are generally meant to facilitate general patient health information management and health record-keeping activities.

7. **Mobile apps that meet the definition of Medical Device Data Systems** – These are apps that are intended to transfer, store, convert format, and display medical device data, without controlling or altering the functions or parameters of any connected medical device, as defined in the MDDS classification regulation (21 CFR 880.6310). These mobile apps include those that are used as a secondary display to a regulated medical device when these apps are not intended to provide primary diagnosis, treatment decisions, or to be used in connection with active patient monitoring (i.e., mobile apps that meet the MDDS definition).

See Appendix B for additional examples for the above categories.

VI. Regulatory requirements

This guidance, including 0 and existing medical device regulatory classifications in Appendix D, is intended to assist manufacturers in determining if a product is a mobile medical app and FDA's expectations for that product. Additional information can be found in "Device Advice: Classify Your Medical Device" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm. This section describes in greater detail the regulatory requirements applicable to mobile medical apps under this guidance (as described in Section V).

Manufacturers of mobile medical apps are subject to the requirements described in the applicable device classification regulation below. Depending on the classification and the associated regulation for the mobile medical apps, manufacturers of mobile medical apps are required to follow associated controls established by the regulation.

In general, the associated controls for each class of device are outlined below.

Class I devices: General Controls, including:

- Establishment registration, and Medical Device listing (21 CFR Part 807);
- Quality System (QS) regulation (21 CFR Part 820);
- Labeling requirements (21 CFR Part 801);
- Medical Device Reporting (21 CFR Part 803);
- Premarket notification (21 CFR Part 807);
- Reporting Corrections and Removals (21 CFR Part 806); and
- Investigational Device Exemption (IDE) requirements for clinical studies of investigational devices (21 CFR Part 812).

Class II devices: General Controls (as described for Class I), Special Controls, and (for most Class II devices) Premarket Notification.

Class III devices: General Controls (as described for Class I), and Premarket Approval (21 CFR Part 814).

Appendix E provides a brief summary of the above requirements. Additional information is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, under "Overview of Medical Device Regulation" and "How to Market Your Device."
If you need further assistance, you may contact the Division of Industry and Consumer Education: Email: DICE@fda.hhs.gov; phone: 301-796-7100 or 800-638-2041.

Appendix A Examples of mobile apps that are NOT medical devices

This Appendix provides a representative list of mobile app functionalities to illustrate the types of mobile apps that could be used in a healthcare environment, in clinical care or patient management, but are not considered medical devices. Because these mobile apps are not considered medical devices, FDA does not regulate them. The FDA understands that there may be other unique and innovative mobile apps that may not be covered in this list that may also constitute healthcare related mobile apps. **This list is not exhaustive**; it is only intended to provide clarity and assistance in identifying when a mobile app is not considered to be a medical device.

Specific examples of mobile apps that FDA does not consider to be devices and with no regulatory requirements under the current laws administered by FDA include:

1. Mobile apps that are intended to provide access to electronic "copies" (e.g., e-books, audio books) of medical textbooks or other reference materials with generic text search capabilities. These are not devices because these apps are intended to be used as reference materials and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease by facilitating a health professional's assessment of a specific patient, replacing the judgment of clinical personnel, or performing any clinical assessment. Examples include mobile apps that are:
    - Medical dictionaries;
    - Electronic copies of medical textbooks or literature articles such as the Physician's Desk Reference or Diagnostic and Statistical Manual of Mental Disorders (DSM);
    - Library of clinical descriptions for diseases and conditions;
    - Encyclopedia of first-aid or emergency care information;
    - Medical abbreviations and definitions;
    - Translations of medical terms across multiple languages.

2. Mobile apps that are intended for health care providers to use as educational tools for medical training or to reinforce training previously received. These may have more functionality than providing an electronic copy of text (e.g., videos, interactive diagrams), but are not devices because they are intended generally for user education and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease by facilitating a health professional's assessment of a specific patient, replacing the judgment of clinical personnel, or performing any clinical assessment. Examples include mobile apps that are:
    - Medical flash cards with medical images, pictures, graphs, etc.;
    - Question/Answer quiz apps;
    - Interactive anatomy diagrams or videos;
    - Surgical training videos;
    - Medical board certification or recertification preparation apps;
    - Games that simulate various cardiac arrest scenarios to train health professionals in advanced CPR skills.

3. Mobile apps that are intended for general patient education and facilitate patient access to commonly used reference information. These apps can be patient-specific (i.e., filters information to patient-specific characteristics), but are intended for increased patient awareness, education, and empowerment, and ultimately support patient-centered health care. These are not devices because they are intended generally for patient education, and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease by aiding clinical decision-making (i.e., to facilitate a health professional's assessment of a specific patient, replace the judgment of a health professional, or perform any clinical assessment). Examples include mobile apps that:
    - Provide a portal for healthcare providers to distribute educational information (e.g., interactive diagrams, useful links and resources) to their patients regarding their disease, condition, treatment or up-coming procedure;
    - Help guide patients to ask appropriate questions to their physician relevant to their particular disease, condition, or concern;
    - Provide information about gluten-free food products or restaurants;
    - Help match patients with potentially appropriate clinical trials and facilitate communication between the patient and clinical trial investigators;
    - Provide tutorials or training videos on how to administer first-aid or CPR;
    - Allow users to input pill shape, color or imprint and displays pictures and names of pills that match this description;
    - Find the closest medical facilities and doctors to the user's location;
    - Provide lists of emergency hotlines and physician/nurse advice lines;
    - Provide and compare costs of drugs and medical products at pharmacies in the user's location.

4. Mobile apps that automate general office operations in a health care setting and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Examples include mobile apps that:
    - Determine billing codes like ICD-9 (international statistical classification of diseases);
    - Enable insurance claims data collection and processing and other apps that are similarly administrative in nature;
    - Analyze insurance claims for fraud or abuse;
    - Perform medical business accounting functions or track and trend billable hours and procedures;
    - Generate reminders for scheduled medical appointments or blood donation appointments;
    - Help patients track, review and pay medical claims and bills online;
    - Manage shifts for doctors;
    - Manage or schedule hospital rooms or bed spaces;
    - Provide wait times and electronic check-in for hospital emergency rooms and urgent care facilities;
    - Allow healthcare providers or staff in healthcare settings to process payments (for example, using a HIPAA compliant app to process payments);
    - Track or perform patient satisfaction survey after an encounter or a clinical visit.

5. Mobile apps that are generic aids or general purpose products. These apps are not considered devices because they are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Examples include mobile apps that:
    - Use the mobile platform as a magnifying glass (but are not specifically intended for medical purposes[31]);
    - Use the mobile platform for recording audio, note-taking, replaying audio with amplification, or other similar functionalities;
    - Allow patients or healthcare providers to interact through email, web-based platforms, video or other communication mechanisms (but are not specifically intended for medical purposes);
    - Provide maps and turn-by-turn directions to medical facilities;
    - Allow health care providers to communicate in a secure and protected method (for example using a HIPAA compliant app to send messages between health care providers in a hospital).

[31] Medical purpose magnifiers are regulated either under 21 CFR 886.5840 - Magnifying spectacles ("devices that consist of spectacle frames with convex lenses intended to be worn by a patient who has impaired vision to enlarge images"), or under 21 CFR 886.5540 - Low-vision magnifiers ("a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device may be held in the hand or attached to spectacles").

Appendix B Examples of mobile apps for which FDA intends to exercise enforcement discretion

This Appendix provides examples of mobile apps that **MAY** meet the definition of medical device but for which FDA intends to exercise enforcement discretion. These mobile apps may be intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Even though these mobile apps MAY meet the definition of medical device, FDA intends to exercise enforcement discretion for these mobile apps because they pose lower risk to the public.

The FDA understands that there may be other unique and innovative mobile apps that may not be covered in this list that may also constitute healthcare related mobile apps. This list is not exhaustive; it is only intended to provide clarity and assistance in identifying the mobile apps that will not be subject to regulatory requirements at this time.

- Mobile apps that help patients with diagnosed psychiatric conditions (e.g., post-traumatic stress disorder (PTSD), depression, anxiety, obsessive compulsive disorder) maintain their behavioral coping skills by providing a "Skill of the Day" behavioral technique or audio messages that the user can access when experiencing increased anxiety;

- Mobile apps that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women;

- Mobile apps that use GPS location information to alert asthmatics of environmental conditions that may cause asthma symptoms or alert an addiction patient (substance abusers) when near a pre-identified, high-risk location;

- Mobile apps that use video and video games to motivate patients to do their physical therapy exercises at home;

- Mobile apps that prompt a user to enter which herb and drug they would like to take concurrently and provide information about whether interactions have been seen in the literature and a summary of what type of interaction was reported;

- Mobile apps that help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks;

- Mobile apps that prompt the user to manually enter symptomatic, behavioral or environmental information, the specifics of which are pre-defined by a health care provider, and store the information for later review;

- Mobile apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling and preventive recommendations from well-known and established authorities;

- Mobile apps that use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care provider;

- Mobile apps that guide a user through a questionnaire of signs and symptoms to provide a recommendation for the type of health care facility most appropriate to their needs;

- Mobile apps that record the clinical conversation a clinician has with a patient and sends it (or a link) to the patient to access after the visit;

- Mobile apps that are intended to allow a user to initiate a pre-specified nurse call or emergency call using broadband or cellular phone technology;

- Mobile apps that enable a patient or caregiver to create and send an alert or general emergency notification to first responders;

- Mobile apps that keep track of medications and provide user-configured reminders for improved medication adherence;

- Mobile apps that provide patients a portal into their own health information, such as access to information captured during a previous clinical visit or historical trending and comparison of vital signs (e.g., body temperature, heart rate, blood pressure, or respiratory rate);

- Mobile apps that aggregate and display trends in personal health incidents (e.g., hospitalization rates or alert notification rates);

- Mobile apps that allow a user to collect (electronically or manually entered) blood pressure data and share this data through e-mail, track and trend it, or upload it to a personal or electronic health record;

- Mobile apps that provide oral health reminders or tracking tools for users with gum disease;

- Mobile apps that provide prediabetes patients with guidance or tools to help them develop better eating habits or increase physical activity;

- Mobile apps that display, at opportune times, images or other messages for a substance abuser who wants to stop addictive behavior;

- Mobile apps[32] that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness, such as those that:

  - Provide tools to promote or encourage healthy eating, exercise, weight loss or other activities generally related to a healthy lifestyle or wellness;
  - Provide dietary logs, calorie counters or make dietary suggestions;
  - Provide meal planners and recipes;
  - Track general daily activities or make exercise or posture suggestions;
  - Track a normal baby's sleeping and feeding habits;
  - Actively monitor and trend exercise activity;
  - Help healthy people track the quantity or quality of their normal sleep patterns;
  - Provide and track scores from mind-challenging games or generic "brain age" tests;
  - Provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
  - Use social gaming to encourage healthy lifestyle habits;
  - Calculate calories burned in a workout.

- Mobile apps that transfer, store, convert formats, and display medical device data without modifying the data and do not control or alter the functions or parameters of any connected medical device (i.e., mobile apps that meet the definition of MDDS under 21 CFR 880.6310).

- Mobile apps that meet the definition of MDDS and connect to a nursing central station and display medical device data to a physician's mobile platform for review. Product code: OUG (21 CFR 880.6310).

- Mobile apps that are not intended for diagnostic image review such as image display for multidisciplinary patient management meetings (e.g., rounds) or patient consultation (and include a persistent on-screen notice, such as "for informational purposes only and not intended for diagnostic use"). Such devices would be considered medical image communications devices under 21 CFR 892.2020, product code LMD,

- Mobile apps for providers that help track or manage patient immunizations by assessing the need for immunization, consent form, and immunization lot number;

- Mobile apps that provide drug-drug interactions and relevant safety information (side effects, drug interactions, active ingredient) as a report based on demographic data (age, gender), clinical information (current diagnosis), and current medications;

[32] When these items are not marketed, promoted or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or do not otherwise meet the definition of medical device, FDA does not regulate them. When they are marketed, promoted or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or otherwise meet the definition of medical device, FDA intends to exercise enforcement discretion.

- Mobile apps that enable, during an encounter, a health care provider to access their patient's personal health record (health information) that is hosted on a web-based or other platform;

- Mobile apps that allow a user to, collect, log, track and trend data, such as blood glucose, blood pressure, heart rate, weight or other data from a device to eventually share with a heath care provider, or upload it to an online (cloud) database, personal or electronic health record.

Appendix C Examples of mobile apps that are the focus of FDA's regulatory oversight (mobile medical apps)

This Appendix provides examples of mobile apps that are considered medical devices (i.e., mobile medical apps), on which FDA will focus its regulatory oversight. These mobile apps meet the definition of medical device in the FD&C Act and their functionality poses a risk to a patient's safety if the mobile app were to not function as intended. Each example below provides a list of possible relevant product code(s) and/or regulation number.

FDA also encourages mobile medical app manufacturers to search FDA's public databases, such as the "Product Classification" database and the "510(k) Premarket Notification" database, to determine the level of regulation for a given device and for the most up-to-date information about the relevant regulatory requirements. These databases can be accessed through the following links:
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) and
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.)

Mobile apps that transform a mobile platform into a regulated medical device and therefore are mobile medical apps: These mobile apps use a mobile platform's built-in features such as light, vibrations, camera, or other similar sources to perform medical device functions (e.g., mobile medical apps that are used by a licensed practitioner to diagnose or treat a disease). Possible product codes: Varies depending on the intended use and function of the mobile medical app; see additional examples below.

- Mobile apps that use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart (electrocardiograph or ECG). Possible product code(s): DPS, MLC, OEY (21 CFR 870.2340), MLO, MWJ (21 CFR 870.2800).

- Mobile apps that use a sensor or electrode attached to the mobile platform or tools within the mobile platform itself (e.g., microphone and speaker) to electronically amplify and "project sounds associated with the heart, arteries and veins and other internal organs" (i.e., an electronic stethoscope). Possible product code: DQD (21 CFR 870.1875(b)).

- Mobile apps that use a sensor or electrode attached to the mobile platform or tools within the mobile platform itself (e.g., accelerometer) to measure physiological parameters during cardiopulmonary resuscitation (CPR) and give feedback about the quality of CPR being delivered. Possible product code: LIX (21 CFR 870.5200).

- Mobile apps that use a sensor attached to the mobile platform or tools within the mobile platform itself to record, view, or analyze eye movements for use in the diagnosis of balance disorders (i.e., nystagmograph). Possible product code: GWN (21 CFR 882.1460).

- Mobile apps that use tools within the mobile platform (e.g., speaker) to produce controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders (i.e., an audiometer). Possible product code: EWO (21 CFR 874.1050).

- Mobile apps that use a sensor attached to the mobile platform or tools within the mobile platform itself (e.g., accelerometer) to measure the degree of tremor caused by certain diseases (i.e., a tremor transducer). Possible product code: GYD (21 CFR 882.1950).

- Mobile apps that use a sensor attached to the mobile platform or tools within the mobile platform itself (e.g., accelerometer, microphone) to measure physiological parameters (e.g., limb movement, electrical activity of the brain (EEG)) during sleep and are intended for use in diagnosis of specific diseases or conditions such as sleep apnea. Possible product code(s): OLV (21 CFR 882.1400), LEL, MNR (21 CFR 868.2375), FLS, NPF (21 CFR 868.2377).

- Mobile apps that use an attachment to the mobile platform to measure blood oxygen saturation for diagnosis of specific disease or condition. Possible product code(s): DQA, NLF, MUD, NMD (21 CFR 870.2700) or DPZ (21 CFR 870.2710).

- Mobile apps that present donor history questions to a potential blood donor and record and/or transmit the responses to those questions for a blood collection facility to use in determining blood donor eligibility prior to collection of blood or blood components. Possible product code: MMH

- Mobile apps that use an attachment to the mobile platform to measure blood glucose levels. Possible product code: NBW (21 CFR 862.1345).

- Mobile apps that use that use an attachment to the mobile platform (e.g., light source, laser) to treat acne, reduce wrinkles, or remove hair. Possible product code: OLP, OHT, OHS (21 CFR 878.4810), OZC (21 CFR 890.5740).

- Mobile apps that use a microphone or speaker within a mobile platform to serve as a audiometer to allow healthcare providers to determine hearing loss at different frequencies. Possible product code: EWO (21 CFR 874.1050)

- Mobile apps that analyze an image of a skin lesion using mathematical algorithms, such as fractal analysis, and provide the user with an assessment of the risk of the lesion.

Mobile apps that connect to an existing device type for purposes of controlling its operation, function, or energy source and therefore are mobile medical apps: These mobile apps are those that control the operation or function (e.g., changes settings) of an implantable or body worn medical device. Possible product codes: Varies depending on the intended use and function of the parent medical device; see additional examples below.

- Mobile apps that alter the function or settings of an infusion pump. Possible product codes: MEB, FRN, LZH, LZG, OPP, MEA (21 CFR 880.5725), FIH (21 CFR 876.5820), LKK.

- Mobile apps that act as wireless remote controls or synchronization devices for computed tomography (CT) or X-Ray machines. Possible product code: JAK (21 CFR 892.1750), IZL (21 CFR 892.1720), KPR (21 CFR 892.1680).

- Mobile apps that control or change settings of an implantable neuromuscular stimulator. Possible product code(s): GZC (21 CFR 882.5860).

- Mobile apps that calibrate, control, or change settings of a cochlear implant. Possible product code(s): MCM.

- Mobile apps that control the inflation or deflation of a blood-pressure cuff. Possible product code: DSJ (21 CFR 870.1100), DSK (21 CFR 870.1110), DXN (21 CFR 870.1130).

- Mobile apps that are used to calibrate hearing aids and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer. Possible product code ETW (21 CFR 874.3310).

Mobile apps that are used in active patient monitoring or analyzing patient-specific medical device data from a connected device and therefore are mobile medical apps:

- Mobile apps that connect to bedside (or cardiac) monitors and transfer the data to a central viewing station for display and active patient monitoring. Possible product code(s): DSI, MHX, MLD (21 CFR 870.1025), DRT, MWI, MSX (21 CFR 870.2300).

- Mobile apps that connect to a perinatal monitoring system and transfer uterine contraction and fetal heart rate data to another display to allow for remote monitoring of labor progress. Possible product code(s): HGM (21 CFR 884.2740).

- Mobile apps that are intended to display images for diagnostic review may be regulated as a picture archiving and communications system. Possible product code LLZ, (21 CFR 892.2050).

Appendix D Examples of current regulations

This Appendix provides additional examples of classifications for regulated medical devices, the Class according to which they are regulated, and their regulation numbers as listed in Title 21 of the Code of Federal Regulations (CFR). This list is intended as a starting point for mobile medical app manufacturers to assist them in identifying regulated medical devices.

In the table below -- Regulation number 8xx.yyyy refers to regulation 21 CFR 8xx.yyyy; Device class 1, 2, 3 -- indicates the classification that applies to the device; Submission type "510(k) exempt," -- means that the manufacturer is not required to submit a premarket notification (i.e., 510(k)) prior to marketing the device. However, the 510(k) exemption may be subject to certain limitations. Submission type "510(k)," -- means that the manufacturer is typically required to submit a premarket notification.

Regulation number	Regulation Description	Example Device(s) within the Regulation (and current product code)	Device Class	Submission Type
862.1345	Glucose test system	System, Test, Blood Glucose, Over The Counter (NBW)	2	510(k)
862.2100	Calculator/data processing module for clinical use	Digital Image, Storage And Communications, Non-Diagnostic, Laboratory Information System (NVV)	1	510(k) exempt
868.1850	Monitoring spirometer	Spirometer, Monitoring (W/Wo Alarm) (BZK)	2	510(k)
868.1920	Esophageal stethoscope with electrical conductors	Stethoscope, Esophageal, With Electrical Conductors (BZT)	2	510(k)
868.2375	Breathing Frequency Monitor	Ventilatory Effort Recorder (MNR)	2	510(k)
868.2377	Apnea Monitor	Monitor, Apnea, Home Use (NPF)	2	510(k)
870.1025	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Detector and Alarm, Arrhythmia (DSI)	2	510(k)
870.1110	Blood-Pressure Computer	Computer, Blood-Pressure (DSK)	2	510(k)
870.1130	Noninvasive blood pressure measurement system	System, Measurement, Blood-Pressure, Non-Invasive (DXN)	2	510(k)
870.1875(b)	Stethoscope	Lung Sound Monitor (OCR) Stethoscope, Electronic (DQD)	2 2	510(k) 510(k)
870.2300	Cardiac Monitor (including cardiotachometer and rate alarm)	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm) (DRT) Monitor, Physiological, Patient(Without Arrhythmia Detection Or Alarms) (MWI) System, Network And Communication, Physiological Monitors (MSX)	2 2 2	510(k) 510(k) 510(k)
870.2340	Electrocardiograph	Monitor, St Segment (MLC) Single Lead Over-the-Counter Electrocardiograph (OEY)	2 2	510(k) 510(k)
870.2700	Oximeter	Oximeter (DQA)	2	510(k)

Regulation number	Regulation Description	Example Device(s) within the Regulation (and current product code)	Device Class	Submission Type
870.2770	Impedance plethysmograph	Analyzer, Body Composition (MNW)	2	510(k)
870.2800	Medical magnetic tape recorder	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)	2	510(k)
		Recorder, Event, Implantable Cardiac, (Without Arrhythmia Detection) (MXC)	2	510(k)
874.1050	Audiometer	Audiometer (EWO)	2	510(k) or 510(k) exempt
874.3400	Tinnitus masker	Masker, Tinnitus (KLW)	2	510(k)
874.4770	Otoscope	Otoscope (ERA)	1	510(k) exempt
876.1500	Endoscope and accessories	Endoscopic Video Imaging System/Component, Gastroenterology-Urology (FET)	2	510(k)
876.1725	Gastrointestinal motility monitoring system	Recorder, External, Pressure, Amplifier & Transducer (FES)	2	510(k)
878.4160	Surgical camera and accessories	Camera, Cine, Microsurgical, With Audio (FWK)	1	510(k) exempt
		Camera, Still, Microsurgical (FTH)	1	510(k) exempt
		Camera, Television, Endoscopic, With Audio (FWG)	1	510(k) exempt
878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology	Light Based Over The Counter Wrinkle Reduction (OHS)	2	510(k)
		Over-The-Counter Powered Light Based Laser For Acne (OLP)	2	510(k)
880.2400	Bed-patient monitor	Monitor, Bed Patient (KMI)	1	510(k) exempt
880.2700	Stand-on patient scale	Scale, Stand-On, Patient (FRI)	1	510(k) exempt
880.2910	Clinical electronic thermometer	Thermometer, Electronic, Clinical (FLL)	2	510(k)
880.5580	Acupuncture needle	Locator, Acupuncture Point (BWJ)	2	510(k)
880.6350	Battery-powered medical examination light	Light, Examination, Medical, Battery Powered (KYT)	1	510(k) exempt
882.1400	Electroencephalograph	Full-montage electroencephalograph (GWQ)	2	510(k)
		Standard polysomnograph with electroencephalograph (OLV)	2	510(k)
882.1550	Nerve conduction velocity measurement device	Device, Nerve conduction velocity measurement (JXE)	2	510(k)
882.1620	Intracranial pressure monitoring device	Device, Monitoring, Intracranial pressure (GWM)	2	510(k)
882.1890	Evoked response photic stimulator	Stimulator, Photic, Evoked response (GWE)	2	510(k)
882.1900	Evoked response auditory stimulator	Stimulator, Auditory, Evoked response (GWJ)	2	510(k)
882.1950	Tremor Transducer	Transducer, Tremor (GYD)	2	510(k)
884.2730	Home uterine activity monitor	Monitor, Heart Rate, Fetal, Non-Stress Test (Home Use) (MOH)	2	510(k)
884.2740	Perinatal monitoring system and accessories	System, Monitoring, Perinatal (HGM)	2	510(k)
884.2800	Computerized labor	System, Monitoring, For Progress Of Labor	2	510(k)

Regulation number	Regulation Description	Example Device(s) within the Regulation (and current product code)	Device Class	Submission Type
	monitoring system	(NPB)		
884.2900	Fetal stethoscope	Stethoscope, Fetal (HGN)	1	510(k) exempt
884.6120	Assisted reproductive accessories	Accessories, Assisted Reproduction (MQG)	2	510(k)
884.6190	Assisted reproductive microscopes and microscope accessories	Microscope And Microscope Accessories, Reproduction, Assisted (MTX)	1	510(k) exempt
886.1510	Eye movement monitor	Monitor, Eye Movement, Diagnostic (HMC)	2	510(k)
886.1570	Ophthalmoscope	Ophthalmoscope, Battery-powered (HLJ)	2	510(k)
886.1930	Tonometer and Accessories	Tonometer, Ac-Powered (HPK)	2	510(k)
886.5540	Low-vision magnifier	Magnifier, Hand-Held, Low-Vision (HJF) Spectacle Microscope, Low-Vision (HKC)	1 1	510(k) exempt 510(k) exempt
892.1560	Ultrasonic pulsed echo imaging system	System, Imaging, Optical Coherence Tomography (Oct) (NQQ)	2	510(k)
892.2030	Medical image digitizer	Digitizer, Image, Radiological (LMA) Digitizer, Images, Ophthalmic (NFH)	2 2	Enforcement Discretion for 510(k) submission[33] Enforcement Discretion for 510(k) submission [34]
892.2050	Picture archiving and communications system	System, Image Processing, Radiological (LLZ) System, Image Management, Opthalmic (NFJ)	2 2	510(k) 510(k)

[33] See "Guidance for Industry and Food and Drug Administration Staff - Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices" (December 20, 2011) available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283904.htm

[34] See footnote 31.

Appendix E Brief description of certain device regulatory requirements

This Appendix provides a high level description of certain regulatory requirements for medical devices, including mobile medical apps. The FDA has additional resources and publications online that describe these and other requirements in detail.

1. Establishment Registration and Medical Device Listing

Under 21 CFR Part 807, manufacturers of medical devices are required to annually register their establishments[35] with FDA and provide a list of the devices they market. The registration and listing requirement is a means of keeping FDA advised of who is manufacturing devices, and of the types of devices an establishment is manufacturing. Mobile medical app manufacturers are required to register their establishments with FDA and to list[36] by identifying to FDA the mobile medical apps they are marketing.

Additional information can be found in "Device Advice: Device Registration and Listing" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm. If you need further assistance, you may contact the Division of Risk Management Operations, Regulatory Policy and Systems Branch: Email: reglist@fda.hhs.gov, phone: 301-796-7400. Assistance is also available from, Division of Industry and Consumer Education: Email: DICE@fda.hhs.gov
phone: 301-796-7100 or 800-638-2041.

2. Investigational Device Exemption (IDE) requirements

An IDE allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA. Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of non-significant risk must be approved by the IRB only before the study can begin.

Mobile medical app manufacturers who are creating mobile apps with novel technologies are encouraged to engage in early collaboration meetings with the FDA to receive recommendations for testing and development of those devices requiring clinical investigations to support marketing.

Additional information about these meetings is described in guidance issued on February 28, 2001: "Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff." This document is available at

[35] Under 21 CFR 807.3(c), "*Establishment"* is defined as "a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed."
[36] See 21 CFR part 807.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073604.htm.

Further information regarding the investigational device exemption can be found in "Device Advice: Investigational Device Exemption" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm.

3. Labeling requirements

Medical device manufacturers are required to comply with applicable labeling regulations found in 21 CFR Part 801 for medical devices and Part 809 for in vitro diagnostic products.

4. Premarket submission for approval or clearance

Mobile medical app manufacturers should identify the current classification covering their mobile medical app. Manufacturers are required to prepare and submit to the FDA an appropriate premarket submission, as required for their device classification.

Additional information can be found in "Device Advice: Device Registration and Listing" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm.

5. Quality System Regulation (QS Regulation)

Mobile medical app manufacturers are required to comply with the QS regulation. [37] The QS regulation does not prescribe in detail how a manufacturer must produce a specific device, but provides a framework for all manufacturers to develop and follow to help ensure that their products consistently meet applicable requirements and specifications. As part of this framework, mobile medical app manufacturers are required to develop requirements for their products that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, and distribute their devices.

Furthermore, mobile medical app manufacturers are required, as part of the QS regulation (21 CFR 820.30), to appropriately verify and validate their mobile medical apps along with the mobile platform to ensure safe and effective operation of the mobile medical app.

Mobile medical app manufacturers are required to ensure that adequate controls and processes are in place through purchasing controls to ensure safe distribution, installation, and operation of the mobile medical app.

Additional information regarding the QS regulation and can be found at "Quality System (QS) Regulation/Medical Device Good Manufacturing Practices"

[37] See 21 CFR part 820.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm.

6. Medical Device Reporting (MDR) (Adverse event reporting)

The Medical Device Reporting (MDR) regulation requires manufacturers and importers of medical devices to submit reports to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device they market may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that they market would be likely to cause or contribute to a reportable death or serious injury if the malfunction were to recur.[38] MDR requires medical device manufacturers to:

- Submit MDR reportable events involving their medical devices as described in 21 CFR 803.10(c) and 803.50;
- Submit 5-day reports as described in 21 CFR 803.53;
- Submit supplemental reports as described in 21 CFR 803.56;
- Develop, maintain, and implement written procedures for the identification and evaluation of all medical device events to determine whether the event is MDR reportable as described in 21 CFR 803.17;
- Conduct an investigation of each event and evaluate the cause of the event as described in 21 CFR 803.50(b)(3); and
- Establish and maintain complete files for all complaints concerning adverse medical device events as described in 21 CFR 803.18.

The MDR report (FDA Form 3500A) must contain all the information described in 21 CFR 803.52 that is reasonably known to the manufacturer. Information reasonably known includes any information that:

- Can be obtained by contacting a user facility, importer, or other initial reporter;
- Is in the possession of the manufacturer; or
- Can be obtained by analysis, testing, or other evaluation of the device.

For additional instructions on how to complete the 3500A form, refer to the document titled "Instructions for Completing Form FDA 3500A" at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm.

For additional guidance on the MDR regulation and the reporting requirements, refer to the document titled "Medical Device Reporting for Manufacturers" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm.

For Questions about Medical Device Reporting, including interpretation of MDR policy:

[38] See 21 CFR part 803.

- Call: (301) 796-6670 (voice)
- Email: RSMB@fda.hhs.gov
- Mail: Food and Drug Administration, Center for Devices and Radiological Health, Reporting Systems Monitoring Branch, 10903 New Hampshire Avenue, WO Bldg. 66, Room 3217, Silver Spring, MD 20993-0002

7. Correcting Problems

A mobile medical app manufacturer may voluntarily take action at any time or may be requested to take action by the FDA to correct problems. Voluntary action is usually taken by device manufacturers. Examples of the types of actions that a mobile medical app manufacturer may be requested to take include, but are not limited to:

- Inspecting the device for problems;
- Repairing the device;
- Adjusting settings on the device; and
- Upgrading software to reduce risk from a "bug" or unintended response.

Under certain circumstances, FDA may initiate a request that a manufacturer address a problem with a device through other means, including by removal of the product from the market. When recommending corrective action, the FDA intends to take into account the essential role that certain mobile medical apps take as an integral part of a larger patient care system.

Reporting Corrections to FDA:

In accordance with 21 CFR 806.10, mobile medical app manufacturers are required to promptly report, within 10 working days from the time the correction is initiated, to the FDA certain actions concerning device corrections and removals for the mobile medical app. Specifically, mobile medical app manufacturers are required to report to FDA any corrections made to a mobile medical app to reduce a risk to health posed by the mobile medical app or to remedy a violation of the FD&C Act caused by the mobile medical app which may present a risk to health.

The reporting requirement does not extend to all modifications to mobile medical apps. For example, certain actions that would improve the quality of a mobile medical app but that would not reduce a risk to health posed by the mobile medical app or remedy a violation of the FD&C Act are not required to be reported under 21 CFR 806.1(b)[39]. If there is not a "risk to health" involved, a report to FDA is not required, but the mobile medical app manufacturer must keep a record of the correction. An example of such action taken by the manufacturer could be changes

[39] Under 21 CFR 806.1(b), the following actions are exempt from the reporting requirements of part 806:
(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.
(2) Market withdrawals as defined in 21 CFR 806.2(h).
(3) Routine servicing as defined in 21 CFR 806.2(k).
(4) Stock recoveries as defined in 21 CFR 806.2(l).

made to correct a defect that creates a nuisance for the user but does not present a risk to the health of the user or patient.

More information about reporting requirements under 21 CFR Part 806 is available in "Device Advice: Recalls, Corrections, and Removals" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm.

Appendix F Frequently Asked Questions (FAQs)

1) I have a mobile app not identified in this guidance. What is the best way to get additional information from the FDA about my product?

Answer: FDA recognizes that this guidance does not describe all types of mobile apps used in healthcare. Some manufacturers may be unsure whether their mobile app is considered a medical device which is subject to regulatory oversight, or whether their medical device could be under FDA's intent to exercise enforcement discretion. If the device is subject to regulatory oversight, manufacturers may have questions about which regulatory requirements are applicable to their specific mobile app.

After reviewing this guidance, FDA encourages mobile app manufacturers to contact the Agency to obtain more information using one of the following ways:

- Phone or e-mail - For general regulatory information, contact the Division of Industry and Consumer Education (DICE). Email: DICE@fda.hhs.gov; phone: 301-796-7100 or 800-638-2041.
  If your question relates to apps used in blood establishments or another area of CBER regulation, contact the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring; e-mail: ocod@fda.hhs.gov; phone: 1-800-835-4709 or 240-402-7800.

- Online – The FDA has several resources and publications online that describe various regulatory requirements in detail. FDA's "Device Advice" website (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm) and online courses at "CDRH Learn" (http://www.fda.gov/Training/CDRHLearn/default.htm) are a good place to start. Other sections in this guidance provide links to more detailed information related to more specific topics.

- Letter - For written feedback about the classification and the regulatory requirements that may be applicable to a mobile medical app that is a device, manufacturers should use the 513(g) process. Specifically, a manufacturer should submit the following for a 513(g) submission:
  - User fee,
  - Cover letter,
  - Description of the mobile app,
  - Description of what the mobile app is to be used for, and
  - Any proposed labeling or promotional material for the mobile app and, as applicable, any labeling or promotional material of a similar, legally marketed device, if available.

  FDA will generally issue a response to the 513(g), in the form of a confidential letter to the manufacturer, within 60 days of receipt of the request for information. For more specific information about what to include in a 513(g) and where to send it, refer to FDA's guidance document titled "FDA and Industry Procedures for Section 513(g) Requests for Information

Under the Federal Food, Drug, and Cosmetic Act" at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209841.htm. For more information about 513(g) user fees, refer to FDA's guidance document titled "User Fees for 513(g) Requests for Information" at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209852.htm.

2) Why does FDA recommend that manufacturers follow the Quality System (QS) regulation for those mobile apps that MAY be devices and could be mobile medical apps but for which FDA intends to exercise enforcement discretion?

Answer: FDA believes all manufacturers of medical device software should have in place an adequate quality management system that helps ensure that their products consistently meet applicable requirements and specifications and can support the software throughout its total life cycle. Having and maintaining an adequate quality management system is also important since the FDA has found that the majority of software-related failures in medical devices are due to design errors. In one study, the most common problem was failure to validate software prior to routine maintenance.[40]

Adequate quality management systems incorporate appropriate risk management strategies, good design practices, adequate verification and validation, and appropriate methods to correct and prevent risks to patients and adverse events that may arise from the use of the product. All of these elements are part of FDA's QS regulation.

3) Is FDA's QS regulation similar to software development practices I already use?

Answer: Most likely. Though not all of the principles in the QS regulation are applicable to the development and manufacture of quality mobile medical apps[41], the majority of them are applicable and are consistent with commonly used and accepted good software development practices, such as those from the Institute of Electrical and Electronics Engineers' (IEEE), Software Engineering Body of Knowledge (SWEBOK), and Carnegie Mellon Software Engineering Institute's Capability Maturity Model Integration (CMMI) methods.

The FDA's approach to QS regulation is also harmonized with certain international standards such as ISO 9001 and ISO 13485.[42] Similar to these international standards, the QS regulation does not prescribe in detail how a manufacturer must produce a specific device but provides a framework for all manufacturers to develop and follow to help ensure that their products consistently meet applicable requirements and specifications. The QS regulation can apply to and be scaled for any size manufacturer and any type of product. It also allows for a

[40] See footnote 19.
[41] Certain portions of the QS regulation that apply to medical device hardware (such as the production and process controls outlined in 21 CFR 820.70) may not clearly apply to mobile medical apps.
[42] ISO 9001:2008 "Quality management systems--Requirements," and ISO 13485:2003 ``Medical devices-Quality management systems-Requirements for regulatory purposes." See also ANSI/AAMI/ISO 13485:2003.

manufacturer to choose those requirements most appropriate for its given device and manufacturing process.[43]

4) What are some examples of parts of the QS regulation that are of particular importance to mobile medical apps and where can I find more information about them?

Answer: Though not a complete list, some examples of principles within the QS regulation that are relevant to all mobile medical app manufacturers include risk assessment and management, design controls, and corrective and preventive actions. Risk assessment and management is a critical part of good quality management systems. Good design practices are important to the development and manufacture of safe mobile medical apps. It is also important for manufacturers to have procedures in place to identify, analyze, correct, and prevent app-related causes of patient or user harm. References related to these examples are provided in Appendix E of this guidance. Additional references about these principles which mobile medical app manufacturers may find useful include the following:

FDA's "Design Control Guidance for Medical Device Manufacturers" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm

FDA's "General Principles of Software Validation" guidance at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

5) Do all the mobile medical apps have to submit a premarket submission and receive FDA clearance or approval before marketing?

Answer: No, not all mobile medical app manufacturers have to submit a premarket submission (i.e., a 510(k) or PMA) prior to marketing their app. This determination depends on the classification of the device. Manufacturers of devices that are exempt from 510(k) or PMA requirements do not have to file a submission with FDA prior to marketing their device. For example, the majority of class I devices are exempt from the premarket submission requirements and are subject to the least regulatory control.

Regardless of whether medical devices are subject to the premarket submission requirements, most medical devices (including Class I devices) have to comply with other basic regulatory requirements that are called "General Controls." More information about what "General Controls" are and what a medical device manufacturer should do to comply with these requirements, can be found in "Device Advice: General Controls for Medical Devices" at

[43] See 21 CFR 820.1 (stating "if a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.")

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm and at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm.

6) Some FDA classifications state they are "510(k) exempt." What does 510(k) exempt mean and how do I know if it applies to my product?

Answer: If a classification states the device type is "510(k) exempt," this means that the manufacturer is not required to submit a premarket notification (i.e., a 510(k)) prior to marketing the device. However, the 510(k) exemption may be subject to certain limitations. Manufacturers are encouraged to confirm the device's exempt status and any limitations to that status that may apply in accordance with 21 CFR Parts 862-892. Additional information about 510(k) exempt devices can be found at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm.

7) If a 510(k) is required for my mobile medical app, what type of software documentation does FDA recommend I include in the submission?

Answer: FDA's recommendations for the software-related documentation that you provide in your premarket submission are addressed in detail in the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This guidance can be accessed on FDA's website here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm.

If the mobile medical app uses off-the-shelf software, manufacturers should also refer to FDA's "Guidance for Industry, FDA Reviewers, and Compliance on Off-the-Shelf Software Use in Medical Devices" available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073778.htm.

8) I am a medical device manufacturer and making my product labeling available electronically using a mobile app. Is my app considered a mobile medical app?

Answer: Mobile apps that provide electronic access and are intended for use as a digital version of medical device labeling or instructions for use are not considered medical device on their own and therefore are not considered mobile medical apps. These are apps from a device manufacturer that provide information to support the company's own device. Examples include apps that provide an electronic copy of cleared or approved medical device labeling or apps that provide video instruction for how to use a medical device. These types of apps are not considered devices within themselves, but instead are considered part of the medical device labeling and are subject to the regulatory labeling requirements relevant to that particular product.

9) Does an electronic method of collecting clinical investigations for example through a mobile app considered a mobile medical app, what requirements apply?

Answer: Mobile apps used for data collection in clinical studies (such as electronic Patient Reported Outcomes (ePRO) apps) are not considered on its own a mobile medical app. However, manufacturers and users of this type of mobile app should see FDA's draft guidance related to use of computers in clinical trials, "Electronic Source Data in Clinical Investigations," [44] issued on November 20, 2012. When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of this guidance, check the CDER guidance webpage at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

10) I am a medical device manufacturer. Is an electronic method of collecting and storing quality systems information in my manufacturing process considered a medical device or a mobile medical app?

Answer: Mobile apps used in the production process for medical devices, or for collecting, storing and maintaining quality system data collection for medical devices (including complaint submissions) are not considered medical device on their own and therefore are not considered mobile medical apps. These types of apps do not meet the definition of medical device but are part of the quality system. However these mobile apps are required to comply with the appropriate good manufacturing practices (GMP) regulations (see 21 CFR Part 820).

Appendix G Additional Resources

AAMI = Association for the Advancement of Medical Instrumentation
ANSI = American National Standards Institute
IEC = International Electrotechnical Commission
IEEE = Institute of Electrical and Electronics Engineers
ISO = International Organization for Standardization

1. Guidance for Industry and FDA Staff - Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007 (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm185871.htm).

2. ISO/IEC 90003:2004, *Software engineering -- Guidelines for the application of ISO 9001:2000 to computer software*, 2004.

3. ISO 9001:2008, *Quality management systems – Requirements*, 2008.

4. ISO 13485:2003, *Medical devices - Quality management systems - Requirements for regulatory purposes*, 2003. Note: This has also been adopted in the U.S. as ANSI/AAMI/ISO 13485:2003, *Medical devices - Quality management systems - Requirements for regulatory purposes*, 2003 (identical adoption).

5. ISO 9000:2005 *Quality management systems – Fundamentals and vocabulary*, 2005.

6. ISO 14971:2007, Medical Devices - Risk Management - Part 1: Application of Risk Analysis, 2007. Note: This has also been adopted in the U.S. as ANSI/AAMI/ISO 14971:2007, *Medical devices - Application of risk management to medical devices*, 2007 (identical adoption).

7. Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077812.htm).

8. Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software" -- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070634.htm

9. IEC 62304:2006, *Medical device software – Software life cycle processes*, 2006. Note: This is also adopted in the U.S as ANSI/AAMI/IEC 62304:2006, *Medical device software - Software life cycle processes*, 2006 (identical adoption).

10. IEEE Std 1012-2004, *IEEE Standard for Software Verification and Validation*, 2004.

11. IEEE 1012-2012, *IEEE Standard for System and Software Verification and Validation*, 2012.

12. *IEEE Standards Collection, Software Engineering*, 1994. ISBN 1-55937-442-X.

13. ISO/IEC 25051:2006, *Software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Requirements for quality of Commercial Off-The-Shelf (COTS) software product and instructions for testing*, 2006.

14. ISO/IEC 12207:2008, *Systems and software engineering – Software life cycle processes, 2008* and IEEE Std 12207-2008, *Systems and software engineering – Software life cycle processes, 2008.*

15. ISO/IEC 14598:1999, *Information technology - Software product evaluation*, 1999.

16. AAMI TIR32:2004, *Medical device software risk management*, 2004.

17. AAMI TIR36:2007, *Validation of software for regulated processes*, 2007.

18. ANSI/AAMI/IEC TIR80002-1:2009, Medical device software - Part 1: *Guidance on the application of ISO 14971 to medical device software*, 2009. (Identical adoption of IEC/TR 80002-1:2009)

19. Guidance for the Submission of Premarket Notifications for Medical Image Management Devices (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073720.htm)

20. *Clause 14* of IEC 60601-1:2005, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*, 2005 OR *Clause 14* of ANSI/AAMI ES60601-1:2005, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*, 2005 (adoption with national deviations of IEC 60601-1:2005).

21. IEC 61508-2:2010, *Functional safety of electrical/electronic/programmable electronic safety-related systems*, 2010.

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

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Guidance for Industry and Food and Drug Administration Staff

Document Issued on: October 2, 2014

The draft of this document was issued on June 14, 2013.

For questions regarding this document contact the Office of Device Evaluation at 301-796-5550 or Office of Communication, Outreach and Development (CBER) at 1-800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Office of In Vitro Diagnostics and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD, 20852. Identify all comments with the docket number FDA-2013-D-0616-0001[. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1825 to identify the guidance you are requesting.

Additional copies of this guidance document are also available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach and Development 10903 New Hampshire Avenue, Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, by telephone, 1-800-835-4709 or 240-402-7800, by email, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

The need for effective cybersecurity to assure medical device functionality and safety has become more important with the increasing use of wireless, Internet- and network- connected devices, and the frequent electronic exchange of medical device-related health information. This guidance has been developed by the FDA to assist industry by identifying issues related to cybersecurity that manufacturers should consider in the design and development of their medical devices as well as in preparing premarket submissions for those devices. The recommendations contained in this guidance document are intended to supplement FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm) and "Guidance to Industry: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077812.htm).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Scope

This guidance provides recommendations to consider and information to include in FDA medical device premarket submissions for effective cybersecurity management. Effective cybersecurity management is intended to reduce the risk to patients by decreasing the likelihood that device functionality is intentionally or unintentionally compromised by inadequate cybersecurity.

This guidance document is applicable to the following premarket submissions for devices that contain software (including firmware) or programmable logic as well as software that is a medical device:[1]

- Premarket Notification (510(k)) including Traditional, Special, and Abbreviated
- *De novo* submissions
- Premarket Approval Applications (PMA)
- Product Development Protocols (PDP)
- Humanitarian Device Exemption (HDE) submissions.

3. Definitions

Asset[2] - is anything that has value to an individual or an organization.

Authentication - is the act of verifying the identity of a user, process, or device as a prerequisite to allowing access to the device, its data, information, or systems.

Authorization - is the right or a permission that is granted to access a device resource.

Availability – data, information, and information systems are accessible and usable on a timely basis in the expected manner (i.e. the assurance that information will be available when needed).

Confidentiality – data, information, or system structures are accessible only to authorized persons and entities and are processed at authorized times and in the authorized manner,

[1] Manufacturers may also consider applying the cybersecurity principles described in this guidance as appropriate to Investigational Device Exemption submissions and to devices exempt from premarket review.
[2] As defined in ISO/ICE 27032:2012(E) Information technology — Security techniques — Guidelines for cybersecurity.

thereby helping ensure data and system security. Confidentiality provides the assurance that no unauthorized users (i.e. only trusted users) have access to the data, information, or system structures.

Cybersecurity - is the process of preventing unauthorized access, modification, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient.

Encryption - is the cryptographic transformation of data into a form that conceals the data's original meaning to prevent it from being known or used.

Harm[3] - is defined as physical injury or damage to the health of people, or damage to property or the environment.

Integrity – in this document means that data, information and software are accurate and complete and have not been improperly modified.

Life-cycle[2] – all phases in the life of a medical device, from initial conception to final decommissioning and disposal.

Malware - is software designed with malicious intent to disrupt normal function, gather sensitive information, and/or access other connected systems.

Privileged User[3] - is a user who is authorized (and, therefore, trusted) to perform security-relevant functions that ordinary users are not authorized to perform.

Risk[2] – is the combination of the probability of occurrence of harm and the severity of that harm.

Risk Analysis[2] – is the systematic use of available information to identify hazards and to estimate the risk.

4. General Principles

Manufacturers should develop a set of cybersecurity controls to assure medical device cybersecurity and maintain medical device functionality and safety.

FDA recognizes that medical device security is a shared responsibility between stakeholders, including health care facilities, patients, providers, and manufacturers of medical devices. Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats. This in turn may have the potential to result in patient illness, injury, or death.

[3] As defined in ANSI/AAMI/ISO 14971:2007 Medical devices – Application of risk management to medical devices.

Manufacturers should address cybersecurity during the design and development of the medical device, as this can result in more robust and efficient mitigation of patient risks. Manufacturers should establish design inputs for their device related to cybersecurity, and establish a cybersecurity vulnerability and management approach as part of the software validation and risk analysis that is required by 21 CFR 820.30(g).[4] The approach should appropriately address the following elements:

- Identification of assets, threats, and vulnerabilities;
- Assessment of the impact of threats and vulnerabilities on device functionality and end users/patients;
- Assessment of the likelihood of a threat and of a vulnerability being exploited;
- Determination of risk levels and suitable mitigation strategies;
- Assessment of residual risk and risk acceptance criteria.

5. Cybersecurity Functions

The Agency recommends that medical device manufacturers consider the following cybersecurity framework core functions to guide their cybersecurity activities: Identify, Protect, Detect, Respond, and Recover.[5]

Identify and Protect

Medical devices capable of connecting (wirelessly or hard-wired) to another device, to the Internet or other network, or to portable media (e.g. USB or CD) are more vulnerable to cybersecurity threats than devices that are not connected. The extent to which security controls are needed will depend on the device's intended use, the presence and intent of its electronic data interfaces, its intended environment of use, the type of cybersecurity vulnerabilities present, the likelihood the vulnerability will be exploited (either intentionally or unintentionally), and the probable risk of patient harm due to a cybersecurity breach.

Manufacturers should also carefully consider the balance between cybersecurity safeguards and the usability of the device in its intended environment of use (e.g. home use vs. health care facility use) to ensure that the security controls are appropriate for the intended users. For example, security controls should not unreasonably hinder access to a device intended to be used during an emergency situation.

The Agency recommends that medical device manufacturers provide justification in the premarket submission for the security functions chosen for their medical devices.

[4] 21 CFR Part 820 – Quality Systems Regulations: 21 CFR 820.30 Subpart C – Design Controls of the Quality System Regulation.

[5] National Institute of Standards and Technology. Framework for Improving Critical Infrastructure Cybersecurity. Available at: http://www.nist.gov/cyberframework/upload/cybersecurity-framework-021214-final.pdf.

Examples of security functions to consider for protection of medical devices should include, but should not be limited to, the following:

Limit Access to Trusted Users Only

- Limit access to devices through the authentication of users (e.g. user ID and password, smartcard, biometric);
- Use automatic timed methods to terminate sessions within the system where appropriate for the use environment;
- Where appropriate, employ a layered authorization model by differentiating privileges based on the user role (e.g. caregiver, system administrator) or device role;
- Use appropriate authentication (e.g. multi-factor authentication to permit privileged device access to system administrators, service technicians, maintenance personnel);
- Strengthen password protection by avoiding "hardcoded" password or common words (i.e. passwords which are the same for each device, difficult to change, and vulnerable to public disclosure) and limit public access to passwords used for privileged device access;
- Where appropriate, provide physical locks on devices and their communication ports to minimize tampering;
- Require user authentication or other appropriate controls before permitting software or firmware updates, including those affecting the operating system, applications, and anti-malware.

Ensure Trusted Content

- Restrict software or firmware updates to authenticated code. One authentication method manufacturers may consider is code signature verification;
- Use systematic procedures for authorized users to download version-identifiable software and firmware from the manufacturer;
- Ensure capability of secure data transfer to and from the device, and when appropriate, use methods for encryption.

Detect, Respond, Recover

- Implement features that allow for security compromises to be detected, recognized, logged, timed, and acted upon during normal use;
- Develop and provide information to the end user concerning appropriate actions to take upon detection of a cybersecurity event;
- Implement device features that protect critical functionality, even when the device's cybersecurity has been compromised;
- Provide methods for retention and recovery of device configuration by an authenticated privileged user.

Manufacturers may elect to provide an alternative method or approach, with appropriate justification.

6. Cybersecurity Documentation

The type of documentation the Agency recommends you submit in your premarket submission is summarized in this section. These recommendations are predicated on your effective implementation and management of a quality system in accordance with the Quality System Regulation, including Design Controls.

In the premarket submission, manufacturers should provide the following information related to the cybersecurity of their medical device:

1. Hazard analysis, mitigations, and design considerations pertaining to intentional and unintentional cybersecurity risks associated with your device, including:
   - A specific list of all cybersecurity risks that were considered in the design of your device;
   - A specific list and justification for all cybersecurity controls that were established for your device.

2. A traceability matrix that links your actual cybersecurity controls to the cybersecurity risks that were considered;

3. A summary describing the plan for providing validated software updates and patches as needed throughout the lifecycle of the medical device to continue to assure its safety and effectiveness. The FDA typically will not need to review or approve medical device software changes made solely to strengthen cybersecurity.

4. A summary describing controls that are in place to assure that the medical device software will maintain its integrity (e.g. remain free of malware) from the point of origin to the point at which that device leaves the control of the manufacturer; and

5. Device instructions for use and product specifications related to recommended cybersecurity controls appropriate for the intended use environment (e.g. anti-virus software, use of firewall).

7. Recognized Standards

The following is a list of FDA recognized consensus standards dealing with Information Technology (IT) and medical device security.

1. CLSI, AUTO11-A - IT Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard.
2. IEC, TR 80001-2-2 Edition 1.0 2012-07 - Application of risk management for IT Networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls.
3. AAMI/ANSI/IEC, TIR 80001-2-2:2012, - Application of risk management for IT Networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls.
4. IEC, /TS 62443-1-1 Edition 1.0 2009-07 - Industrial communication networks - Network and system security - Part 1-1: Terminology, concepts and models.
5. IEC, 62443-2-1 Edition 1.0 2010-11 - Industrial communication networks - Network and system security - Part 2-1: Establishing an industrial automation and control system security program
6. IEC, /TR 62443-3-1 Edition 1.0 2009-07 - Industrial communication networks - Network and system security - Part 3-1: Security technologies for industrial automation and control systems.

For an updated list of FDA recognized consensus standards the Agency recommends that you refer to the FDA Recognized Consensus Standards Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm), and type "security" in the title search for the current list of IT and medical device security consensus standards that are recognized by the Agency. For information on recognized consensus standards, see the guidance document "Frequently Asked Questions on Recognition of Consensus Standards" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm074973.htm).

Contains Nonbinding Recommendations

Postmarket Management of Cybersecurity in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

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For questions regarding this document, contact Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5434, Silver Spring, MD 20993-0002, 301-796-6937. For questions regarding this document as applied to devices regulated by CBER, contact the Office of Communication, Outreach and Development in CBER at 1-800-835-4709 or 240-402-8010 or ocod@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of the Center Director
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov . Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2015-D-5105. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Additional copies are available from the Center for Biologics Evaluation and Research (CBER), by written request, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Table of Contents

Postmarket Management of Cybersecurity in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) is issuing this guidance to inform industry and FDA staff of the Agency's recommendations for managing postmarket cybersecurity vulnerabilities for marketed and distributed medical devices. In addition to the specific recommendations contained in this guidance, manufacturers are encouraged to address cybersecurity throughout the product lifecycle, including during the design, development, production, distribution, deployment and maintenance of the device[1]. A growing number of medical devices are designed to be networked to facilitate patient care. Networked medical devices, like other networked computer systems, incorporate software that may be vulnerable to cybersecurity threats. The exploitation of vulnerabilities may represent a risk to health and typically requires continual maintenance throughout the product life cycle to assure an adequate degree of protection against such exploits. Proactively addressing cybersecurity risks in medical devices reduces the overall risk to health.

This guidance clarifies FDA's postmarket recommendations and emphasizes that manufacturers should monitor, identify, and address cybersecurity vulnerabilities and exploits as part of their postmarket management of medical devices. This guidance establishes a risk-based framework for assessing when changes to medical devices for cybersecurity vulnerabilities require reporting to the Agency and outlines circumstances in which FDA does not intend to enforce reporting requirements under 21 CFR part 806. 21 CFR part 806 requires device manufacturers or importers to report promptly to FDA certain actions concerning device corrections and removals. However, the majority of actions taken by manufacturers to address cybersecurity vulnerabilities and exploits, referred to as "cybersecurity routine updates and patches," are generally considered

[1] See FDA Guidance titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190)

to be a type of device enhancement[2] for which the FDA does not require advance notification or reporting under 21 CFR part 806. For a small subset of actions taken by manufacturers to correct device cybersecurity vulnerabilities and exploits that may pose a risk to health, the FDA would require medical device manufacturers to notify the Agency.[3] Risks to health posed by the device may result in patient harm. This guidance recommends how to assess whether the risk[4] of patient harm is sufficiently controlled or uncontrolled. This assessment is based on an evaluation of the likelihood of exploit, the impact of exploitation on the device's safety and essential performance,[5] and the severity of patient harm if exploited.

This document is not intended to provide guidance on reporting to FDA when a device has or may have caused or contributed to a death or serious injury as required by section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Medical Device Reporting (MDR) Regulation in 21 CFR part 803. For an explanation of the current reporting and recordkeeping requirements applicable to manufacturers of medical devices, please refer to the Medical Device Reporting for Manufacturers Guidance (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM359566).

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database Web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm .

FDA's guidance documents, including this final guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

On February 19, 2013, the President issued Executive Order 13636 – Improving Critical Infrastructure Cybersecurity (EO 13636; https://www.gpo.gov/fdsys/pkg/FR-2013-02-19/pdf/2013-03915.pdf), which recognized that resilient infrastructure is essential to preserving national security, economic stability, and public health and safety in the United States. EO 13636

[2] See FDA Guidance titled: "Distinguishing Medical Device Recalls from Medical Device Enhancements" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM418469.pdf).
[3] See 21 CFR 806.10.
[4] ANSI/AAMI/ISO 14971: 2007/(R)2010: *Medical Devices – Application of Risk Management to Medical Devices*, section 2.16 – definition of risk.
[5] ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) *Medical electrical equipment— Part 1: General requirements for basic safety and essential performance* (IEC 60601-1:2005, MOD), section 3.27 defines "Essential Performance" as performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk."

states that cyber threats to national security are among the most serious, and that stakeholders must enhance the cybersecurity and resilience of critical infrastructure. This includes the Healthcare and Public Health Critical Infrastructure Sector (HPH Sector). Furthermore, Presidential Policy Directive 21 – Critical Infrastructure Security and Resilience (PPD-21; https://www.whitehouse.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil) issued on February 12, 2013 tasks Federal Government entities to strengthen the security and resilience of critical infrastructure against physical and cyber threats such that these efforts reduce vulnerabilities, minimize consequences, and identify and disrupt threats. PPD-21 encourages all public and private stakeholders to share responsibility in achieving these outcomes.

In recognition of the shared responsibility for cybersecurity, the security industry has established resources including standards, guidelines, best practices and frameworks for stakeholders to adopt a culture of cybersecurity risk management. Best practices include collaboratively assessing cybersecurity intelligence information for risks to device functionality and clinical risk. FDA believes that, in alignment with EO 13636 and PPD-21, public and private stakeholders should collaborate to leverage available resources and tools to establish a common understanding that assesses risks for identified vulnerabilities in medical devices among the information technology community, healthcare delivery organizations (HDOs), the clinical user community, and the medical device community. These collaborations can lead to the consistent assessment and mitigation of cybersecurity threats and vulnerabilities, and their impact on medical devices, ultimately reducing potential risk of patient harm.

Cybersecurity risk management is a shared responsibility among stakeholders including the medical device manufacturer, the user, the Information Technology (IT) system integrator, Health IT developers, and an array of IT vendors that provide products that are not regulated by the FDA. FDA seeks to encourage collaboration among stakeholders by clarifying, for those stakeholders it regulates, recommendations associated with mitigating cybersecurity threats to device functionality and device users.

As stated in the FDA guidance document titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190), when manufacturers consider cybersecurity during the design phases of the medical device lifecycle, the resulting impact is a more proactive and robust mitigation of cybersecurity risks. Similarly, a proactive and risk-based approach to the postmarket phase for medical devices, through engaging in cybersecurity information sharing and monitoring, promoting "good cyber hygiene" through routine device cyber maintenance, assessing postmarket information, employing a risk-based approach to characterizing vulnerabilities, and timely implementation of necessary actions can further mitigate emerging cybersecurity risks and reduce the impact to patients.

To further aid manufacturers in managing their cybersecurity risk, the Agency encourages the use and adoption of the voluntary "Framework for Improving Critical Infrastructure Cybersecurity" (https://www.nist.gov/sites/default/files/documents/cyberframework/cybersecurity-framework-021214.pdf) that has been developed by the National Institute of Standards and Technology (NIST) with collective input from other government agencies and the private sector.

Critical to the adoption of a proactive, rather than reactive, postmarket cybersecurity approach is the sharing of cyber risk information and intelligence within the medical device community. This information sharing can enhance management of individual cybersecurity vulnerabilities and provide advance cyber threat information to additional relevant stakeholders to manage and enhance cybersecurity in the medical device community and HPH Sector.

Executive Order 13691 – Promoting Private Sector Cybersecurity Information Sharing (EO 13691; https://www.whitehouse.gov/the-press-office/2015/02/13/executive-order-promoting-private-sector-cybersecurity-information-shari), released on February 13, 2015, encourages the development of Information Sharing Analysis Organizations (ISAOs), to serve as focal points for cybersecurity information sharing and collaboration within the private sector as well as between the private sector and government. EO 13691 also mandates that the ISAO "…protects the privacy and civil liberties of individuals, that preserves business confidentiality, [and] that safeguards the information being shared…." ISAOs gather and analyze critical infrastructure information in order to better understand cybersecurity problems and interdependencies, communicate or disclose critical infrastructure information to help prevent, detect, mitigate, or recover from the effects of cyber threats, or voluntarily disseminate critical infrastructure information to its members or others involved in the detection and response to cybersecurity issues.[6]

The ISAOs (https://www.dhs.gov/isao) are intended to be: Inclusive (groups from any and all sectors, both non-profit and for-profit, expert or novice, should be able to participate in an ISAO); Actionable (groups will receive useful and practical cybersecurity risk, threat indicator, and incident information via automated, real-time mechanisms if they choose to participate in an ISAO); Transparent (groups interested in an ISAO model will have adequate understanding of how that model operates and if it meets their needs); and Trusted (participants in an ISAO can request that their information be treated as Protected Critical Infrastructure Information (https://www.dhs.gov/pcii-program). Such information is shielded from any release otherwise required by the Freedom of Information Act or State Sunshine Laws and is exempt from regulatory use and civil litigation if the information satisfies the requirements of the Critical Infrastructure Information Act of 2002 (6 U.S.C. §§ 131 et seq.)).

The FDA Center for Devices and Radiological Health has entered into a Memorandum of Understanding with one such ISAO, the National Health Information Sharing & Analysis Center, (NH-ISAC)[7] in order to assist in the creation of an environment that fosters stakeholder collaboration and communication, and encourages the sharing of information about cybersecurity threats and vulnerabilities that may affect the safety, effectiveness, integrity, and security of the medical devices and the surrounding Health IT infrastructure.

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[6] See Homeland Security Act (https://www.dhs.gov/xlibrary/assets/hr_5005_enr.pdf), 6 U.S.C. § 212 (2002).

[7] See Memorandum of Understanding between the National Health Information Sharing & Analysis Center, Inc. (NH-ISAC), The Medical Device Innovation, Safety and Security Consortium (MDISS), and the U.S. Food and Drug Administration Center for Devices and Radiological Health (http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm524376.htm).

The Agency wishes to promote collaboration among the medical device and Health IT community to develop a shared understanding of the risks posed by cybersecurity vulnerabilities to medical devices and foster the development of a shared understanding of risk assessment to enable stakeholders to consistently and efficiently assess patient safety and public health risks associated with identified cybersecurity vulnerabilities and take timely, appropriate action to mitigate the risks. This approach will also enable stakeholders to provide timely situational awareness to the HPH community and take efforts to preemptively address the cybersecurity vulnerability through appropriate mitigation and/or remediation before it impacts the safety, effectiveness, integrity or security of medical devices and the Health IT infrastructure.

The Agency considers voluntary participation in an ISAO a critical component of a medical device manufacturer's comprehensive proactive approach to management of postmarket cybersecurity threats and vulnerabilities and a significant step towards assuring the ongoing safety and effectiveness of marketed medical devices. For companies that actively participate in such a program, and follow other recommendations in this guidance, the Agency does not intend to enforce certain reporting requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see Section VII).

More information about active participation in an ISAO can be found in Section IX.

III. Scope

This guidance applies to any marketed and distributed medical device including: 1) medical devices that contain software (including firmware) or programmable logic; and 2) software that is a medical device, [8] including mobile medical applications.[9] In addition, this guidance applies to medical devices that are considered part of an interoperable[10] system and to "legacy devices," i.e., devices that are already on the market or in use.

This guidance supplements the information addressed in the FDA guidance document titled "Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software"

[8] Under section 201(h) of the FD&C Act, device is defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including a component part or accessory which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals." In addition, please note that the International Medical Device Regulators Forum (IMDRF) Software as a Medical Device (SaMD) December 9, 2013, section 5.1 defines "Software as a Medical Device" as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device (http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf).

[9] See FDA Guidance: "Mobile Medical Applications" (http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf).

[10] See FDA Guidance "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482649).

(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077812.htm).

This guidance does not apply to investigational devices.[11]

IV. Definitions

For the purposes of this guidance, the following definitions are used:

A. Compensating Controls

A cybersecurity compensating control is a safeguard or countermeasure deployed, in lieu of, or in the absence of controls designed in by a device manufacturer. These controls are external to the device design, configurable in the field, employed by a user, and provide supplementary or comparable cyber protection for a medical device[12]. For example, a manufacturer's assessment of a cybersecurity vulnerability determines that unauthorized access to a networked medical device will most likely impact the device's safety or essential performance. However, the manufacturer determines that the device can safely and effectively operate without access to the host network, in this case the hospital network. The manufacturer instructs users to configure the network to remove the ability of unauthorized/unintended access to the device from the hospital network. This type of counter measure is an example of a compensating control.

B. Controlled Risk

Controlled risk is present when there is sufficiently low (acceptable) residual risk of patient harm due to a device's particular cybersecurity vulnerability.

C. Cybersecurity Routine Updates and Patches

Cybersecurity "routine updates and patches" are changes to a device to increase device security and/or remediate only those vulnerabilities associated with controlled risk of patient harm. These types of changes are not to reduce uncontrolled risk of patient harm, and therefore not to reduce a risk to health or to correct a violation of the FD&C Act. They include any regularly scheduled security updates or patches to a device, including upgrades to the software, firmware, programmable logic, hardware, or security of a device to increase device security, as well as updates or patches to address vulnerabilities associated with controlled risk performed earlier than their regularly scheduled deployment cycle even if they are distributed to multiple units. Cybersecurity routine updates and patches are generally considered to be a type of device enhancement that may be applied to vulnerabilities associated with controlled risk and is not considered a repair. Cybersecurity routine updates and patches may also include changes to

[11] Manufacturers may also consider applying the cybersecurity principles described in this guidance as appropriate to Investigational Device Exemption submissions and to devices exempt from premarket review.

[12] This definition is adapted from NIST Special Publication "Assessing Security and Privacy Controls in Federal Information Systems and Organizations," NIST SP 800-53A Rev. 4.

product labeling, including the instructions for use, to strengthen cybersecurity through increased end-user education and use of best practices. Because "cybersecurity routine updates and patches are generally considered to be device enhancements, manufacturers are generally not required to report these updates and patches as corrections under 21 CFR part 806. See Section VII for more details on reporting requirements for vulnerabilities with controlled risk. Security updates made to remediate vulnerabilities associated with a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death are not considered to be cybersecurity routine updates or patches.

D. Cybersecurity Signal

A cybersecurity signal is any information which indicates the potential for, or confirmation of, a cybersecurity vulnerability or exploit that affects, or could affect a medical device. A cybersecurity signal could originate from traditional information sources such as internal investigations, postmarket surveillance, or complaints, and/or security-centric sources such as CERTS (Computer/Cyber, Emergency Response/Readiness Teams), such as ICS-CERT[13], ISAOs[14], threat indicators, and security researchers. Signals may be identified within the HPH Sector. They may also originate in another critical infrastructure sector (e.g., defense, financial) but have the potential to impact medical device cybersecurity.

E. Exploit

An exploit is an instance where a vulnerability or vulnerabilities have been exercised (accidently or intentionally) by a threat and could impact the safety or essential performance of a medical device or use a medical device as a vector to compromise a connected device or system.

F. Patient Harm

Harm[15] is the physical injury or damage to the health of people, or damage to property or the environment. Patient harm is defined as physical injury or damage to the health of patients, including death. Risks to health posed by the device may result in patient harm. This guidance outlines the assessment of whether the risk[16] of patient harm is sufficiently controlled or uncontrolled. This assessment is based on an evaluation of the likelihood of exploit, the impact of exploitation on the device's safety and essential performance, and the severity of patient harm if exploited (see section VI).

Other harms, such as loss of confidential information, including compromise of protected health information (PHI), are not considered "patient harms" for the purposes of this guidance.

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[13] ICS-CERT - Industrial Control Systems Cyber Emergency Response Team

[14] *See* Department of Homeland Security, "Frequently Asked Questions about Information Sharing and Analysis Organizations (ISAOs)."

[15] ANSI/AAMI/ISO 14971: 2007/(R)2010: *Medical Devices – Application of Risk Management to Medical Devices*, section 2.2 – definition of harm.

[16] ANSI/AAMI/ISO 14971: 2007/(R)2010: *Medical Devices – Application of Risk Management to Medical Devices*, section 2.16 – definition of risk.

Nevertheless, the FDA recommends that manufacturers consider protecting the confidentiality of such information as part of their overall comprehensive risk management program. Although protecting the confidentiality of PHI is beyond the scope of this document, it should be noted that manufacturers and/or other entities, depending on the facts and circumstances, may be obligated to protect the confidentiality, integrity and availability of PHI throughout the product life cycle, including disposal, in accordance with applicable federal and state laws, including the Health Information Portability and Accountability Act (HIPAA).[17] Changes to a device that are made solely to address loss of confidentiality are typically considered to be device enhancements.

G. Remediation

Remediation is any action(s) taken to reduce an uncontrolled risk of patient harm posed by a device cybersecurity vulnerability to an acceptable level. Remediation actions may include complete solutions to remove a cybersecurity vulnerability from a medical device or compensating controls that adequately mitigate the risk (e.g., notification to customers and the user community identifying a control the user can implement). An example of remediation is a notification to the customers and the user community that discloses the vulnerability, the impact to the device, the potential for patient harm, and provides a strategy to reduce the risk of patient harm to an acceptable and controlled level. If the customer notification does not provide a strategy to reduce the risk of patient harm to an acceptable and controlled level, then the remediation is considered incomplete.

H. Threat

Threat is any circumstance or event with the potential to adversely impact the device, organizational operations (including mission, functions, image, or reputation), organizational assets, individuals, or other organizations through an information system via unauthorized access, destruction, disclosure, modification of information, and/or denial of service.[18] Threats exercise vulnerabilities, which may impact the safety or essential performance of the device.

I. Threat Modeling

Threat modeling is a methodology for optimizing Network/Application/Internet Security by identifying objectives and vulnerabilities, and then defining countermeasures to prevent, or

[17] The HHS Office for Civil Rights enforces the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which protects the privacy of individually identifiable health information that covered entities or their business associates create, receive, maintain, or transmit; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; the HIPAA Breach Notification Rule, which requires covered entities and business associates to provide notification following a breach of unsecured protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety. See Health information Privacy at: http://www.hhs.gov/ocr/privacy/index.html.

[18] NIST SP 800-53; SP 800-53A; SP 800-27; SP 800-60; SP 800-37; CNSSI-4009. Note: Adapted from NIST definition (SP 800-53).

mitigate the effects of, threats to the system.[19] For medical devices, threat modeling can be used to strengthen security by identifying vulnerabilities and threats to a particular product, products in a product line, or from the organization's supply chain that can cause patient harm.

J. Uncontrolled Risk

Uncontrolled risk is present when there is unacceptable residual risk of patient harm due to inadequate compensating controls and risk mitigations.

K. Vulnerability

A vulnerability is a weakness in an information system, system security procedures, internal controls, human behavior, or implementation that could be exploited by a threat.

V. General Principles

FDA recognizes that medical device cybersecurity is a shared responsibility among stakeholders including health care facilities, patients, providers, and manufacturers of medical devices. Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats. This in turn may have the potential to result in patient illness, injury or death.

Effective cybersecurity risk management is intended to reduce the risk to patients by decreasing the likelihood that device functionality is intentionally or unintentionally compromised by inadequate cybersecurity. An effective cybersecurity risk management program should incorporate both premarket and postmarket lifecycle phases and address cybersecurity from medical device conception to obsolescence It is recommended that manufacturers apply the NIST Framework for Improving Critical Infrastructure Cybersecurity (i.e., Identify, Protect, Detect, Respond and Recover; https://www.nist.gov/sites/default/files/documents/cyberframework/cybersecurity-framework-021214.pdf in the development and implementation of their comprehensive cybersecurity programs. Alignment of the NIST Framework for Improving Critical Infrastructure Cybersecurity five core functions to management of cybersecurity in medical devices is discussed in the Appendix in greater detail.

A. Premarket Considerations

The FDA guidance document titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf) clarifies recommendations for manufacturers to address cybersecurity

[19] See "Threat Modeling" as defined in the Open Web Application Security Project (OWASP; https://www.owasp.org/index.php/Category:Threat_Modeling).

during the design and development of the medical device, as this can result in more robust and efficient mitigation of patient risks. Manufacturers should establish design inputs for their device related to cybersecurity, and establish a cybersecurity vulnerability and management approach as part of the software validation and risk analysis that is required by 21 CFR 820.30(g). The approach should appropriately address the following elements:

- Identification of assets, threats, and vulnerabilities;
- Assessment of the impact of threats and vulnerabilities on device functionality and end users/patients;
- Assessment of the likelihood of a threat and of a vulnerability being exploited;
- Determination of risk levels and suitable mitigation strategies;
- Assessment of residual risk and risk acceptance criteria.

B. Postmarket Considerations

Because cybersecurity risks to medical devices are continually evolving, it is not possible to completely mitigate risks through premarket controls alone. Therefore, it is essential that manufacturers implement comprehensive cybersecurity risk management programs and documentation consistent with the Quality System Regulation (21 CFR part 820), including but not limited to complaint handling (21 CFR 820.198), quality audit (21 CFR 820.22), corrective and preventive action (21 CFR 820.100), software validation and risk analysis (21 CFR 820.30(g)) and servicing (21 CFR 820.200).

Cybersecurity risk management programs should emphasize addressing vulnerabilities which may permit the unauthorized access, modification, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient, and may result in patient harm. Manufacturers should respond in a timely fashion to address identified vulnerabilities. Critical components of such a program include:

- Monitoring cybersecurity information sources for identification and detection of cybersecurity vulnerabilities and risk;
- Maintaining robust software lifecycle processes that include mechanisms for:
    - monitoring third party software components for new vulnerabilities throughout the device's total product lifecycle;
    - design verification and validation for software updates and patches that are used to remediate vulnerabilities, including those related to Off-the-shelf software;
- Understanding, assessing and detecting presence and impact of a vulnerability;
- Establishing and communicating processes for vulnerability intake and handling
- Note: The FDA has recognized ISO/IEC 30111:2013: Information Technology – Security Techniques – Vulnerability Handling Processes;
- Using threat modeling to clearly define how to maintain safety and essential performance of a device by developing mitigations that protect, respond and recover from the cybersecurity risk;

- Adopting a coordinated vulnerability disclosure policy and practice. The FDA has recognized ISO/IEC 29147:2014: Information Technology – Security Techniques – Vulnerability Disclosure which may be a useful resource for manufacturers; and
- Deploying mitigations that address cybersecurity risk early and prior to exploitation.

Postmarket cybersecurity information may originate from an array of sources including independent security researchers, in-house testing, suppliers of software or hardware technology, health care facilities, and information sharing and analysis organizations. It is strongly recommended that manufacturers participate in an ISAO that shares vulnerabilities and threats that impact medical devices. Sharing and dissemination of cybersecurity information and intelligence pertaining to vulnerabilities and threats across multiple sectors is integral to a successful postmarket cybersecurity surveillance program.

To manage postmarket cybersecurity risks for medical devices, a company should have a structured and systematic approach to risk management and quality management systems consistent with 21 CFR part 820. For example, such a program should include:

- Methods to identify, characterize, and assess a cybersecurity vulnerability.
- Methods to analyze, detect, and assess threat sources. For example:
    - A cybersecurity vulnerability might impact all of the medical devices in a manufacturer's portfolio based on how their products are developed; or
    - A cybersecurity vulnerability could exist vertically (i.e., within the components of a device) which can be introduced at any point in the supply chain for a medical device manufacturing process.

It is recommended as part of a manufacturer's cybersecurity risk management program that the manufacturer incorporate elements consistent with the NIST Framework for Improving Critical Infrastructure Cybersecurity (i.e., Identify, Protect, Detect, Respond, and Recover; https://www.nist.gov/sites/default/files/documents/cyberframework/cybersecurity-framework-021214.pdf).

FDA recognizes that medical devices and the surrounding network infrastructure cannot be completely secured. Design, architecture, technology, and software development environment choices may result in the inadvertent incorporation of vulnerabilities. The presence of a vulnerability does not necessarily trigger patient harm concerns. Rather it is the impact of the vulnerability on the safety and essential performance of the device which may present a risk of patient harm. Vulnerabilities that do not appear to currently present a risk of patient harm should be assessed by the manufacturer for future impact.

C. Maintaining Safety and Essential Performance

Compromise of safety or essential performance of a device can result in patient harm and may require intervention to prevent patient harm.

Manufacturers should define, as part of the comprehensive cybersecurity risk management, the safety and essential performance of their device, the resulting severity of patient harm if compromised, and the risk acceptance criteria. These steps allow manufacturers to triage vulnerabilities for remediation (see Section VI for additional information on risk assessments).

Threat modeling is important in understanding and assessing the exploitability of a device vulnerability and potential for patient harm. Threat modeling can also be used in determining whether a proposed or implemented remediation can provide assurance that the risk of patient harm due to a cybersecurity vulnerability is reasonably controlled. Importantly, acceptable mitigations will vary depending upon the severity of patient harm that may result from exploitation of a vulnerability affecting the device. For example, a cybersecurity vulnerability affecting the temperature reading of a thermometer may have different risks than a cybersecurity vulnerability affecting the dosage of an insulin infusion pump because of the severity of patient harm.

VI. Medical Device Cybersecurity Risk Management

As part of their risk management process consistent with 21 CFR part 820, a manufacturer should establish, document, and maintain throughout the medical device lifecycle an ongoing process for identifying hazards associated with the cybersecurity of a medical device, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls. This process should include risk analysis, risk evaluation, risk control, and incorporation of production and post-production information. Elements identified in the Appendix of this guidance should be included as part of the manufacturer's cybersecurity risk management program to support an effective risk management process. Manufacturers should have a defined process to systematically conduct a risk evaluation and determine whether a cybersecurity vulnerability affecting a medical device presents an acceptable or unacceptable risk. It is not possible to describe all hazards, associated risks, and/or controls associated with medical device cybersecurity vulnerabilities in this guidance. It is also not possible to describe all scenarios where risk is controlled or uncontrolled. Rather, FDA recommends that manufacturers define and document their process for objectively assessing the cybersecurity risk for their device(s).

As outlined below, it is recommended that such a process focus on assessing the *risk of patient harm* by considering:

1) The exploitability of the cybersecurity vulnerability, and
2) The severity of patient harm if the vulnerability were to be exploited.

Such analysis should also incorporate consideration of compensating controls and risk mitigations.

A. Assessing Exploitability of the Cybersecurity Vulnerability

Manufacturers should have a process for assessing the exploitability of a cybersecurity vulnerability. In many cases, estimating the probability of a cybersecurity exploit is very difficult due to factors such as; complexity of exploitation, availability of exploits, and exploit toolkits. In the absence of data on the probability of the occurrence of harm, conventional medical device risk management approaches suggest using a "reasonable worst-case estimate" or setting the default value of the probability to one. While these approaches are acceptable, FDA suggests that manufacturers instead consider using a cybersecurity vulnerability assessment tool or similar scoring system for rating vulnerabilities and determining the need for and urgency of the response.

One such tool, the "Common Vulnerability Scoring System," Version 3.0, for example, provides numerical ratings corresponding to high, medium and low by incorporating a number of factors in assessing exploitability including:[20]

- Attack Vector (physical, local, adjacent, network)
- Attack Complexity (high, low)
- Privileges Required (none, low, high)
- User Interaction (none, required)
- Scope (changed, unchanged)
- Confidentiality Impact (high, low, none)
- Integrity Impact (none, low, high)
- Availability Impact (high, low, none)
- Exploit Code Maturity (high, functional, proof-of-concept, unproven)
- Remediation Level (unavailable, work-around, temporary fix, official fix, not defined)
- Report Confidence (confirmed, reasonable, unknown, not defined)

In using any vulnerability scoring system (or tool), weighting of the individual factors that contribute to the composite score should be carefully considered.

Other resources that may aid in the triage of vulnerabilities are: AAMI TIR57: Principles for medical device security – Risk management[21], IEC 80001: Application of risk management for IT Networks incorporating medical devices[22], the National Vulnerability Database[23] (NVD), the Common Vulnerabilities and Exposures[24] (CVE), Common Weakness Enumeration[25] (CWE), Common Weakness Scoring System[26] (CWSS), Common Attack Pattern Enumeration and

[20] For a full description of each factor, see "Common Vulnerability Scoring System," Version 3.0: Specification Document (https://www.first.org/cvss/specification-document).
[21] AAMI TIR57: Principles for medical device security—Risk management - See more at: http://www.aami.org/productspublications/ProductDetail.aspx?ItemNumber=3729#sthash.CqfSLyu9.dpuf
[22] IEC/TR 80001-2-1:2012 Application of risk management for IT-networks incorporating medical devices
23 National Vulnerability Database (NVD; https://nvd.nist.gov/).
[24] Common Vulnerabilities and Exposures (CVE; https://cve.mitre.org/).
[25] Common Weakness Enumeration (CWE; http://cwe.mitre.org/index.html).
[26] Common Weakness Scoring System (CWSS; http://cwe.mitre.org/cwss/cwss_v1.0.1.html).

Classification[27] (CAPEC), Common Configuration Enumeration[28] (CCE) Common Platform Enumeration[29] (CPE).

B. Assessing Severity of Patient Harm

Manufacturers should also have a process for assessing the severity of patient harm, if the cybersecurity vulnerability were to be exploited. While there are many potentially acceptable approaches for conducting this type of analysis, one such approach may be based on qualitative severity levels as described in ANSI/AAMI/ISO 14971: 2007/(R)2010: Medical Devices – Application of Risk Management to Medical Devices:

Common Term	Possible Description
Negligible:	Inconvenience or temporary discomfort
Minor:	Results in temporary injury or impairment not requiring professional medical intervention
Serious:	Results in injury or impairment requiring professional medical intervention
Critical:	Results in permanent impairment or life-threatening injury
Catastrophic:	Results in patient death

C. Evaluation of Risk of Patient Harm

A key purpose of conducting the cyber-vulnerability risk assessment is to evaluate whether the risk of patient harm is controlled (acceptable) or uncontrolled (unacceptable). One method of assessing the acceptability of risk involves using a matrix with combinations of "exploitability" and "severity of patient harm" to determine whether the risk of patient harm is controlled or uncontrolled. A manufacturer can then conduct assessments of the exploitability and severity of patient harm and then use such a matrix to assess the risk of patient harm for the identified cybersecurity vulnerabilities.

For risks that remain uncontrolled, additional remediation should be implemented.

The following figure is an example matrix that shows a possible approach to evaluate the relationship between exploitability and patient harm. It can be used to assess the risk of patient harm from a cybersecurity vulnerability as controlled or uncontrolled. While in some cases the evaluation will yield a definite determination that the situation is controlled or uncontrolled, it is possible that in other situations this determination may not be as distinct. Nevertheless, in all cases, FDA recommends that manufacturers make a binary determination that a vulnerability is either controlled or uncontrolled using an established process that is tailored to the product, its safety and essential performance, and the situation. Risk mitigations, including compensating controls, should be implemented when necessary to bring the residual risk to an acceptable level.

[27] Common Attack Pattern Enumeration and Classification (CAPEC; http://capec.mitre.org/).
[28] Common Configuration Enumeration (CCE; https://nvd.nist.gov/cce/index.cfm).
[29] Common Platform Enumeration (CPE; https://nvd.nist.gov/cpe.cfm).

Figure – Evaluation of Risk of Patient Harm. The figure shows the relationship between exploitability and severity of patient harm, and can be used to assess the risk of patient harm from a cybersecurity vulnerability. The figure can be used to categorize the risk of patient harm as controlled or uncontrolled.

VII. Remediating and Reporting Cybersecurity Vulnerabilities

Based on the vulnerability assessment described in the previous section, the exploitability of an identified vulnerability and its severity of patient harm can help determine the risk of patient harm and can be categorized as either "controlled" (acceptable residual risk) or "uncontrolled" (unacceptable residual risk). When determining how to manage a cybersecurity vulnerability, manufacturers should incorporate already implemented compensating controls and risk mitigations into their risk assessment.

FDA encourages efficient, timely and ongoing cybersecurity risk management for marketed devices by manufacturers. For cybersecurity routine updates and patches, the FDA will, typically, not need to conduct premarket review to clear or approve the medical device software changes.[30] In addition, manufacturers should:

- Adopt a coordinated vulnerability disclosure policy and practice that includes acknowledging receipt of the initial vulnerability report to the vulnerability submitter[31,32];

[30] Premarket notification (510(k)) would be required for countermeasures that would be considered significant changes or modifications to a device's design, components, method of manufacture or intended use (See 21 CFR 807.81(a)(3)).

[31] ISO/IEC 29147:2014: Information Technology – Security Techniques – Vulnerability Disclosure which may be a useful resource for manufacturers.

- Proactively practice good cyber hygiene, reassess risk assessments regularly, and seek opportunities to reduce cybersecurity risks even when residual risk is acceptable;
- Remediate cybersecurity vulnerabilities to reduce the risk of patient harm to an acceptable level;
- Conduct appropriate software validation under 21 CFR 820.30(g) to assure that any implemented remediation effectively mitigates the target vulnerability without unintentionally creating exposure to other risks;
- Properly document the methods and controls used in the design, manufacture, packaging, labeling, storage, installation and servicing of all finished devices as required by 21 CFR part 820;
- Identify and implement compensating controls to adequately mitigate the cybersecurity vulnerability risk, especially when new device design controls[33] may not be feasible or immediately practicable. In addition, manufacturers should consider the level of knowledge and expertise needed to properly implement the recommended control;
- Provide users with relevant information on recommended device and compensating controls and residual cybersecurity risks so that they can take appropriate steps to mitigate the risk and make informed decisions regarding device use; and
- Recognize that some changes made to strengthen device security might also significantly affect other device functionality (e.g., use of a different operating system) and assess the scope of change to determine if additional premarket or postmarket regulatory actions are appropriate.

In addition to the general recommendations described above, Sections VII.A and VII.B. below clarify specific recommendations for managing controlled and uncontrolled risks of patient harm.[34] While FDA recognizes that multi-stakeholder engagement is necessary to fully address cybersecurity risks, the examples provided in the controlled risk and uncontrolled risk sections below clarify FDA's regulatory expectations for medical device manufacturers.

A. Controlled Risk of Patient Harm

Controlled risk is present when there is sufficiently low (acceptable) residual risk of patient harm due to the vulnerability.

Manufacturers are encouraged to proactively promote good cyber hygiene and reduce cybersecurity risks even when residual risk is acceptable. The following are recommendations for changes or compensating control actions taken to address vulnerabilities associated with controlled risk:

[32] ISO/IEC 30111:2013: Information Technology – Security Techniques – Vulnerability Handling Processes.
[33] See 21 CFR part 820.30(g) Design controls
[34] Please note that manufacturers and user facilities may have additional reporting requirements from sources other than FDA.

- Changes to a device that are made solely to strengthen cybersecurity are typically considered device enhancements[35], which may include cybersecurity routine updates and patches, and are generally not required to be reported, under 21 CFR part 806.
- Even when risks are controlled, manufacturers may wish to deploy an additional control(s) as part of a "defense-in-depth" strategy. Typically, these changes would be considered a cybersecurity routine update or patch, a type of device enhancement;
- Device changes made solely to address a vulnerability that, if exploited, could lead to compromise of PHI, would typically be considered a cybersecurity routine update or patch;
- For premarket approval (PMA) devices with periodic reporting requirements under 21 CFR 814.84, newly acquired information concerning cybersecurity vulnerabilities and device changes made as part of cybersecurity routine updates and patches should be reported to FDA in a periodic (annual) report. See Section VIII for recommended content to include in the periodic report.

Examples of Vulnerabilities Associated with Controlled Risk and their Management:

- A device manufacturer receives a user complaint that a gas blood analyzer has been infected with malware and there was concern that the malware may alter the data on the device. The outcome of a manufacturer investigation and impact assessment confirms the presence of malware and finds that the malware does not result in the manipulation of unencrypted data stored and flowing through the device. The device's safety and essential performance is not impacted by the malware and the manufacturer's risk assessment determines that the risk of patient harm due to the vulnerability is controlled. The device manufacturer communicates to users on how to remove the malware and decides to develop a defense-in-depth strategy; these changes would be considered a cybersecurity routine update and patch, a type of device enhancement.

- A researcher publicly discloses exploit code for a four year old vulnerability in commercial off-the-shelf database software. The vulnerable version of the software is in a percentage of the manufacturer's installed base and in two separate product lines including a multi-analyte chemistry analyzer. The manufacturer determines that the vulnerability is the result of a misconfigured database setting and could allow an unauthorized user to view patient health information in the database. The vulnerability does not permit the unauthorized user the ability to edit data in the database. Thus, the manufacturer determines the vulnerability has acceptable and controlled risk of patient harm. The manufacturer notifies their customers and the user community of the issue, details the secure configuration setting, and documents the effectiveness of the cybersecurity routine update for the configuration setting.

[35] *See* FDA guidance titled "Distinguishing Medical Device Recalls from Medical Device Enhancements" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM418469.pdf)

- A device manufacturer is notified of an open, unused communication port by the U.S. Department of Homeland Security Industrial Control Systems-Cyber Emergency Response Team (ICS-CERT). Subsequent analyses show that a design feature of the device prevents unauthorized remote firmware download onto the device. The threat is mitigated substantially by the need for physical access due to this device feature and the residual risk of patient harm is considered "acceptable." The manufacturer takes steps to further enhance the device's security by taking steps to close the unused communication port(s) and provide adequate communication to device users (e.g., user facilities) to facilitate the patch. If the manufacturer closes the open communication ports, the change would be considered a cybersecurity routine update or patch, a type of device enhancement. The change does not require reporting under 21 CFR part 806 (see the "Distinguishing Medical Device Recalls from Medical Enhancements Guidance" [http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm418469.pdf] for additional clarity of reporting requirements and recommendations for device enhancements).

- A device manufacturer receives a user complaint that a recent security software scan of the PC component of a class III medical device has indicated that the PC is infected with malware. The outcome of a manufacturer investigation and impact assessment confirms the presence of malware and that the primary purpose of the malware is to collect internet browsing information. The manufacturer also determines that the malware has actively collected browsing information, but that the device's safety and essential performance is not and would not be impacted by such collection. The manufacturer's risk assessment determines that the risk of patient harm due to the vulnerability is controlled. Since the risk of patient harm is controlled, the manufacturer can update the product and it will be considered a cybersecurity routine update or patch. In this case, the manufacturer does not need to report this software update to the FDA in accordance with 21 CFR 806.10. Because the device is a class III device, the manufacturer should report the changes to the FDA in its periodic (annual) report required for holders of an approved PMA under 21 CFR 814.84.

B. Uncontrolled Risk to Safety and Essential Performance

Uncontrolled risk is present when there is unacceptable residual risk of patient harm due to insufficient risk mitigations and compensating controls. In assessing risk, manufacturers should consider the exploitability of the vulnerability and the severity of patient harm if exploited. If the risk of patient harm is assessed as uncontrolled, additional risk control measures should be applied.

Manufacturers should remediate uncontrolled risks as quickly as possible. The following are recommendations for changes or compensating control actions to address vulnerabilities associated with uncontrolled risk:

- Manufacturers should remediate the vulnerabilities to reduce the risk of patient harm to an acceptable level;

- While fixing the vulnerability may not be feasible or immediately practicable, manufacturers should identify and implement risk mitigations and compensating controls to adequately mitigate the risk;
- Customers and the user community should be provided with relevant information on recommended controls and residual cybersecurity risks so that they can take appropriate steps to mitigate the risk and make informed decisions regarding device use;
- Manufacturers must report these vulnerabilities to the FDA according to 21 CFR part 806, unless reported under 21 CFR parts 803 or 1004[36]. However, the FDA does not intend to enforce reporting requirements under 21 CFR part 806 for specific vulnerabilities with uncontrolled risk when the following circumstances are met:
    1) There are no known serious adverse events or deaths associated with the vulnerability;
    2) As soon as possible but no later than 30 days after learning of the vulnerability, the manufacturer communicates with its customers and user community regarding the vulnerability, identifies interim compensating controls, and develops a remediation plan to bring the residual risk to an acceptable level. Controls should not introduce more risk to the device's safety and essential performance than the original vulnerability. The manufacturer must document[37] the timeline rationale for its remediation plan.[38] The customer communication should, at minimum:
        a. Describe the vulnerability including an impact assessment based on the manufacturer's current understanding,
        b. State that manufacturer's efforts are underway to address the risk of patient harm as expeditiously as possible,
        c. Describe compensating controls, if any, and
        d. State that the manufacturer is working to fix the vulnerability, or provide a defense-in-depth strategy to reduce the probability of exploit and/or severity of harm, and will communicate regarding the availability of a fix in the future.
    3) As soon as possible but no later than 60 days after learning of the vulnerability, the manufacturer fixes the vulnerability, validates the change, and distributes the deployable fix to its customers and user community such that the residual risk is brought down to an acceptable level. In some circumstances, a compensating control could produce a long-term solution provided the risk of patient harm is brought to an acceptable level. Controls should not introduce more risk to the device's safety and essential performance than the original vulnerability. Additionally, the manufacturer should follow-up with end-users as needed beyond the initial 60 day period;[39]

[36] See 21 CFR 806.10(f).
[37] See 21 CFR 820.100 Corrective action and preventive action.
[38] See 21 CFR 7.42 Recall strategy for elements of a remediation plan
[39] See 21 CFR 7 (b)(3) – Effectiveness checks.

4) The manufacturer actively participates as a member of an ISAO that shares vulnerabilities and threats that impact medical devices, such as NH-ISAC (see section IX) and provides the ISAO with any customer communications upon notification of its customers;

- Remediation of devices with annual reporting requirements (e.g., class III devices) should be included in the annual report;
- The manufacturer should evaluate the device changes to assess the need to submit a premarket submission (e.g., PMA supplement[40], 510(k), etc.) to the FDA;
- For PMA devices with periodic reporting requirements under 21 CFR 814.84, information concerning cybersecurity vulnerabilities, and the device changes and compensating controls implemented in response to this information should be reported to FDA in a periodic (annual) report. See Section VIII for recommended content to include in the periodic report.

In the absence of remediation, a device with uncontrolled risk of patient harm may be considered to have a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death. The product may be considered in violation of the FD&C Act and subject to enforcement or other action.

Examples of Vulnerabilities Associated with Uncontrolled Risk of Patient Harm That Must Be Remediated and Response Actions:

- A manufacturer is made aware of open, unused communication ports. The manufacturer acknowledges receipt of the vulnerability report to the submitter/identifier and subsequent analysis determines that the device's designed-in features do not prevent a threat from downloading unauthorized firmware onto the device, which could be used to compromise the device's safety and essential performance. Although there are no reported serious adverse events or deaths associated with the vulnerability, the risk assessment concludes the risk of patient harm is uncontrolled. The manufacturer communicates with its customers, the ISAO, and user community regarding the vulnerability, identifies and implements interim compensating controls, develops a remediation plan, and notifies users within 30 days of becoming aware of the vulnerability. Furthermore, within 60 days of becoming aware of the vulnerability, the manufacturer develops a more permanent solution/fix (in this case a software update to close the unused communication port(s)), validates the change, distributes the deployable fix or work around to its customers, and implements all other aspects of its remediation plan. If the manufacturer actively participates as a member of an ISAO and shares information about the vulnerability within the ISAO, FDA does not intend to enforce compliance with the reporting requirements in 21 CFR part 806. For class III devices, the manufacturer does submit a summary of the remediation as part of its periodic (annual) report to FDA.

[40] See 21 CFR 814.39, see also FDA webpage titled, "PMA Supplements and Amendments" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050467.htm).

- A manufacturer becomes aware of a vulnerability via a researcher that its class III medical device (e.g., implantable defibrillator, pacemaker, etc.) can be reprogrammed by an unauthorized user. If exploited, this vulnerability could result in permanent impairment, a life-threatening injury, or death. The manufacturer is not aware that the vulnerability has been exploited and determines that the vulnerability is related to a hardcoded password. The risk assessment concludes that the exploitability of the vulnerability is moderate and the risk of patient harm is uncontrolled. The manufacturer notifies appropriate stakeholders, and distributes a validated emergency patch within 60 days. The manufacturer does not actively participate as a member of an ISAO and therefore reports this action to the FDA under 21 CFR 806.10.

- A vulnerability known to the security community, yet unknown to a medical device manufacturer, is incorporated into a class II device during development. Following clearance, the manufacturer becomes aware of the vulnerability and determines that the device continues to meet its specifications, and that no device malfunctions or patient injuries have been reported. There is no evidence that the identified vulnerability has been exploited. However, it was determined that the vulnerability introduced a new failure mode to the device that impacts its essential performance, and the device's design controls do not mitigate the risk. The manufacturer conducts a risk assessment and determines that without additional mitigations, the risk of patient harm is uncontrolled. Since the manufacturer does not currently have a software update to mitigate the impact of this vulnerability on the device's essential performance, within 30 days of learning of the vulnerability the manufacturer notifies its customers, the ISAO, and user community of the cybersecurity risk and instructs them to disconnect the device from the hospital network to prevent unauthorized access to the device. The company's risk assessment concludes that the risk of patient harm is controlled with this additional mitigation. The manufacturer determines that removal of the device from the network is not a viable long-term solution and distributes a patch within 60 days of learning of the vulnerability. If the company is an active participating member of an ISAO, FDA does not intend to enforce compliance with the reporting requirement under 21 CFR part 806.

- A hospital reports that a patient was harmed after a medical device failed to perform as intended. A manufacturer investigation determines that the medical device malfunctioned as a result of exploitation of a previously unknown vulnerability in its proprietary software. The outcome of the manufacturer's investigation and impact assessment determines that the exploit indirectly impacts the device's safety and essential performance and may have contributed to a patient death. The manufacturer files a report in accordance with reporting requirements under 21 CFR part 803. The manufacturer also determines the device would be likely to cause or contribute to a serious injury or death if the malfunction were to recur; therefore, the manufacturer notifies its customers and user community, develops a validated emergency patch and files a report in accordance with 21 CFR 806.10 to notify FDA.

VIII. Recommended Content to Include in PMA Periodic Reports

For PMA devices with periodic reporting requirements under 21 CFR 814.84, information concerning cybersecurity vulnerabilities, and device changes and compensating controls implemented in response to this information should be reported to FDA in a periodic (annual) report.

It is recommended that the following information be provided for changes and compensating controls implemented for the device:

- A brief description of the vulnerability prompting the change including how the firm became aware of the vulnerability;
- A summary of the conclusions of the firm's risk assessment including whether the risk of patient harm was controlled or uncontrolled;
- A description of the change(s) made, including a comparison to the previously approved version of the device;
- The rationale for making the change;
- Reference to other submissions/devices that were modified in response to this same vulnerability;
- Identification of event(s) related to the rationale/reason for the change (e.g., MDR number(s), recall number);
- Unique Device Identification (UDI)[41] should be included, if available;
- A link to an ICS-CERT advisory or other government or ISAO alert (https://ics-cert.us-cert.gov/advisories), if applicable;
- All distributed customer notifications;
- The date and name of the ISAO to which the vulnerability was reported, if any; and
- Reference to other relevant submission (PMA Supplement[42], 30-Day Notice, 806 report, etc.), if any, or the scientific and/or regulatory basis for concluding that the change did not require a submission/report.

IX. Criteria for Defining Active Participation by a Manufacturer in an ISAO

Active participation by a manufacturer in an ISAO can assist the company, the medical device community and the HPH Sector by proactively addressing cybersecurity vulnerabilities and minimizing exploits through the timely deployment of risk control measures including communication and coordination with patients and users.

[41] See the web page titled "Unique Device Identification – UDI" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ for more information

[42] See 21 CFR 814.39.

FDA intends to consider the following in determining whether a manufacturer is an active participant in an ISAO:

1. The manufacturer is a member of an ISAO that shares vulnerabilities and threats that impact medical devices;
2. The ISAO has documented policies pertaining to participant agreements, business processes, operating procedures, and privacy protections;
3. The manufacturer shares vulnerability information with the ISAO, including any customer communications pertaining to cybersecurity vulnerabilities; and
4. The manufacturer has documented processes for assessing and responding to vulnerability and threat intelligence information received from the ISAO. This information should be traceable to medical device risk assessments, countermeasure solutions, and mitigations.

Manufacturers that wish to be considered by FDA to be active participants in an ISAO are recommended to maintain objective evidence documenting that they meet the four criteria above.

X. Appendix: Elements of an Effective Postmarket Cybersecurity Program

It is recommended that the following elements, consistent with the NIST Framework for Improving Critical Infrastructure Cybersecurity (i.e., Identify, Protect, Detect, Respond, and Recover; https://www.nist.gov/sites/default/files/documents/cyberframework/cybersecurity-framework-021214.pdf), be included as part of a manufacturer's cybersecurity risk management program.

A. Identify

i. Maintaining Safety and Essential Performance

Compromise of safety or essential performance of a device can result in patient harm and may require intervention to prevent patient harm.

Manufacturers should define, as part of their comprehensive cybersecurity risk management plan, the safety and essential performance of their device, the resulting severity of patient harm if compromised, and the risk acceptance criteria. These steps allow manufacturers to triage vulnerabilities for remediation (see Section VI for additional information on risk assessments).

Threat modeling is important to understanding and assessing the exploitability of a device vulnerability and its potential for patient harm. Threat modeling can also be used in determining whether a proposed or implemented remediation can provide assurance that the risk of patient harm due to a cybersecurity vulnerability is reasonably controlled. Importantly, acceptable mitigations will vary depending upon the severity of patient harm that may result from exploitation of a vulnerability affecting the device. For example, a cybersecurity vulnerability affecting the temperature reading of a thermometer may have different risks than a cybersecurity vulnerability affecting the dosage of an insulin infusion pump because of the severity of patient harm.

ii. Identification of Cybersecurity Signals

Manufacturers are required to analyze complaints, returned product, service records, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems (21 CFR 820.100). Manufacturers are encouraged to actively identify cybersecurity signals that might affect their product, and engage with the sources that report them. It is important to recognize that signals can originate from sources familiar to the medical device workspace such as internal investigations, post market surveillance and or/complaints. It is also important to recognize that cybersecurity signals may originate from cybersecurity-centric sources such as Cyber Emergency

Response Teams (CERTS), ISAOs, security researchers, or from other critical infrastructure sectors such as the Defense or Financial Sectors. Irrespective of the originating source, a clear, consistent and reproducible process for intake and handling of vulnerability information should be established and implemented by the manufacturer. FDA has recognized ISO/IEC 29147:2014, *Information Technology - Security Techniques - Vulnerability Disclosure* and ISO/IEC 30111:2013: Information Technology – Security Techniques – Vulnerability Handling Processes that may be useful resources for manufacturers. Manufacturers should develop strategies to enhance their ability to detect signals (e.g., participating in an ISAO for medical devices). Manufacturers can also enhance their postmarket detection of cybersecurity risks by incorporating detection mechanisms into their device design and device features to increase the detectability of attacks and permit forensically sound evidence capture.

B. Protect/Detect

i. Vulnerability Characterization and Assessment

The FDA recommends that manufacturers characterize and assess identified vulnerabilities because it will provide information that will aid manufacturers to triage remediation activities. When characterizing the exploitability of a vulnerability, the manufacturer should consider factors such as remote exploitability, attack complexity, threat privileges, actions required by the user, exploit code maturity, and report confidence. Scoring systems such as the "Common Vulnerability Scoring System" (CVSS)[43] provide a consistent framework for assessing exploitability by quantifying the impact of the factors that influence exploitability. See Section VI for additional guidance on vulnerability risk assessment.

ii. Risk Analysis and Threat Modeling

The FDA recommends that manufacturers conduct cybersecurity risk analyses that include threat modeling for each of their devices and to update those analyses over time. Risk analyses and threat modeling should aim to triage vulnerabilities for timely remediation. Threat modeling is a procedure for optimizing Network/Application/Internet Security by identifying objectives and vulnerabilities, and then defining countermeasures to prevent, or mitigate the effects of, threats to the system. Threat modeling provides traditional risk management and failure mode analysis paradigms, and a framework to assess threats from active adversaries/malicious use. For each vulnerability, a summary report should be produced that concisely summarizes the risk analysis and threat modeling information. Due to the cyclical nature of the analyses, the information should be traceable to related documentation.

[43] "Common Vulnerability Scoring System," Version 3.0, Scoring Calculator (https://www.first.org/cvss/calculator/3.0).

iii. Analysis of Threat Sources[44]

The FDA recommends manufacturers to analyze possible threat sources. A threat source is defined as the intent and method targeted at the intentional exploitation of a vulnerability or a situation and method that may accidentally trigger a vulnerability.[45] Analysis of threat sources, as part of risk analysis and threat modeling provides a framework for risk introduced by an active adversary. Therefore, characterization of threat sources will be advantageous to manufacturers in accessing risks not covered by traditional failure mode analysis methods.

iv. Incorporation of Threat Detection Capabilities

Medical devices may not be capable of detecting threat activity and may be reliant on network monitoring. Manufacturers should consider the incorporation of design features that establish or enhance the ability of the device to detect and produce forensically sound postmarket evidence capture in the event of an attack. This information may assist the manufacturer in assessing and remediating identified risks.

v. Impact Assessment on All Devices

The FDA recommends that manufacturers have a process to assess the impact of a cybersecurity signal horizontally (i.e., across all medical devices within the manufacturer's product portfolio and sometimes referred to as variant analyses) and vertically (i.e., determine if there is an impact on specific components within the device). A signal may identify a vulnerability in one device, and that same vulnerability may impact other devices including those in development, or those not yet cleared, approved or marketed. Therefore, it will be advantageous to manufacturers to conduct analyses for cybersecurity signals such that expended detection resources have the widest impact.

C. Protect/Respond/Recover

i. Compensating Controls Assessment (Detect/Respond)

- The FDA recommends that manufacturers implement device-based features, i.e. device design controls[46], as a primary mechanism to mitigate the risk of patient harm. Manufacturers should assess and provide users with compensating controls such that the risk of patient harm is further mitigated. In total, these efforts represent a defense-in-depth strategy for medical device cybersecurity. Section VII describes recommendations for

[44] National Institute of Standards and Technology, "Guide for Conducting Risk Assessments," NIST Special Publication 800-30 Revision 1 (http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-30r1.pdf).
[45] National Institute of Standards and Technology, "Security and Privacy Controls for Federal Information Systems and Organizations," NIST Special Publication 800-53, Revision 4, Appendix B (http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf).
[46] See 21 CFR 820.30(g).

remediating and reporting identified cybersecurity vulnerabilities, including the development, implementation and user notification concerning fixes. Manufacturers should also adopt a coordinated vulnerability disclosure policy and practice that includes acknowledging receipt of the vulnerability to the vulnerability submitter within a specified time frame.[47,48] The FDA has recognized ISO/IEC 29147:2014: Information Technology – Security Techniques – Vulnerability Disclosure that may be a useful resource for manufacturers.

D. Risk Mitigation of Safety and Essential Performance

Once the preceding information has been assessed and characterized, manufacturers should determine if the risk of patient harm presented by the vulnerability are adequately controlled by existing device features and/or manufacturer defined compensating controls (i.e., residual risk levels are acceptable). Actions taken should reflect the magnitude of the problem and align with the risks encountered. Manufacturers should also include an evaluation of residual risk, benefit/risk, and risk introduced by the remediation. Manufacturers should design their devices to ensure that risks inherent in remediation are properly mitigated including ensuring that the remediation is adequate and validated, that the device designs incorporate mechanisms for secure and timely updates.

Changes made for vulnerabilities of controlled risk are generally considered device enhancements, not recalls. Cybersecurity routine updates and patches are generally considered a type of device enhancement.

[47] The FDA has recognized ISO/IEC 29147:2014: Information Technology – Security Techniques – Vulnerability Disclosure

[48] ISO/IEC 30111:2013: Information Technology – Security Techniques – Vulnerability Handling Processes

Radio Frequency Wireless Technology in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Science and Engineering Laboratories

Center for Biologics Evaluation and Research

Preface

Public Comment

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Table of Contents

Radio Frequency Wireless Technology in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

FDA has developed this guidance document to assist industry and FDA staff in identifying and appropriately addressing specific considerations related to the incorporation and integration of radio frequency (RF) wireless technology in medical devices. There has been rapid growth in medical devices that incorporate RF wireless technology due to the expansion of this technology. With the increasing use of RF wireless medical devices, continuing innovation and advancements in wireless technology, and an increasingly crowded RF environment, RF wireless technology considerations should be taken into account to help provide for the safe and effective use of these medical devices. This guidance highlights and discusses RF wireless technology considerations that can have an effect on the safe and effective use of medical devices. These considerations include the selection of wireless technology, quality of service, coexistence, security, and electromagnetic compatibility (EMC). Consideration of these areas can help provide reasonable assurance of safety and effectiveness for medical devices that incorporate RF wireless technology, and are supplementary to other device-specific guidances or guidelines.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Scope

This guidance document addresses considerations that may affect the safe and effective use of medical devices that incorporate RF wireless technology (also referred to as wireless medical devices), including the selection of wireless technology, quality of service, coexistence, security, and EMC. These issues should be considered for all medical devices that incorporate RF wireless technology, such as Wireless Medical Telemetry Service (WMTS); Medical Device Radiocommunication Service (MedRadio) (including the former Medical Implant Communications Service (MICS)) as well as Medical Micropower Network (MNN) and Medical Body Area Network (MBAN); cellular communication chipsets; and RF identification (RFID) products. Such RF wireless technologies operate under a grant of certification and/or issuance of a license from the Federal Communications Commission (FCC).

This guidance also provides recommendations for information to be included in FDA premarket submissions for medical devices and device systems that incorporate RF wireless technology. Requirements by other agencies are not covered within this document, although we note that requirements established by the FCC may be applicable.

The recommendations in this guidance are intended for RF wireless medical devices including those that are implanted, worn on the body or other external wireless medical devices intended for use in hospitals, homes, clinics, clinical laboratories, and blood establishments. Both wireless induction-based devices and radiated RF technology device systems are within the scope of this guidance. The use of RF energy to generate images of the internal structures of the body such as in magnetic resonance imaging systems is outside the scope of this guidance document.

See Appendix A for a glossary of key terms associated with RF wireless technology and wireless medical devices that have been adapted from the IEC 60050-161 International Electrotechnical Vocabulary (IEV) and other sources.

3. Considerations for Design, Testing, and Use of Wireless Medical Devices

Designers and manufacturers of wireless medical devices should consider the ability of their devices to function properly in the intended use environments where other RF wireless technologies will likely be located. In the design, testing, and use of wireless medical devices, the correct, timely, and secure transmission of medical data and information is important for the safe and effective use of both wired and wireless medical devices and device systems. This is especially important for medical devices that perform critical functions such as those that are life-supporting or life-sustaining. For wirelessly enabled

medical devices, risk management should include considerations for robust RF wireless design, testing, deployment, and maintenance throughout the life cycle of the product.[1] Examples of potentially problematic wireless-related hazards and effects include:

- poorly characterized or poorly utilized wireless systems (e.g., wireless networks);
- lost, corrupted, or time-delayed transmissions, and degradations in wireless transmissions including when caused by competing wireless signals or electromagnetic interference (EMI) to the medical device or its wireless transmissions;
- lack or compromise of wireless security; and
- potential misuse of a wireless medical device because of lack of or inadequate instructions for use.

As part of a comprehensive quality system under 21 CFR Part 820, medical device manufacturers must manage risks including those associated with RF wireless technology that is incorporated into the medical device or device system. ISO 14971 *Second edition 2007-03-01 Medical devices—Application of risk management to medical devices* can be a useful tool in risk analysis and risk management.[2] Because there are risks associated with RF wireless systems, we recommend that you carefully consider which device functions should be made wireless and which device functions should employ wired connectivity.

FDA recommends that you address known safety issues involving RF wireless technologies early in the device design and development process. Safety issues might be discovered during the design and development process for which risk mitigation measures might be necessary to ensure an overall acceptable level of risk. FDA also recommends that risk acceptability criteria be based on information about the device and its intended use, including, but not limited to, applicable standards, accepted design practices, and experience with similar devices. For example, FDA recommends that you use reports of EMI-related events and other relevant experience when estimating probability of occurrence as part of risk analysis. In addition, where multiple alarms are incorporated into a device or device system via wireless links, we recommend that you address priorities for accessing the wireless system, and priorities related to the function of the wireless technology itself.

In validating the design of your wireless medical device under 21 CFR 820.30(g), you must include risk analysis of RF wireless communications and control functions as part of your design validation. Because it is possible for an electromagnetic disturbance (EMD) to affect important medical device functions, mitigation measures for some risks could aid the device operator in recognizing a hazardous situation and taking action to prevent harm. For

[1] Risk management is a key component of the quality system, and includes risk analysis, which is part of the design control requirements under the quality systems regulation. 21 CFR 820.30(g).
[2] ISO 14971 is on FDA's list of recognized consensus standards, which is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=30268.

example, design validation might reveal that steps to reestablish an RF wireless connection such as re-initialization could compromise safety under some use conditions.

When considering possible adverse outcomes, you should also consider risks to other devices and patients whose wireless connections might suffer from, or be the source of, interference. In addition, you should consider the potential impact of unintended interference and purposeful attempts to disrupt a wireless medical device or an associated device network's functionality.

The following considerations should be appropriately tailored to the selected RF wireless technology, and the intended use and use environments for your medical device. The following discussion of these considerations includes information dealing with general and design considerations, risk management, verification and validation, and information shared with users. Note that access to information (e.g., user manual, other device labeling) concerning these key considerations plays an important role in users being able to properly set up, use and maintain medical devices and device systems with wireless technology.

a. Selection and performance of wireless technology

When selecting the type(s) of wireless technology, it is vital to determine and understand the medical device functions that are to be wirelessly enabled and the intended use of the medical device. The medical device functions and intended uses should be appropriately matched with the wireless technology's capabilities and expected performance. In addition, issues relating to the integrity of data transmitted wirelessly (including latency and throughput, detection, correction, and corruption control and/or prevention) and safety-related requirements of your device should be considered. Potential risks that can affect consistent and timely wireless medical device functions include data corruption or loss and interference from simultaneous transmitters in a given location, which can increase latency and transmitted signal error rates. For wireless medical devices and device systems, error control processes should be incorporated to assure the integrity of data transmitted wirelessly and to manage potential risks related to maximum delay of data transfer. Parameters such as bit error rate, packet loss, and signal-to-noise ratio are useful tools in assessing and assuring data integrity and timeliness of data transmission.

In addition, the device performance and specifications related to the wirelessly enabled medical device functions should be considered in choosing the appropriate RF wireless technology (e.g., WMTS, IEEE 802.11) and RF frequency of operation. It is important to note that many medical devices are authorized to operate as unlicensed devices (under Part 15 of the FCC rules[3]) in the industrial, scientific, and medical (ISM) frequency bands (e.g., 2400-2493.5 MHz), and as such, are not entitled to interference protection. There is

[3] For additional information on frequency bands and use, please refer to http://www.fcc.gov/encyclopedia/accessing-spectrum and http://www.fcc.gov/encyclopedia/rules-regulations-title-47.

a potential for interference in this frequency band because it is already heavily used by many other communications and industrial products. In many cases, RF wireless medical devices and transmission streams can incorporate technology (e.g., frequency hopping protocols, correction protocols) to minimize effects of interference that may lead to data errors or corruption. Also, to help protect against EMI to other medical devices in the vicinity, FDA recommends that wireless medical device manufacturers limit the RF output of their devices to the lowest power necessary to reliably accomplish the intended functions.

Consideration should be given to any limitations or restrictions for proper operation and RF wireless performance (e.g., alarms, back-up functions, alternative modes of operation) when the RF wireless link is lost or corrupted. In addition, worldwide frequency band allocation and international compatibility is critical to the operations of RF wireless devices, and should be considered in the design and development of wireless medical devices.

When choosing a RF wireless frequency band or a commercial wireless radio component, FDA recommends that you consider:

- International availability and band allocation (e.g., applicable International Telecommunication Union Radiocommunication Sector (ITU-R)[4] recommendations) for medical devices because medical devices serve patients located in multiple geographic locations and patients may change their geographic locations.
- Whether your device needs to have primary or secondary radio service classification, which depends upon the wireless frequency band you choose.
- Incumbent users of the selected and adjacent bands, if any, and how they can impact a medical device's operation.
- Applicable interference mitigation techniques if you are planning to use a shared RF wireless frequency band.
- For implantable and body-worn medical devices, tissue propagation characteristics and specific absorption rate as appropriate.

When considering commercial off-the-shelf RF wireless components or systems that conform to industry standards (such as IEEE 802.11 standards), medical device manufacturers should take into account that some equipment might not have been adequately tested or qualified to address the needs and risks for use in medical devices. This is because such equipment may conform to standards that are not written specifically for medical devices. Under the quality system regulation, procedures and controls must be established for wireless medical devices and their components, including components

[4] http://www.itu.int/en/ITU-R/Pages/default.aspx

that are purchased and included as part of the device or device system, to ensure that the device and its components conform to specified design requirements related to the RF wireless considerations noted above.[5]

b. Wireless Quality of Service

Wireless Quality of Service (QoS) refers to the necessary level of service and performance needed for the wireless functions of the medical device. While the QoS of cellular telephone networks might be acceptable for voice communication, it might not be sufficient for certain medical functions. Connections lost without warning, failure to establish connections, or degradation of service can have serious consequences, especially when the medical device relies heavily on the wireless connection. Such situations can compromise the wireless transmission of high-priority medical device alarms, time-sensitive continuous physiological waveform data, and real-time control of therapeutic medical devices (such as wireless footswitches).

If the wireless medical device will be part of a network, wireless QoS should be carefully considered in conjunction with the intended use of the wireless medical device. The following should be assessed: acceptable latency, acceptable level of probability for loss of information within the network, accessibility, and signal priorities of the network.

When the network is chosen or designated, FDA recommends use of a risk management approach to deployment, security, and maintenance of the network's QoS. Depending on the intended use of the device, additional failure modes may need to be considered. Once failure modes and associated risks are identified, we recommend a justification of acceptable risk, or testing or other measures to demonstrate appropriate risk mitigation.

c. Wireless coexistence

A key factor affecting a wireless medical device's performance is the limited amount of RF spectrum available, which can result in potential competition among wireless technologies for simultaneous access to the same spectrum. Because conflicts among wireless signals can be expected, most wireless communication technologies incorporate methods to manage these conflicts and minimize disruptions in the shared wireless environment. The selection of RF wireless operating frequency and modulation should take into account other RF wireless technologies and users that might be expected to be in the vicinity of the wireless medical device system. These other wireless systems can pose risks that could result in medical device signal loss or delay that should be considered in the risk management process. To address this issue, FDA recommends that you address your device's environmental specifications and needs, including:

[5] *See, e.g.*, 21 CFR 820.30(f) (design verification); 21 CFR 820.30(g) (design validation); 21 CFR 820.50 (purchasing controls); and 21 CFR 820.80 (acceptance activities).

- Associated sources of EMD expected in specific known use environments, and
- Co-channel and adjacent channel interference from medical devices and other users of the RF band.

If the RF wireless medical device is expected to be used in proximity to other RF wireless in-band (i.e., the same or nearby RF frequency) sources, FDA recommends addressing such risks through testing for coexistence of the device wireless system in the presence of the number and type of in-band sources expected to be in proximity to the device. Depending upon the wireless medical device, this should also include multiple units of the subject device operating in the same vicinity, such as when patients are sitting adjacent to one another in a waiting room. Once failure modes and associated risks are identified, we recommend a justification of acceptable risk, or testing or other measures to demonstrate appropriate risk mitigation.

d. Security of wireless signals and data

Security of RF wireless technology is a means to prevent unauthorized access to patient data or hospital networks and to ensure that information and data received by a device are intended for that device. Authentication and wireless encryption play vital roles in an effective wireless security scheme. While most wireless technologies have encryption schemes available, wireless encryption might need to be enabled and assessed for adequacy for the medical device's intended use. In addition, the security measures should be well coordinated among the medical device components, accessories, and system, and as needed, with a host wireless network. Security management should also consider that certain wireless technologies incorporate sensing of like technologies and attempt to make automatic connections to quickly assemble and use a network (e.g., a discovery mode such as that available in Bluetooth™ communications). For certain types of wireless medical devices, this kind of discovery mode could pose safety and effectiveness concerns, for example, where automatic connections might allow unintended remote control of the medical device.

FDA recommends that wireless medical devices utilize wireless protection (e.g., wireless encryption,[6] data access controls, secrecy of the "keys" used to secure messages) at a level appropriate for the risks presented by the medical device, its environment of use, the type and probability of the risks to which it is exposed, and the probable risks to patients from a security breach. FDA recommends that the following factors be considered during your device design and development:

- Protection against unauthorized wireless access to device data and control. This should include protocols that maintain the security of the communications while

[6] At the time of publication of this guidance, this included WiFi Protected Access (WPA2) for IEEE 802.11 technology.

avoiding known shortcomings of existing older protocols (such as Wired Equivalent Privacy (WEP)).

- Software protections for control of the wireless data transmission and protection against unauthorized access.

Use of the latest up-to-date wireless encryption is encouraged. Any potential issues should be addressed either through appropriate justification of the risks based on your device's intended use or through appropriate design verification and validation.

For more information on this topic, see FDA's draft guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm356186.htm). FDA's draft guidance represents FDA's proposed approach on this topic.

e. EMC of the wireless technology

FDA recommends that EMC be an integral part of the development, design, testing, and performance for RF wireless medical devices. This should include consideration of applicable telecommunications standards and regulations and the potential for device RF emissions that might cause EMI with other equipment. In addition, RF wireless technology (by itself and in conjunction with the medical device) would also need to meet applicable FCC requirements. Risk management activities should include using risk analysis to identify any potential issues associated with EMC and determining risk acceptability criteria based on information about the device and its intended use, including foreseeable misuse, sources of environmental EMD (e.g., radio transmitters, computer RF wireless equipment), and the potential for RF emissions to affect other devices.

EMC testing should include tests focused on the medical device wireless functions and technology. Some voluntary consensus standards such as the FDA-recognized[7] consensus standard IEC 60601-1-2 "Medical Electrical Equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests" contain an exemption from the electromagnetic immunity provisions in the "exclusion band" (passband) where the medical device's RF wireless receiver or transmitter operates. Consequently, such standards do not adequately address whether the wireless communications will operate properly in the presence of in-band EMD (e.g., other RF emissions overlapping the frequency band utilized by the medical device wireless signals). Therefore, the medical device's wireless

[7] For a current list of FDA-recognized consensus standards, see the Recognized Consensus Standards Database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

communication(s) should be actively transmitting while testing for susceptibility during all EMC immunity testing.

EMC considerations are also covered in other standards that might be helpful for medical devices that incorporate RF wireless technology. For example, EMC considerations for active implantable medical devices are covered under documents such as the ISO 14708-1 standard (see Appendix B).

Adequate information for the user is especially important if the device might be used in high electric or magnetic field strength environments, and particularly if the device cannot be made to function as intended in these environments. To help ensure safe and effective use of your device, FDA recommends that the information for users include the following:

- Conformance to the IEC 60601-1-2 standard or other appropriate standards, and
- EMC susceptibilities discovered during testing, and mitigations such as recommended separation distances from other devices or EMD sources.

The IEC 60601-1-2 standard specifies that certain information based upon the EMC testing be included in "accompanying documents." This information includes a summary of the test findings and additional EMC-related information such as classification of the electrical power supply and use conditions.

f. Information for proper set-up and operation

To help assure proper set-up, configuration, and performance of the wireless medical device, appropriate information should be provided to users. The following are suggested items to consider as part of this information:

- The specific RF wireless technology type (e.g., IEEE 802.11b), characteristics of the modulation, and effective radiated RF power.
- Specification of each RF frequency or frequency band of transmission and the preferred frequency or frequency band (if applicable), and specification of the bandwidth of the receiving section of the equipment or system in those bands.
- Appropriate FCC labeling.
- A warning that other equipment could interfere with the medical device or device system, even if the other equipment complies with CISPR[8] emission requirements.

[8] Comité Internationale Spécial des Perturbations Radioelectrotechnique (International Special Committee on Radio Interference). CISPR electromagnetic emission standards are referenced in the IEC 60601-1-2 standard. See Appendix B.

- Information about the needed quality of service and security for the wireless technology.
- Functions and performance of the wireless data transmissions including data throughput, latency, and data integrity.
- Information about any limitations on the number, output power, or proximity of other in-band transmitters used in the vicinity that might adversely impact a device's system operation.
- Information for the user to understand the RF wireless technology's capabilities and be able to recognize and address issues that might arise. For devices with intended use locations that are in complex RF wireless environments and consist of multiple wireless products, this should include assessment and management of the RF wireless transmitters and their use in the vicinity including transmitters both inside and outside the facility.
- Information for the user to understand the implications and limitations of using RF wireless technology outside the United States, where allocations and technical parameters may be different, possibly affecting the functioning of the device.

g. Considerations for maintenance

Device Life Cycle - FDA recommends that you continue to manage the risks associated with the use of wireless technology described above for the entire life cycle of your device. Your procedures for implementing corrective and preventive action must include, among other things, analyses for possible trends in nonconformance information and complaints, such as reports of failures, which could include erratic or unexpected behavior of the medical device.[9] Examples of such behavior include reprogramming of stimulation devices, commands missed or misinterpreted by operating room controllers, unexplained inconsistencies of an infusion pump, and failure to activate alarm signals in alarm conditions.

Because electromagnetic emissions and exposure can vary significantly with various structures, materials, and RF wireless emitter sources in the vicinity, FDA recommends that in analyzing failure trends, you consider factors such as location, user application, and repeat component failures. Potential problems include:

- Additional events that may have contributed to the EMI or disruption of wireless technology resulting in inappropriate or unnecessary diagnostic procedures or interventions;
- Additional equipment used in conjunction with the device;
- Environmental conditions that might have contributed to the event; and

[9] 21 CFR 820.100(a).

- Repeated device failures at the same facility or in other geographic areas.

If you identify a failure or malfunction of an RF wireless function, you must investigate the cause and take action(s) to correct the problem and prevent its recurrence.[10] You must analyze production and repair records and other sources of quality data to determine the cause of the nonconformance.[11] Any corrective action and preventative action taken must be verified or validated to ensure that such action is effective and does not adversely affect the finished device.[12] FDA further recommends that you assess any product lines that use similar designs or are subject to the same environment to determine whether corrective and preventive actions are needed for those products.

Servicing - When servicing electrically powered medical devices, FDA recommends that you maintain the integrity of RF wireless functions and design elements intended to ensure EMC. Care should be taken to ensure EMI protection is present and in good condition. Such EMI protection can include components that may be removed during service such as shields, metal covers, ferrite beads, bonds, screws, ground wires and straps. In addition, FDA recommends that you do not paint metal surfaces that are intentionally left bare for RF shielding continuity. To reduce EMI susceptibility as electronic equipment ages, we recommend that you clean connector contacts that might have oxidized because oxidized contacts can act as semiconductors.

4. Recommendations for Premarket Submissions[13] for Devices that Incorporate RF Wireless Technology

When preparing a premarket submission for a device that incorporates RF wireless technology, FDA recommends that you include the following information, as appropriate, for your specific medical device.

[10] 21 CFR 820.100(a).
[11] 21 CFR 820.100(a).
[12] 21 CFR 820.100(a).
[13] This guidance document applies to the following premarket submissions for devices: premarket notifications (510(k)), *de novo* petitions, premarket approval applications (PMA), product development protocols (PDP), humanitarian device exemption (HDE) applications, and Biologics License Applications (BLA). Manufacturers may also consider applying the recommendations provided in this guidance, as appropriate, to investigational device exemption (IDE) applications and investigational new drug (IND) submissions to CBER related to BLA devices.

a. Description of device

In order to facilitate the review of the submission, the device description for a wireless medical device should include the following information specific to the wireless technology and functions:

- A description of the wireless technology and functions, and the intended use of the medical device and intended use environment. This should include the form and specific type of wireless technology that is incorporated into the device (e.g., IEEE 802.11b, IEEE 802.15 Bluetooth™), RF frequencies and maximum output powers, range, and where and how the wireless technology is to be used.

- A description of how the design of the device's wireless function(s) assures timely, reliable, accurate, and secure data and wireless information transfer. This includes the wireless QoS needs and security measures.

- If wireless technology is used for transmission, reception, or process involving alarm signals, a description of the alarm signal, its priority, and how the RF wireless-related risks are managed and, if appropriate, mitigated.

- Identify whether other wireless products or devices are able to make a wireless connection to the device. If so, summarize the products or devices and their function and how the subject medical device functions are protected from adverse effects of such connections to the other products or devices.

b. Risk-based approach to verification and validation

1. Wireless Quality of Service – The submission should include information to describe the wireless QoS needed for the intended use and use environment of the medical device. This includes addressing any risks and potential performance issues that might be associated with data rates, latency, and communications reliability as described in Section 3-b.

2. Wireless coexistence – Any risks and potential performance issues that might be associated with wireless coexistence in a shared wireless environment should be addressed via testing and analysis with other wireless products or devices that can be expected to be located in the wireless medical device's intended use environment. See Section 3-c. The information addressing coexistence should include the following:

- A summary of the coexistence testing, set-up, findings, and analysis.

- The wireless products (interferers) that were used in the coexistence testing, and their wireless RF frequencies, maximum output powers, and separation distances from the device.

- The specific pass/fail criteria for this testing.

- How the device and wireless functions were monitored during the testing and determined to meet the pass/fail criteria.

- If it is reasonable to expect multiple units of the subject wireless medical device to be used in the same vicinity, the information should also address how the association and security between devices is established and maintained to prevent cross-talk among the devices.

3. Security of wireless signals and data - The submission should identify any risks, potential performance issues, and, if appropriate, risk mitigation measures that might be associated with wireless security. The information should include the specific measures needed to protect against unauthorized wireless access to the medical device control or data and to ensure that information and data received by a device are intended for that device. For wireless technology with a discovery mode or similar active connection mode, specific information should be included addressing the discovery mode and how outside users can be prevented from sensing or connecting to the medical device. See Section 3-d.

4. EMC of the wireless technology – Information should be provided about how EMC has been addressed for the device and all wireless functions. However, as mentioned in section 3-e., the widely used IEC 60601-1-2 consensus standard does not at present adequately address wireless technology EMC. Therefore, testing, analysis, and appropriate mitigation might be necessary to adequately address any risks or potential performance issues that might be associated with the EMC of the wireless medical device. If modifications to the medical device were made to pass any EMC testing, please include a description of, and justification for, the modifications.

c. Test data summaries

FDA recommends that the final RF wireless and EMC testing[14] and results be summarized in your premarket submission, which should contain the following information:

- Description of the tests performed (e.g., RF wireless performance, EMC immunity and emissions, test levels or limits) and the protocol used;

[14] By final testing we refer to testing performed on the final integrated product.

- Reference to appropriate medical device, RF wireless technology, or EMC standards for the tests;
- Explanations for any deviations from the selected standards;
- Mode(s) of device operation during testing, with an explanation of the significance of these modes;
- Specific pass/fail criteria for the testing such as specific device-related acceptability criteria for each device mode or function tested. These criteria should include the following:
    - Specific device functions that should not degrade (such as CPU failure);
    - Device functions that may degrade (such as display fluctuation); and
    - Device recovery from degradation (such as after removal of the electrostatic discharge (ESD)).
- If modifications were made to the medical device in order to pass testing, a statement that all modifications will be incorporated into all final production units.

d. Labeling related to wireless medical devices

To facilitate the safe and effective use of the wireless medical device, the proposed labeling should include risk mitigation measures that address RF wireless issues and any precautions users should take. You should be aware that while labeling statements, such as warnings, may be helpful, they are not a substitute for risk mitigation measures or other design control activities, and are typically not adequate to prevent adverse events.

FDA recommends that the following information be included in the device labeling:

- A summary of the medical device wireless functions and specific wireless technology incorporated into the medical device or device system including equipment or system specifications (e.g., the standard IEEE 802.11 b/g, IEEE 802.15.4 Bluetooth™ class II);
- A summary of the operating characteristics of the wireless technology, effective RF radiated power output and operating range, modulation, and bandwidth of receiving section;
- A brief description of the wireless QoS needed for safe and effective operation;
- A brief description of the recommended wireless security measures such as the WPA2 wireless encryption for IEEE 802.11 technology;

- Information addressing wireless issues and what to do if problems occur;

- Information about any wireless coexistence issues and mitigations. This can include precautions for proximity to other wireless products, and specific recommendations for separation distances from such products;

- Appropriate EMC and telecommunications standards compliance and test results summary;

- Appropriate RF wireless communications information such as those required by FCC rules; and

- Warnings about possible effects from RF sources in the vicinity of the device (e.g., electromagnetic security systems, cellular telephones, RFID or other in-band transmitters).

In addition, FDA recommends that your labeling also include all of the information as outlined in the appropriate reference standards (e.g., IEC 60601-1-2). You should also consider any other appropriate FDA guidances or special controls guidelines applicable to your device for additional labeling information.

Appendix A: Glossary for Wireless Medical Devices and Device Systems

The following definitions were adapted from IEC 60050-161 International Electrotechnical Vocabulary (IEV), IEEE Standard 802.15.2™-2003, the IEEE Standard 11073-00101™ - 2008, and other sources.[15]

Data integrity — Assurance that transmitted files are not deleted, modified, duplicated, or forged without detection.

Electromagnetic compatibility (EMC) — the ability of a device to function (a) properly in its intended electromagnetic environment, and (b) without introducing excessive *electromagnetic disturbances* that might interfere with other devices.

Electromagnetic disturbance (EMD) — any electromagnetic phenomenon that might degrade the performance of an equipment, such as medical devices or any electronic equipment. Examples include power line voltage dips and interruptions, electrical fast transients (EFTs), electromagnetic fields (radio frequency radiated emissions), electrostatic discharges, and conducted emissions.

Electromagnetic interference (EMI) — degradation of the performance of a piece of equipment, transmission channel, or system (such as medical devices) caused by an electromagnetic disturbance. Note: *Disturbance* and *interference* are cause and effect, respectively.

Electrostatic discharge (ESD) — the rapid transfer of an electrostatic charge between bodies of different electrostatic potential, either in proximity in air (air discharge) or through direct contact (contact discharge).

Emissions — electromagnetic energy emanating from a device generally falling into two categories: conducted and radiated. Both categories of emission can occur simultaneously, depending on the configuration of the device.

> **Conducted emissions** — electromagnetic energy emanating from a product through a conductor by means of resistance, inductance, or capacitance. Conductors include AC power cords, metallic enclosures of a subsystem, or cables that interconnect subsystems or the patient to the product. Conducted emissions include power line harmonics, surges, and radio frequency energy, especially in the frequency range 150 kHz to 80 MHz.
>
> **Radiated emissions** — electromagnetic energy emanating from a device and propagating through space or a medium (which can affect the distance and direction of propagation). *Radiated emissions* include both intentional emissions such as radio transmissions

[15] Sources include: Federal Standard 1037C Telecommunications: Glossary of Telecommunications Terms.

carrying information and unintentional emissions associated with electrically powered equipment such as motors, power supplies, and computer components.

Immunity — the ability of an electrical or electronic product to operate as intended without performance degradation in the presence of an *electromagnetic disturbance*.

Latency — the time it takes for a unit of information to cross a wireless link or network connection from sender to receiver, which is also known as transfer delay.

Quality of service (QoS) — the necessary level of performance in a data communications system or other service, typically encompassing multiple performance parameters, such as reliability of data transmission, transfer rate, error rate, and mechanisms and priority levels for time-critical signals.

Radio frequency (RF) — a frequency in the portion of the electromagnetic spectrum that is between the audio-frequency and the infrared portions, and is useful for radio transmission. Commonly used radio frequencies range from 9 kHz to 100 GHz.

Radio frequency interference (RFI) — one type of *EMI* resulting from *radiated emissions* at one or more radio frequencies, which causes degradation of the reception of a wanted signal by a radio-frequency *electromagnetic disturbance*.

Radio frequency (RF) wireless medical device — a medical device that includes at least one function that is implemented using RF wireless communications; examples of functions that might be implemented wirelessly include data transfer, device control, programming, power transmission, remote sensing and monitoring, and identification.

Security — a collection of services, policies, mechanisms, and controls that provides information confidentiality, integrity, and availability by restricting unauthorized parties from accessing, manipulating, or leveraging particular system resources. Some security services might include data encryption, data integrity-checking, user and device authentication, and non-repudiation.

Specific absorption rate (SAR) — a measure of the rate at which energy is absorbed by the body when exposed to an RF electromagnetic field. It is defined as the power absorbed per mass of tissue and has units of watts per kilogram. SAR is usually averaged either over the entire body, or over a small sample volume (typically 1 g or 10 g of tissue).

Susceptibility — the potential for equipment (including medical devices) to respond to an *electromagnetic disturbance*. The inability of a device, equipment or system to perform without degradation in the presence of an *electromagnetic disturbance.* Note: *Susceptibility* is a lack of *immunity*.

Wireless coexistence — the ability of one wireless system to perform a task in a given shared environment where other systems (in that environment) have an ability to perform their tasks and might or might not be using the same set of rules.

Appendix B: Reference Standards and Information

FDA recommends that you refer to the FDA Recognized Consensus Standards Database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm, and type "electromagnetic compatibility" in the title search for EMC standards that FDA recognizes for use in premarket submissions. For information on recognized consensus standards, see the guidance document "Frequently Asked Questions on Recognition of Consensus Standards," http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm074973.htm.

The list below illustrates national and international consensus standards and other standards, and documents and information related to EMC, medical device EMC, and telecommunications. FDA recognizes some of these standards for use in regulatory submissions. However, this list serves as a reference only and is not intended to substitute for or represent specific suggestions or recommendations. We recommend that you refer to FDA guidances or special controls guidelines applicable to your specific device.

Association for the Advancement of Medical Instrumentation (AAMI)

AAMI TIR No. 18-2010, Guidance on electromagnetic compatibility of medical devices in healthcare facilities

ANSI/AAMI PC69:2007, Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

ANSI/AAMI/IEC 60601-1-2:2007/ (R) 2012, Medical Electrical Equipment—Part 1–2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. This is the U.S. version of the IEC 60601-1-2 standard (see IEC below)

American National Standards Institute (ANSI) Accredited Standards Committee C63 (ASC C63)

ANSI C63.4:2009, American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz

ANSI C63.10:2009, American National Standard for Methods for Testing Unlicensed Wireless Devices

ANSI C63.18:1997, American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters

ANSI C63.19:2007, American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids

Electrostatic Discharge Association (ESD Association)

ANSI/ESD S20.20-2007, ESD Association Standard for the Development of an Electrostatic Discharge Control Program for Protection of Electrical and Electronic Parts, Assemblies and Equipment (Excluding Electrically Initiated Explosive Devices)

Federal Communications Commission[16]

Code of Federal Regulations, Title 47 – Telecommunications, Chapter I - Federal Communications Commission, Subchapter A – General

- Part 2 – Frequency Allocations and Radio Treaty Matters; General Rules and Regulations
- Part 15 – Radiofrequency Devices
- Part 18 – Industrial, Scientific, and Medical Equipment

Subchapter D - Safety and Special Radio Services

- Part 95 – Personal Radio Services

International Electrotechnical Commission (IEC)

The IEC 60601 family specifies safety standards for medical electrical equipment. EMC is addressed in IEC 60601-1-2, and IEC 60601-2-X provides standards for particular types of medical electrical equipment.

IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests. This is a collateral standard to the third edition of IEC 60601-1. The third edition of IEC 60601-1-2 was published in 2007 and contains essentially the same

[16] For further information about these or other FCC requirements, please refer to http://www.fcc.gov/encyclopedia/rules-regulations-title-47 .

information that was in the second edition IEC 60601-1-2:2001 and Amendment 1:2004, reformatted according to the third edition of the IEC 60601-1 standard. Emissions and immunity requirements in the third edition IEC 60601-1 are specified under Clause 17.

IEC 60601-2-X standards are for particular types of medical electrical equipment. Requirements of IEC 60601-2-X standards supersede those of IEC 60601-1 and IEC 60601-1-2. Some IEC 60601-2-X standards specify higher immunity test levels or special test setups for EMC. Some might not have been amended yet to reference the third (2007) edition of IEC 60601-1-2 and might still reference an earlier edition. Modifications to IEC 60601-1 for EMC are specified in Clause 17 in the IEC 60601-1-2:2007 edition and Clause 36 in earlier editions. (NOTE: Subclause numbers for similar provisions in IEC 60601-1-2:2007 are different from those in earlier editions.)

IEC 61326-1:2005, Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 1: General requirements. Edition 2.0 was published in 2012.

IEC 61326-2-1:2005, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-1: Particular requirements - Test configurations, operational conditions and performance criteria for sensitive test and measurement equipment for EMC unprotected applications. Edition 2.0 was published in 2012.

IEC 61326-2-6:2005, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment. Edition 2.0 was published in 2012.

IEC 60050-161:1990, International Electrotechnical Vocabulary – Chapter 161: Electromagnetic compatibility. Amendment 2 was published in 1998. IEV online: http://www.electropedia.org/

IEC TR 80001-2-3: 2012, Application of Risk Management for IT-Networks Incorporating Medical Devices – Part 2-3: Guidance for wireless networks

Institute of Electrical and Electronic Engineers (IEEE)

P11073-00101™-2008 - Guide for Health Informatics–Point-of-Care Medical Device Communication–Guidelines for the Use of RF Wireless Technology. There are several standards under the IEEE 11073 family that address health informatics point-of-care medical device communications and provide useful information.

IEEE Std 802.15.2™-2003 IEEE Recommended Practice for Information Technology—Telecommunications and Information Exchange between Systems— Local and Metropolitan Area Networks— Specific Requirements Part 15.2: Coexistence of Wireless Personal Area Networks with Other Wireless Devices Operating in Unlicensed Frequency Bands.

International Organization for Standardization (ISO)

Most ISO standards for medical electrical equipment reference clauses in IEC 60601-1, including Clause 17 (previously Clause 36) and IEC 60601-1-2.

ISO/TR 16056-1, Health informatics – Interoperability of telehealth systems and networks — Part 1: Introduction and definitions

ISO/TR 16056-2, Health informatics – Interoperability of telehealth systems and networks — Part 2: Real-time systems

ISO/TR 18307, Health informatics – Interoperability and compatibility in messaging and communication standards – Key characteristics

ISO 14708-1, Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking, and for information to be provided by the manufacturer

ISO 14708-2, Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers

ISO 14708-3, Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators.

ISO 14708-4, Implants for surgery — Active implantable medical devices — Part 4: Implantable infusion pumps

ISO 14971 Second edition 2007-03-01 Medical devices — Application of risk management to medical devices

ISO 14117, Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices.

ISO technical report TR 21730, Health Informatics – Use of mobile wireless communications and computing technology in healthcare facilities – Recommendations for the management of unintentional electromagnetic interference with medical devices (ISO/TR 21730: 2007(E)).

RTCA, Inc.

RTCA/DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment

SIDLEY

NOVEMBER 10, 2017

SIDLEY UPDATE

U.S. Food and Drug Administration Proposes Changes to the Premarket Pathway for Genetic Health Risk Tests

On Nov. 8, 2017, the Food and Drug Administration (FDA) published two final orders and a notice related to direct-to-consumer (DTC) genetic tests with potentially important implications for developers of such tests. One of the orders, issued under new authority provided by the 21st Century Cures Act, finalizes the exemption from Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) Autosomal Recessive Carrier Screening Gene Mutation Detection Systems; FDA had proposed to exempt these tests after its landmark de novo authorization of 23andMe's Personal Genome Service. The other order codifies FDA de novo authorization concerning 23andMe's Genetic Health Risk (GHR) Assessment Systems (GHR Order). The notice, *Exemptions from Premarket Notification for Class II Devices*, proposes and seeks comments on a simplified path to market for Genetic Health Risk (GHR) genetic tests under which, according to an FDA statement, manufacturers of these tests "would have to come to FDA for a one-time review to ensure that they meet the FDA's requirements, after which they may enter the market with new [genetic health risk] tests without further review." The notice also proposes to exempt four other class II devices from 510(k).

This approach would be limited to GHR tests that rely on qualitative detection of indicated variants and do not provide an overall risk assessment of a person's likelihood of developing disease. It is unclear whether a test that provides a risk profile for certain diseases based on the presence of several variants associated with disease risk would fall within the relevant device classification regulation. In addition, to qualify for the new approach, the test could not be indicated for (i) prenatal testing, (ii) determining predisposition for cancer where the result of the test may lead to additional testing or treatment that may incur morbidity or mortality, (iii) certain pharmacogenomics indications or (iv) assessing the presence of deterministic autosomal dominant variants. *See* 21 C.F.R. § 866.5950(b)(4).

Under the proposal discussed in the notice, GHR tests must comply with these limitations on indications for use and other special controls to be partially exempt from 510(k). Other special controls in 21 C.F.R. § 866.5950 include extensive requirements for labeling, public disclosure of information about test performance, use of FDA reviewed or exempt sample collection kits and requirements to establish analytical and clinical validity. Partial exemption means developers of GHR tests would still have to submit a 510(k) before marketing a GHR test for the first time but could offer the test to detect additional variants or market new GHR tests without seeking FDA review. FDA's press statement compares the proposed policy for GHR tests to the precertification policy FDA is piloting for digital health products in that FDA is seeking a "firm-

based" rather than product-based oversight model that focuses on the product developer's capabilities to consistently design and develop high-quality products.

By allowing test developers to market tests for the detection of additional variants following initial FDA clearance, the proposed policy, if finalized, potentially reduces burden on GHR test developers in two ways. First, premarket burden would be reduced because test developers would likely submit information concerning only their test's detection of a single or a small subset — as opposed to dozens or hundreds — of variants. Second, test developers would be able to expand the indications of their marketed test without further FDA review.

Importantly, however, the exemption from 510(k) remains subject to FDA's standard limitations on exemption, which describe certain changes to a 510(k) exempt device that trigger the need for a 510(k). The notice states that the proposal to exempt GHR devices from 510(k) applies only to GHR tests "for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality." It is unclear how — or whether — this language would apply to genetic health information that is not being marketed for diagnostic purposes; if the language somehow applies, it is also unclear whether this language tracks the exclusion from the GHR classification of certain indications for use or expands the exclusion, potentially excluding indications other than those associated with prenatal testing, cancer, pharmacogenomics and autosomal dominant variants. Additional clarity from FDA in its final notice on these points is needed to ensure that genetic test developers reap the full benefit of the partial exemption from premarket review.

Interested persons can file comments on the notice by Jan. 8, 2018. Under section 510(m)(2) as amended by the 21st Century Cures Act, FDA must publish its final notice concerning the exemption of the five devices within 120 days or by Feb. 5, 2018.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work or

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FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on implementation of agency's streamlined development and review pathway for consumer tests that evaluate genetic health risks

For Immediate Release

November 6, 2017

Statement

At a time when people are more aware of and engaged in their health care than ever before, genetic risk testing can provide helpful information about an individual's predisposition for certain diseases and conditions. These tests can prompt consumers to be more engaged in pursuing the benefits of healthy lifestyle choices and more aware of their health risks. Consumers are increasingly embracing genetic health risk (GHR) testing to better understand their individual risk for developing diseases. This engagement prompts some people to make more informed lifestyle choices.

Direct-to-consumer (DTC) access to GHR tests is made possible by advances in technology. With a small saliva sample, consumers can retrieve their genetic risk result directly from the test provider's website. As consumer interest in genetic risk information grows, opportunities are also expanding for the detection of additional genetic conditions and diseases that can help inform people of their medical risks.

While these tests can offer significant amounts of personal risk information, they're not without their own risks – especially if they provide consumers with incorrect or misleading information that may be used to make health choices without considering the advice of a medical professional. Consider the consequences of a person who is told they're not at risk for coronary heart disease and incorrectly opts to forgo dietary changes or drugs that reduce their risk of heart attack and death.

The accelerated development of these innovative DTC genetic risk tests paired with the known safety considerations presents unique challenges to FDA regulation, as these technologies don't fit squarely into our traditional risk-based approach to device regulation. The agency has been increasingly nimble and creative in adapting its regulatory framework to fit the challenges of new technology platforms. In its consideration of GHR tests, the FDA seeks to strike a balance that provides for an efficient pathway to bring these tests to consumers, without sacrificing the assurances offered by FDA oversight.

We've committed on several fronts to take a fresh look at how we regulate truly novel medical advances to ensure that the FDA is encouraging their development and creating pathways that are risk-based, efficient, achieve the assurance of safety and efficacy, and in the case of tests, analytical and clinical validity, through a framework that is least burdensome. In the past six months, the FDA has announced that we're exploring several such approaches.

One example is the FDA's precertification pilot program (FDA Pre-Cert), which seeks to apply a tailored approach toward digital health technology by looking at the software developer or digital health technology developer, rather than primarily at the product. Another example is the FDA's forthcoming, comprehensive policy framework that will more clearly describe some novel frameworks for how the agency intends to regulate the safety and effectiveness of cell-based regenerative medicine.

Today, the FDA is taking steps to implement a novel regulatory approach for the regulation of GHR tests that applies proper oversight in a flexible, new way. It builds on the important lessons we learned from the FDA's authorization of the first GHR and carrier screening tests sold directly to consumers. Specifically, today the agency issued a notice of its intent to allow GHR tests to be exempted from premarket review under certain conditions. If and when finalized, manufacturers of these types of tests would have to come to FDA for a one-time review to ensure that they meet the FDA's requirements, after which they may enter the market with new GHR tests without further review. The agency also established special controls for these tests in a separate de novo classification order, which outline requirements for assuring the tests' accuracy, reliability and clinical relevance and describe the type of studies and data required to demonstrate performance of certain types of genetic tests. This approach is similar to the proposed firm-based, pre-certification model that we developed for digital health technologies.

Today, the agency also classified certain tests to evaluate vitamin D levels in class II, subject to special controls, and announced its intent to exempt these tests from premarket review. Finally, the FDA issued a final order exempting genetic carrier screening tests from premarket review.

We'll continue to look for opportunities to use this type of firm-based regulatory approach, both for new tests and other novel medical products. Our goal is to streamline the regulatory pathway to get innovative medical products to people more efficiently, while providing the FDA assurances that consumers seek. The FDA, an agency within the U.S. Department of Health and Human Services, protects the public and promotes health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public and promotes health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Consumers

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Related Information

- **Medical Devices; Immunology and Microbiology Devices; Classification of the Genetic Health Risk Assessment System (https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-24159.pdf)**

- Medical Devices; Exemption From Premarket Notification; Class II Devices; Autosomal Recessive Carrier Screening Gene Mutation Detection System (https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-24162.pdf)
- Classification of the Total 25-hydroxyvitamin D Mass Spectrometry Test System (https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-24161.pdf)
- Medical Devices; Exemptions From Premarket Notification: Class II Devices; Request for Comments (https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-24163.pdf)
- April 6, 2017: FDA allows marketing of first direct-to-consumer tests that provide genetic risk information for certain conditions (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm551185.htm)
- February 19, 2015: FDA permits marketing of first direct-to-consumer genetic carrier test for Bloom syndrome (/NewsEvents/Newsroom/PressAnnouncements/ucm435003.htm)

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Discussion Paper on Laboratory Developed Tests (LDTs)
January 13, 2017

The Food and Drug Administration (FDA) recently announced that we would not issue a final guidance on the oversight of laboratory developed tests (LDTs) at the request of various stakeholders to allow for further public discussion on an appropriate oversight approach, and to give our congressional authorizing committees the opportunity to develop a legislative solution.

In gathering feedback on the LDT draft guidances issued in 2014, we continuously engaged with interested stakeholders, including those groups that authored alternative proposals. We analyzed more than 300 sets of comments on the draft guidances and discussion from a subsequent public workshop held in 2015 as well as engaged in many meetings and conferences with various stakeholders. Because we did not issue a final guidance, all that is currently available to the public are the individual comments on the 2014 draft guidances submitted to the federal docket and the transcript of the workshop. In the absence of issuing final guidance and at the request of stakeholders, we feel it is our responsibility to share our synthesis of all the feedback we have received, with the hope that it advances public discussion on future LDT oversight.

As part of this synthesis we have included a possible approach to LDT oversight, which is based on the extensive, and often conflicting, feedback we received from a broad range of stakeholders. This possible approach is intended only to respond to stakeholder feedback and attempt to balance patient protection with continued access and innovation. Given the wide range of perspectives on this issue, no approach is likely to fully satisfy all stakeholders.

The synthesis does not represent the formal position of FDA, nor is it enforceable. We hope to simply advance the public discussion by providing a possible approach to spur further dialogue. This document does not represent a final version of the LDT draft guidance documents that were published in 2014.

INTRODUCTION

Patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions. Inaccurate or false test results, or accurate measurements with an invalid claim regarding the test results' relationship to a disease, can lead to substantial patient harm. LDTs play an increasingly important role in the provision of high-quality health care and many laboratories perform good validation of their LDTs and provide high-quality, professional management of their operations. However, currently, patients and providers cannot uniformly rely on all tests offered for clinical use as some are not subject to active premarket oversight to ensure they provide accurate measurements and valid claims. Furthermore, CMS' evaluation of clinical utility, as part of a coverage determination, would typically follow from FDA review of analytical and clinical validity.

While excessive oversight can discourage innovation, inadequate and inconsistent oversight in which different test developers are treated differently can also discourage innovation by making it difficult for high-quality test developers to compete with poorer performing counterparts. Limited investment and health care funding may be expended on faulty tests rather than focused on tests that lead to improved care. When patients and providers discover that results they relied upon to make treatment and/or diagnostic decisions were inaccurate, their confidence in laboratory testing may be compromised. In a recent example, ovarian cancer screening tests offered to asymptomatic patients were shown not to work only after patients unnecessarily underwent major surgeries with significant recovery and side effects.[1]

Without more active oversight, similarly problematic LDTs will continue to be offered in the future. FDA[2,3,4,5,6, 7,8] and others [9,10,11,12,13,14,15] have consistently asserted that there is a public health need for greater oversight of LDTs. Appropriately tailored oversight can facilitate the development of analytically and clinically valid tests and the generation of the evidence health care providers and patients need to make well-informed decisions.

FDA proposed a comprehensive LDT policy[16] in 2014 that was intended to protect patients, promote innovation, and provide clarity regarding FDA oversight of LDTs. This proposal and the ensuing public workshop[17] prompted extensive comments and discussions among laboratories, health care providers, patients, conventional in vitro diagnostic (IVD) manufacturers, government agencies, and Congress. Based on the extensive community engagement over the last two years, the positions of many groups, including FDA, have evolved.

There is a growing consensus that additional oversight of LDTs is necessary, as reflected in several recent oversight proposals put forward by some organizations representing laboratories and the IVD industry.[18,19,20,21,22] Although these proposals differ in some respects, they generally share the following features:

- A risk-based approach to oversight;
- Independent premarket review for certain tests and for some modified tests;
- A focus on analytical and clinical validity as the basis for test approval;
- Risk classification activities;
- Adverse event reporting;
- Exemption of certain categories of tests from premarket review;
- A robust laboratory quality system;
- "Grandfathering" for tests available prior to a specific date; and,
- Public availability of test performance information.

These proposals differ with respect to which federal agency would be responsible for any additional oversight: FDA, the Clinical Laboratory Improvement Amendments (CLIA) program, which is overseen by the Centers for Medicare and Medicaid Services (CMS), or a hybrid model under which FDA and CMS engage in complementary, non-duplicative oversight have been proposed.

Based on the feedback we have received, the complementary approach in some form is supported by the broadest array of stakeholders, including some members of the laboratory community. This approach may best streamline effective oversight by taking advantage of each federal agency's existing structure and strengths, including FDA's experience in premarket review of diagnostics and its deep knowledge of clinical research methodology pertinent to clinical validity. Such an approach could foster innovation and advance patient access to cutting-edge, high-quality, accurate, and clinically valid tests as long as it is also reasonable, appropriately tailored, and least burdensome.

On the other hand, a CMS-only framework for additional oversight could create inconsistencies in the marketplace. For example, under some proposals the same test would be regulated by FDA if made by a conventional manufacturer but by CMS if made by a laboratory. This would be a developer-based framework, rather than a risk-based framework, as the oversight authority would be determined by who made the test rather than on what the test is intended to do and the risks it presents to patients. This could create jurisdictional challenges as the agency responsible for oversight could continually change over the course of its application to clinical care. For example, a test made by a conventional IVD manufacturer

would be regulated by FDA initially. If a laboratory made a significant modification to that test, it would then be regulated by CMS. If the original manufacturer then made another significant modification, the modification would be regulated by FDA. This would be confusing, at best.

In addition, it could be difficult for a CMS-only LDT framework to duplicate FDA capabilities (and FDA's 40-year experience in assuring the analytical and clinical validity of tests) as CMS's oversight of laboratories through CLIA is fundamentally different from FDA's oversight of the tests themselves.

Adapting CLIA to enable CMS to provide the kind of effective oversight of LDTs that is needed to ensure that they are accurate, reliable, and clinically valid would require a significant change in the nature of what the agency does, rather than minor modifications as some have suggested. By its very nature, a CMS-only framework for LDTs could create costly federal redundancies and inefficiencies.

The approach described below is based on a synthesis of the public feedback FDA received. In gathering feedback, FDA engaged with interested stakeholders, including those groups that authored alternative proposals, and analyzed more than 300 sets of comments on the 2014 draft guidance and a subsequent public workshop held in in 2015 as well as engaged in many meetings and conferences with various stakeholders.

Generally, many patient groups, the oncology community, consumer groups, conventional IVD manufacturers, pharmaceutical companies, and public and private health insurers supported FDA's risk-based, phased-in approach to LDT oversight. The laboratory community, including hospital laboratories, academic medical centers, and laboratory professional societies, generally expressed opposition to FDA's proposed LDT oversight approach. Many who supported FDA oversight expressed concerns about current gaps in LDT oversight and some were concerned that many LDTs are being marketed without any independent review of clinical validity, potentially harming patients and wasting health care dollars. Many of those who opposed FDA oversight expressed concerns about slowed innovation, increased costs, and reduced patient access. The comments FDA received included both general views on LDT oversight as well as more specific comments on the details of the draft guidances. Based on this extensive feedback, several alternatives to what FDA proposed in 2014 should be considered, including:

- Exempting LDTs already on the market from all FDA oversight except for adverse event and malfunction reporting ("grandfathering"), and exempting traditional LDTs (see below) and LDTs for public health surveillance from all oversight;
- Not adopting proposals requesting laboratories to notify FDA of their LDTs on the market because FDA generally would no longer need to classify LDTs currently on the market as the result of "grandfathering";
- Providing additional time before FDA would begin actively overseeing certain regulatory requirements; and
- Shortening the overall phased-in timeframe.

The possible approach described below incorporates these and other changes with the intent to respond to stakeholder feedback and to appropriately balance patient protection with continued access and innovation, with the caveat that given the wide range of perspectives, no approach is likely to fully satisfy all stakeholders. This approach addresses only the LDTs that are designed, manufactured, and used in a CLIA certified lab; many elements would not be appropriate for conventional IVD kits.

FOCUSED OVERSIGHT

Based on the feedback received, a *prospective* oversight framework that focuses on new and significantly modified high and moderate risk LDTs would best serve the public health and advance laboratory medicine. Under such an approach, as further explained below, previously marketed LDTs would not be expected to comply with most or all FDA regulatory requirements, including premarket review, quality systems, and registration and listing, unless necessary to protect the public health. Some refer to this concept as "grandfathering."

Additionally, new and significantly modified LDTs in the following categories would not be expected to comply with premarket review, quality systems, and registration and listing requirements unless necessary to protect the public health:

- Low risk LDTs;
- LDTs for rare diseases;
- Traditional LDTs (i.e., tests that use components that are legally marketed for clinical use[23] and whose output is the result of manual interpretation by a qualified laboratory professional, without the use of automated instrumentation or software for intermediate or final interpretation);
- LDTs intended solely for public health surveillance (i.e., intended solely for use on systematically collected samples for analysis and interpretation of health data that are essential to the planning, implementation and evaluation of public health practice, which is closely integrated with the dissemination of these data to public health officials and linked to disease prevention and control[24]);
- LDTs used in CLIA-certified, high-complexity histocompatibility labs to perform allele typing, antibody screening and monitoring, or crossmatching in connection with organ, stem cell, and tissue transplantation; and
- LDTs intended solely for forensic use.

To protect patients from tests that could lead to harm, the agency would retain its ability to enforce premarket review, quality systems, and other applicable requirements for any LDT, including those listed above, if the agency identified one or more of the following, taking into account all available evidence:

- The LDT is not analytically and clinically valid or there is an absence of sufficient data to support its analytical and clinical validity;
- The manufacturer of an LDT has engaged in deceptive promotion; or
- There is a reasonable probability that the LDT will cause death or serious adverse health consequences.

RISK-BASED, PHASED-IN OVERSIGHT

Consistent with proposals from other stakeholders, premarket review of new and significantly modified LDTs could be phased in over four years, rather than the nine years proposed in FDA's 2014 draft guidance, because LDTs currently on the market generally would be "grandfathered" thereby reducing the overall workload on laboratories and FDA. The agency could focus first on the tests for which the consequences of a false result are known to have the highest risk to the patient, with an additional two years to meet applicable quality systems requirements. The following risk-based approach to phase-in of oversight could be adopted:

- Year One: Serious adverse event and malfunction reporting for all LDTs except: traditional LDTs, LDTs intended solely for public health surveillance, certain stem cell/tissue/organ transplantation LDTs, and LDTs intended solely for forensic use.
- Year Two: Premarket review for new/modified LDTs with the same intended use as an IVD approved under a PMA (i.e., tests that have already been identified as high risk by FDA).
- Year Three: Premarket review for new/modified LDTs with the same intended use as a Class II device type subject to 510(k) clearance (i.e., tests that have already been identified as moderate risk by FDA).
- Year Four: Premarket review for new/modified LDTs that do not fall into the above categories.

To ensure patient access to existing tests is not disrupted, those tests that are introduced between the effective date of such framework and their phase-in date could continue to be offered for clinical use during the period of premarket review. Because FDA Quality System requirements would likely be a new activity for laboratories, and to help foster innovation, such tests would also have an additional two years before having to meet quality system requirements, as described below. In addition, because tests could be offered for clinical use prior to FDA's readiness to review them, registration and listing would occur at the time an LDT receives marketing authorization.

In its 2014 draft guidances and related statements, FDA said that more flexibility is important for new LDTs that address unmet needs in order to promote innovation and patient access to tests leveraging new scientific findings. Stakeholders echoed this belief in their comments to FDA, but expressed some concerns about the unmet needs policy as written in the 2014 draft guidance because it did not provide assurances that these tests for which there is the least practical experience are analytically and clinically valid. On the other hand, some stakeholders commented that the scope of LDTs for unmet needs should be broadened to include tests not made by a health care system laboratory, to promote fair access to such tests. As such, a new approach for a more broadly defined category of LDTs for unmet needs (i.e., any test designed, manufactured, and used in a single laboratory for which there is no FDA cleared or approved alternative at the time the LDT enters the market) should be considered. For example, to promote innovation and patient access, laboratories could have up to 90 days after offering an LDT for an unmet need to send a premarket submission to FDA or an accredited third party reviewer, when applicable, and could continue to offer the test during FDA's or the third party's review (*see* Third Party Review section below).

EVIDENCE STANDARDS

Traditionally, FDA focuses on analytical and clinical validity as the practical bases for test marketing authorization; specifically, FDA evaluates whether there is a reasonable assurance of analytical and clinical validity for the test. CMS evaluates whether there is clinical utility for the specific test. Independent review of analytical and clinical validity by FDA, which today is generally only enforced for high and moderate risk tests made by conventional IVD manufacturers, allows for an unbiased check on the quality of the evidence and ensures that it is sufficient to establish that the test works as claimed or intended. Laboratories that already conduct proper validation should not experience new costs for validating their tests to support marketing authorization.

FDA's premarket review would be complementary to, and not duplicative of, CMS's postmarket oversight of laboratory operational processes as well as its determinations of clinical utility. CMS coverage determinations of clinical utility measures the ability of the test to impact clinically meaningful health outcomes, such as mortality or morbidity, through the adoption of efficacious treatments. CMS's

oversight through the CLIA program is designed to confirm that a lab assesses analytical validity, but does not confirm whether it had results from an analytical validity assessment that were sufficient to support the claimed intended use of the test. Also, while CMS assesses the clinical utility of a test, evaluation of clinical validity is critical to ensure that providers and patients have access to tests that improve care. Independent premarket review of a test's clinical validity is becoming increasingly important to providing high-quality health care because labs and conventional IVD manufacturers are attempting to rapidly translate novel scientific findings/hypotheses to clinical care before data supporting clinical significance is made publicly available. This means LDTs that have not undergone appropriate premarket review may still be putting patients at considerable risk.

Because CMS requires that laboratories establish the performance characteristics of their tests, we anticipate that laboratories that conduct appropriate evaluations would not have to collect additional data to demonstrate analytical validity for FDA clearance or approval. Additionally, in situations where there is a robust and appropriate proficiency testing program, accepted reference and review standards or a certification program for a specific test, such as the National Glycohemoglobin Standardization Program (NGSP) or the Cholesterol Reference Method Laboratory Network (CRMLN), FDA would work collaboratively with health care professional, laboratory, and conventional IVD manufacturer communities, as well as other stakeholders, to determine how such programs could be leveraged to reduce the burden of premarket review. This could significantly expedite premarket review. If the law is changed, availability of such programs and standards may eliminate the need for premarket review of analytical validity through FDA recognition of certain review standards developed by such programs (*see* the Clinical Collaboratives section below).

Clinical validity, especially of established tests, can often be supported by literature, well-curated databases, or other appropriate sources that meet the valid scientific evidence standard. Accordingly, once clinical validity has been well established, laboratories with subsequent tests generally could, in accordance with applicable regulations, leverage such evidence of clinical validity when factors such as indications for use, technology, and standardization are the same, without the need to re-demonstrate clinical validity. This also could apply to tests whose methods are shown to perform similarly to the methods used in the studies reported in the literature.

Controls and oversight mechanisms in place under CMS and the Occupational Safety and Health Administration generally address potential safety issues with LDTs that are unrelated to performance, including the potential for direct harm through transmission of infectious disease, or physical harms to users. However, if any component of an LDT were to come in direct contact with a patient, as with some conventional IVD kits, additional evaluation of safety should be performed.

THIRD PARTY REVIEW

FDA would expand its third party premarket review program to include eligible LDTs. FDA has already begun working towards this goal by exploring opportunities to coordinate with and leverage existing programs, such as New York State's Clinical Laboratory Evaluation Program and the programs run by organizations approved by CLIA to accredit laboratories. Many LDTs that have not been FDA cleared or approved require premarket review by the New York State Department of Health's (NYSDOH) Clinical Laboratory Evaluation Program (CLEP) if the test is performed in New York State or the sample is from New York State. In fact, NYSDOH has reviewed more than 11,000 new and modified LDTs over a ten-year period, which we understand may account for around 50 percent of new and modified LDTs. Many laboratories are therefore well accustomed to complying with premarket review requirements through this program. Arguably, this type of premarket oversight, which is currently provided by NYS for some tests,

is important for *all* high risk and moderate risk laboratory tests so that all patients across the country – not just those in NYS – can be assured they are receiving a test that is analytically and clinically valid. (Note that NYSDOH and FDA are not duplicative. Tests that are reviewed by FDA would not need NYSDOH review because NYS recognizes FDA review. FDA is exploring accepting NYSDOH review in lieu of its own.)

CLINICAL COLLABORATIVES

FDA would expand its collaborative work with the health care professional, laboratory, and conventional IVD manufacturer communities, as well as other stakeholders, to develop measurement and review standards for analytical validity for tests where feasible and beneficial; crowdsource evidence to demonstrate clinical validity for specific types of tests; and develop, for FDA recognition, standards for use in determining clinical validity for specific types of tests. FDA would expand its use of such clinical collaboratives by leveraging, to the extent appropriate, existing entities such as health care professional organizations. By applying such analytical and/or clinical validity standards, FDA and accredited third party reviewers could rely in part or wholly on the interpretation made by the clinical collaborative. FDA oversight would help ensure the quality and consistency of analytical and clinical validity determinations based on valid scientific evidence, while streamlining time and cost, thereby enabling regulatory decisions to be made in near real time when FDA, in collaboration with the clinical community, believes the evidence is adequate to support the intended use of the test.

TRANSPARENCY

Evidence of the analytical and clinical validity of all LDTs would be made publicly available, such as through publication in a journal, on the laboratory's website, or elsewhere, since understanding the test performance and how it was derived is crucial to understanding how to use the results.

For those tests that would be reviewed by FDA, the agency would publish its review memorandum containing such information. For those that are not reviewed by FDA, laboratories should consider making such information public. FDA would work collaboratively with the health care professional, laboratory, conventional IVD manufacturer, and patient communities, as well as other stakeholders, to develop shared and reasonable expectations for the content and format of such information to best meet the needs of health care professionals and patients to make well-informed decisions.

It would continue to be appropriate for laboratories, at their discretion, to respond to specific requests from treating physicians and other health care professionals to run a particular test that is not FDA reviewed for the requested intended use for the sole purpose of diagnosing or treating a specific individual patient.

MODIFICATIONS

Regulatory policy should be sufficiently flexible so as to enable laboratories to make modifications without undue burden, while still providing assurances to users that the modifications do not affect the underlying test's ability to perform as intended. FDA would encourage laboratories to submit prospective change protocols in their premarket submissions that outline specific types of anticipated changes, the procedures that will be followed to implement them, and the criteria that will be met prior to implementation.

Following marketing authorization, modifications made in accordance with the change protocol, including the specific procedures and acceptance criteria, could be made without the need for a new submission. For this reason, premarket review of modifications to an already marketed test (including a "grandfathered" LDT or another manufacturer's IVD kit) would be limited to only those modifications that significantly change performance specifications or intended use of the test and are not made in accordance with the test's approved change protocols, including approved verification and validation methods. The systematic use of the change-protocol approach would narrow the circumstances under which a test modification would be subject to FDA review. Therefore, it would be important that laboratories keep good documentation of the changes they make and how those changes conform to the laboratory's change protocols.

LEVERAGING CMS/CLIA: QUALITY SYSTEM REQUIREMENTS FOR LDTs

In 2015, FDA established an Interagency Task Force on LDT Quality Requirements with CMS, the Center for Disease Control and Prevention, and the National Institutes of Health to evaluate current quality system (QS) requirements and assess where existing quality controls are adequate as well as whether and where additional oversight is warranted to address LDT development activities. Through the Task Force, FDA met with all seven accreditation organizations (AO) approved by CMS to conduct CLIA survey inspections, as well as the two state departments of health approved by CMS for exemption from CLIA program requirements, to better understand how each program operates and the extent of additional oversight their certifications provide beyond CLIA requirements. Most of these organizations' evaluations go beyond the minimum CLIA requirements, but no organization or any combination of organizations evaluate all relevant elements of LDT development addressed by FDA's QS regulation. Furthermore, laboratories are not required to select an AO for the purpose of CLIA accreditation; they may register with the CLIA program and be surveyed by CMS state inspectors who do not evaluate any elements beyond CLIA.

The Task Force confirmed that FDA and CMS oversight is different and complementary. FDA oversight focuses on individual test performance, while CMS oversight focuses on administering the CLIA program of certifying laboratory operations. In addition, CMS reviews LDTs for coverage determinations with a focus on clinical utility – the ability of the test to impact clinically meaningful health outcomes, such as mortality or morbidity, through changes in clinical management and the adoption of efficacious treatments based upon the results of the test. To supplement the Task Force analysis, FDA visited a wide variety of laboratories running LDTs, including large reference labs, academic labs, and specialized single-technology labs. Many laboratories have quality management systems that go beyond CLIA requirements and some carry accreditations to higher quality standards, such as the College of American Pathologists (CAP), NYSDOH and the International Organization for Standardization (ISO). These visits allowed FDA to better appreciate that good professional management of laboratory operations, as required under CLIA and performed routinely in laboratories across the country, can address many quality-related issues pertaining to the development, maintenance, and modification of LDTs. Of note, as well, FDA's current QS requirements are not a panacea to prevent quality-related problems. Quality-related problems may occur with FDA-regulated tests even when all QS requirements are met. However, if these requirements are met such problems should be detected and appropriately addressed in a timely manner.

On the other hand, not all quality-related issues are addressed by CLIA. Neither CLIA nor the programs that accredit to higher standards ensure quality in the design, development, and manufacturing activities comparable to that of the FDA QS regulation. Notably missing from all other accreditation standards are

robust design controls, which are critical to the quality of tests and for which FDA has both longstanding experience and expertise. Design controls allow laboratories to monitor and control the design of their tests to ensure that they are analytically and clinically valid. To obtain the full benefit of design controls, mechanisms should be implemented throughout the test lifecycle that both collect data and provide formal processes by which those data capture production and other quality problems, feed back into the design process, and inform future iterations of the test.

FDA also visited labs where separate rooms that were not part of the CLIA lab were used for the manufacture of key components, such as arrays, that are brought in to a certified CLIA lab across the hallway for use in complex high risk tests offered for clinical use. The design and manufacture of such critical components are currently without any oversight, including through CLIA, as these activities are performed outside of the CLIA certified laboratory.

Therefore, under the approach described in this paper, FDA would leverage certification to CLIA requirements, even though they are not fully consistent with FDA QS requirements, and, for LDTs made within a CLIA-certified laboratory, narrowly focus its assessment on only three FDA QS requirements that address aspects of the test development process not covered by CLIA: design controls; acceptance activities (i.e., mechanisms to ensure that products meet specified requirements coming into the laboratory and throughout testing); and procedures for implementing corrective and preventive actions (CAPA) (i.e., activities to ensure that specific quality problems, including those detected via acceptance testing, are corrected and that changes are made to prevent them from happening in the future). Laboratories may need to expand their existing CAPA activities to cover the design and development phase, and this will help them offer improved tests over time.

FDA would expand its third party inspection program for LDTs so that many of these postmarket inspections could be conducted by FDA-accredited third parties. Such third parties could include AOs and State Departments of Health who already conduct CLIA survey inspections if they meet the requirements for this FDA program. This would allow such third parties, when appropriate, to inspect for the three additional FDA QS requirements at the time of a routine CLIA survey inspection. FDA has already begun working towards this by exploring opportunities to coordinate with and leverage existing programs, such as NYSDOH's CLEP and the programs run by organizations approved by CLIA to accredit laboratories.

POSTMARKET SURVEILLANCE

Postmarket surveillance is a collection of processes and activities FDA uses to monitor the performance of tests once they are on the market to ensure tests continue to perform as intended, among other things. This type of oversight is critical in particular because laboratories and other test developers may make modifications to their tests and processes that are not reviewed by FDA or an accredited third party and that can impact the performance of their tests. These activities are designed to generate information to identify poorly performing tests and other safety problems, accurately characterize real-world performance and clinical outcomes, and facilitate the development of new tests, or new uses for existing tests.

Initially laboratories would report serious adverse events to FDA for all tests except: traditional LDTs[25], LDTs intended solely for public health surveillance[26], certain stem cell/tissue/organ transplantation LDTs[27], and LDTs intended solely for forensic use[28]. In the future, we may be able to decrease or discontinue such reporting as efforts to monitor the performance of tests and other technologies and their impact on patients by leveraging data collected as a part of clinical practice ("real-world data") mature.[29]

Recognizing that laboratories may need additional time to come into compliance with the QS regulations, even for new and significantly modified tests, these laboratories would have an additional two years beyond the premarket review phase-in to meet QS regulation requirements. Initial inspections would be educational in nature as FDA and laboratories work together to bring this additional level of quality to the design and manufacture of LDTs.

CONCLUSION

Many stakeholders, in addition to FDA, have indicated that there is a public health need for greater oversight of LDTs. For example, payers such as CMS expect FDA review of analytical and clinical validity to precede determinations of clinical utility for coverage. Extensive stakeholder feedback further confirmed the importance of balancing the unique qualities of LDTs, while still providing a reasonable assurance that such tests are analytically and clinically valid. An oversight approach should be undertaken in an efficient manner that effectively leverages, without duplicating, CLIA requirements, keeping in mind that CLIA certification only includes the laboratory where such tests are performed. It should include many of the same features that have been proposed by various groups recommending greater oversight of LDTs. Such an approach could appropriately balance patient protection with continued access and innovation. FDA looks forward to continuing to work with all stakeholders in future conversations around the right path forward on LDT oversight.

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[1] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm519540.htm

[2] Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416685.pdf

[3] The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf

[4] 21st Century Cures: Examining the Regulation of Laboratory Developed Tests, Statement of Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives. September 9, 2014. http://www.fda.gov/NewsEvents/Testimony/ucm415867.htm

[5] Examining the Regulation of Diagnostic Tests and Laboratory Operations, Statement of Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives. November 17, 2015. http://www.fda.gov/NewsEvents/Testimony/ucm473922.htm

[6] Direct-to-Consumer Genetic Testing and the Consequences to the Public, Statement of Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. July 22, 2010. http://www.fda.gov/NewsEvents/Testimony/ucm219925.htm

[7] Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071455.pdf

[8] Public Meeting on Oversight of Laboratory Developed Tests, July 20, 2010
http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM226204.pdf

[9] National Human Genome Research Institute (1997). *Promoting Safe and Effective Genetic Testing in the United States*. http://www.genome.gov/10001733.

[10] Secretary's Advisory Committee on Genetic Testing (2000). *Enhancing the Oversight of Genetic Tests: Recommendations of SACGT*. http://www4.od.nih.gov/oba/sacgt/reports/oversight_report.pdf

[11] Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS). U.S. system of oversight of genetic testing: a response to the charge of the Secretary of Health and Human Services. Washington (DC): Department of Health & Human Services. April 2008. http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS

[12] Institute of Medicine. *Evolution of Translational Omics: Lessons Learned and the Path Forward*. Washington, DC: The National Academies Press, 2012.

[13] Representative Letter to OMB Urging Release of LDT Guidance. June 2013. https://louise.house.gov/media-center/press-releases/slaughter-calls-transparency-diagnostics-testing

[14] Senator Letter to OMB Urging Release of LDT Guidance. July 2014. http://www.markey.senate.gov/imo/media/doc/2014-07-02_Deese_LDTs.pdf

[15] Cancer Leadership Council Letter to OMB Urging Release of LDT Guidances. November 2012. http://www.cancerleadership.org/policy/fda/text/121121t.html

[16] Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM416685.pdf

[17] Public Workshop – Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs), January 8-9, 2015. http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm423537.htm

[18] College of American Pathologists' Legislative Proposal for Laboratory Developed Tests (LDT), September 14, 2015. http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution%20Folders/WebContent/pdf/2015-cap-ldt-legislative-proposal.pdf and http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution%20Folders/WebContent/pdf/legislative-ldt-faqs.pdf

[19] Association for Molecular Pathology's Proposal for Modernization of CLIA Regulations for Laboratory Developed Testing Procedures (LDPs). August 14, 2015. https://www.amp.org/advocacy/documents/AMPCLIAmodernizationproposalFINAL8.14.15.pdf

[20] Diagnostic Test Working Group's Proposed Regulatory Framework for In Vitro Clinical Tests. March 5, 2015. http://www.fdalawblog.net/DTWG_final_proposal.pdf

[21] American Clinical Laboratory Association letter to the Office of Information and Regulatory Affairs, Office of Management and Budget. November 11, 2016. http://www.acla.com/wp-content/uploads/2016/11/2016-Nov-11-ACLA-Letter-to-OIRA-re-LDTs.pdf

[22] Discussion Draft on the Regulation of Diagnostic Tests and Laboratory Operations. October 22, 2015. Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives. http://docs.house.gov/meetings/IF/IF14/20151029/104127/BILLS-114pih-HR____.pdf

[23] Components that are legally marketed for clinical use refer to general purpose reagents, immunohistochemical stains, and other components marketed in compliance with applicable FDA regulatory requirements, e.g., properly labeled for *in vitro* diagnostic use (21 CFR 809.10(a)(4)) and manufactured in compliance with quality system requirements (21 CFR Part 820).

[24] Thacker SB, Berkelman RL. History of public health surveillance. In: Public Health Surveillance, Halperin W, Baker EL (Eds.): New York; Van Norstrand Reinhold, 1992.

[25] Components used in a traditional LDT are required to be legally marketed and, therefore, would be under the quality system of the manufacturer. The clinical interpretation of the results is appropriately overseen by CLIA.

[26] Tests used solely for public health surveillance are not used to guide treatment.

[27] Consistent with a 2011 recommendations from the Secretary's Advisory Committee on Organ Transplantation (ACOT) and the Advisory Council on Blood Stem Cell Transplantation (ACBSCT), FDA intends to continue to exercise enforcement discretion in full over LDTs used in CLIA-certified, high-complexity histocompatibility laboratories, when those LDTs are used in connection with organ, stem cell, and tissue transplantation: to perform allele typing; or for antibody screening and monitoring; or for the purpose of conducting real and "virtual" crossmatch tests. ACOT minutes available at: http://www.organdonor.gov/legislation/acotaugust2011notes.html. ACOT meeting recommendations available at: http://www.organdonor.gov/legislation/acotrecs5354.html. ACBSCT meeting minutes available at: http://bloodcell.transplant.hrsa.gov/about/advisory_council/meetings/notes/files/acbsctsummarynotesnov2011.pdf. ACBSCT meeting recommendation available at: http://bloodcell.transplant.hrsa.gov/about/advisory_council/recommendations/rec17_21/index.html#rec17"

[28] Tests used solely for forensic use have different oversight mechanisms available.

[29] For example, FDA is working with other medical device ecosystem stakeholders to establish the National Evaluation System for health Technology (NEST) through the Medical Device Innovation Consortium. *See* Shuren, J, Califf RM, *Need for a National Evaluation System for Health Technology*, JAMA, 2016;316(11):1153-1154.

information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

III. Electronic Access

Persons with access to the internet may obtain the document at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24192 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1129]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing its intent to exempt a list of class II devices from premarket notification requirements, subject to certain limitations. The Agency has determined that, based on established factors, these devices no longer require premarket notification to provide reasonable assurance of safety and effectiveness. FDA is publishing this notice to obtain comments regarding the proposed exemptions, in accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on the notice by January 8, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 8, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 8, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–1129 for ''Medical Devices; Exemptions from Premarket Notification: Class II Devices; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bryce Bennett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5244, Silver Spring, MD 20993, 301–348–1446, *Gregory.Bennett@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION :

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a new device to submit and obtain clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended,

section 510(m)(1)(A) of the FD&C Act requires FDA to publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. FDA is required to publish this notice within 90 days of the date of enactment of the Cures Act and at least once every 5 years thereafter, as FDA determines appropriate. Additionally, FDA must provide at least a 60-day comment period for any such notice required to be published under section 510(m)(1)(A) of the FD&C Act. FDA published this notice in the **Federal Register** of March 14, 2017 (82 FR 13609). Under section 510(m)(1)(B) of the FD&C Act, FDA must publish in the **Federal Register**, within 210 days of enactment of the Cures Act, a list representing its final determination regarding the exemption of the devices that were contained in the list published under section 510(m)(1)(A). FDA published that list in the **Federal Register** of July 11, 2017 (82 FR 31976).

As amended, section 510(m)(2) of the FD&C Act provides that, 1 day after the date of publication of the final list under section 510(m)(1), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. To do so, FDA must publish in the **Federal Register** a notice of its intent to exempt the device, or of the petition, and provide a 60-day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under section 510(m)(2) of the FD&C Act within 180 days of receiving it, the petition shall be deemed granted.

II. Factors FDA May Consider for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (''Class II 510(k) Exemption Guidance'') (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether premarket notification is necessary for class II devices: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

III. Limitations on Exemptions

FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of the class II devices listed in table 1. This determination is based, in part, on the Agency's knowledge of the device, including past experience and relevant reports or studies on device performance (as appropriate), the applicability of general and special controls, and the Agency's ability to limit an exemption.

A. General Limitations of Exemptions

FDA's proposal to grant an exemption from premarket notification for class II devices listed in table 1 applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. FDA proposes that a manufacturer of a listed device would still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when the device meets any of the conditions described in 21 CFR 862.9 to 21 CFR 892.9.

B. Partial Limitations of Exemptions

In addition to the general limitations, FDA may also partially limit an exemption from premarket notification requirements to specific devices within a listed device type when initial Agency assessment determines that the factors laid out in the Class II 510(k) Exemption Guidance (Ref. 1) do not weigh in favor of exemption for all devices in a particular group. In such situations where a partial exemption limitation has been identified, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices. In table 1, for example, FDA is listing the proposed exemption of the genetic health risk assessment system, but limits the exemption to such devices that have received a first-time FDA marketing authorization (*e.g.,* 510(k) clearance) for the genetic health risk assessment system (a ''one-time FDA reviewed genetic health risk assessment system''). FDA believes that a one-time FDA review (*e.g.,* premarket notification) of a genetic health risk assessment system is necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA believes that a one-time FDA review of a genetic health risk assessment system is necessary to mitigate the risk of false negatives and false positives by ensuring that certain information be submitted to FDA to allow the Agency to assess the safety and effectiveness of the devices and the regulatory controls necessary to address those issues as well as to ensure the devices perform to acceptable standards.

IV. List of Class II Devices

FDA is identifying the following list of class II devices that, if finalized, would no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in §§ 862.9 to 892.9:

TABLE 1—CLASS II DEVICES

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
862.1840	Total 25-hydroxyvitamin D Mass Spectrometry Test System.	PSL	

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
866.5950	Genetic Health Risk Assessment System	PTA	Exemption is limited to a genetic health risk assessment system that has received a first-time FDA marketing authorization (e.g., 510(k) clearance) for the genetic health risk assessment system (a ''one-time FDA reviewed genetic health risk assessment system'').
876.1500	Endoscopic Maintenance System	PUP	
880.6710	Purifier, Water, Ultraviolet, Medical	KMG	
884.5960	Vibrator for Therapeutic Use, Genital	KXQ	

V. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*

Dated: October 31, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24163 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0618; FDA–2013–N–1155; FDA–2010–N–0118; FDA–2011–N–0655; FDA–2014–N–0086; FDA–2011–N–0144; FDA–2016–N–2836]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025	7/31/2020
Food Labeling Regulations	0910–0381	7/31/2020
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–0520	7/31/2020
Animal Generic Drug User Fee Act Cover Sheet	0910–0632	7/31/2020
Potential Tobacco Product Violations Reporting Form	0910–0716	7/31/2020
Voluntary Qualified Importer Program Guidance for Industry	0910–0840	7/31/2020
Donor Risk Assessment Questionnaire for the FDA/National Heart, Lung, and Blood Institute—Sponsored Transfusion-Transmissible Infectious Monitoring System	0910–0841	7/31/2020

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24189 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

the performance of the device. The study must be conducted using samples collected from apparently healthy male and female adults at least 21 years of age and older from at least 3 distinct climatic regions within the United States in different weather seasons. The ethnic, racial, and gender background of this study population must be representative of the U.S. population demographics.

(4) The results of the device as provided in the 21 CFR 809.10(b) compliant labeling and any test report generated must be reported as only total 25-hydroxyvitamin D.

Dated: October 31, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24161 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2017–N–4341]

Medical Devices; Immunology and Microbiology Devices; Classification of the Genetic Health Risk Assessment System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the genetic health risk assessment system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the genetic health risk assessment system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective November 7, 2017. The classification was applicable on April 6, 2017.

FOR FURTHER INFORMATION CONTACT: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–5866, *steven.tjoe@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the genetic health risk assessment system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1))). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the FD&C Act.

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 28, 2016, 23andMe, Inc. submitted a request for De Novo classification of the 23andMe Personal Genome Service (PGS) Test. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 6, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 866.5950. We have named the generic type of device genetic health risk assessment system, and it is identified as a qualitative in vitro molecular diagnostic system used for detecting variants in genomic deoxyribonucleic acid (DNA) isolated from human specimens that will provide information to users about their genetic risk of developing a disease to inform lifestyle choices and/or conversations with a health care professional. This assessment system is for over-the-counter use. This device does not determine the person's overall risk of developing a disease.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—GENETIC HEALTH RISK ASSESSMENT SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Incorrect understanding of the device and test system	General controls, Special control (1) (21 CFR 866.5950(b)(1)), Special control (3) (21 CFR 866.5950(b)(3)), and Special control (4) (21 CFR 866.5950 (b)(4)).
Incorrect test results (false positives, false negatives)	General controls, Special control (2) (21 CFR 866.5950(b)(2)), and Special control (3) (21 CFR 866.5950(b)(3)).
Incorrect interpretation of test results	General controls, Special control (1) (21 CFR 866.5950(b)(1)), Special control (3) (21 CFR 866.5950(b)(3)), and Special control (4) (21 CFR 866.5950(b)(4)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine by order that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. We believe this may be such a device. The notice of intent to exempt the device from premarket notification requirements is published elsewhere in this issue of the **Federal Register**.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR parts 801 and 809, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 866.5950 to subpart F to read as follows:

§ 866.5950 Genetic health risk assessment system.

(a) *Identification.* A genetic health risk assessment system is a qualitative in vitro molecular diagnostic system used for detecting variants in genomic deoxyribonucleic acid (DNA) isolated from human specimens that will provide information to users about their genetic risk of developing a disease to inform lifestyle choices and/or conversations with a health care professional. This assessment system is for over-the-counter use. This device does not determine the person's overall risk of developing a disease.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The 21 CFR 809.10 compliant labeling and any prepurchase page and test report generated, unless otherwise specified, must include:

(i) A section addressed to users with the following information:

(A) The limiting statement explaining that this test provides genetic risk information based on assessment of specific genetic variants but does not report on a user's entire genetic profile. This test [does not/may not, as appropriate] detect all genetic variants related to a given disease, and the absence of a variant tested does not rule out the presence of other genetic variants that may be related to the disease.

(B) The limiting statement explaining that other companies offering a genetic risk test may be detecting different genetic variants for the same disease, so the user may get different results using a test from a different company.

(C) The limiting statement explaining that other factors such as environmental and lifestyle risk factors may affect the risk of developing a given disease.

(D) The limiting statement explaining that some people may feel anxious about getting genetic test health results. This is normal. If the potential user feels very anxious, such user should speak to his or her doctor or other health care professional prior to collection of a sample for testing. This test is not a substitute for visits to a doctor or other health care professional. Users should consult with their doctor or other health

care professional if they have any questions or concerns about the results of their test or their current state of health.

(E) Information about how to obtain access to a genetic counselor, board-certified clinical molecular geneticist, or equivalent health care professional about the results of a user's test.

(F) The limiting statement explaining that this test is not intended to diagnose a disease, tell you anything about your current state of health, or be used to make medical decisions, including whether or not you should take a medication or how much of a medication you should take.

(G) A limiting statement explaining that the laboratory may not be able to process a sample, and a description of the next steps to be taken by the manufacturer and/or the customer, as applicable.

(ii) A section in your 21 CFR 809.10 labeling and any test report generated that is for health care professionals who may receive the test results from their patients with the following information:

(A) The limiting statement explaining that this test is not intended to diagnose a disease, determine medical treatment, or tell the user anything about their current state of health.

(B) The limiting statement explaining that this test is intended to provide users with their genetic information to inform lifestyle decisions and conversations with their doctor or other health care professional.

(C) The limiting statement explaining that any diagnostic or treatment decisions should be based on testing and/or other information that you determine to be appropriate for your patient.

(2) The genetic test must use a sample collection device that is FDA-cleared, -approved, or -classified as 510(k) exempt, with an indication for in vitro diagnostic use in over-the-counter DNA testing.

(3) The device's labeling must include a hyperlink to the manufacturer's public Web site where the manufacturer shall make the information identified in paragraph (b)(3) of this section publicly available. The manufacturer's home page, as well as the primary part of the manufacturer's Web site that discusses the device, must provide a hyperlink to the Web page containing this information and must allow unrestricted viewing access. If the device can be purchased from the Web site or testing using the device can be ordered from the Web site, the same information must be found on the Web page for ordering the device or provided in a publicly accessible hyperlink on the Web page for ordering the device. Any changes to the device that could significantly affect safety or effectiveness would require new data or information in support of such changes, which would also have to be posted on the manufacturer's Web site. The information must include:

(i) An index of the material being provided to meet the requirements in paragraph (b)(3) of this section and its location.

(ii) A section that highlights summary information that allows the user to understand how the test works and how to interpret the results of the test. This section must, at a minimum, be written in plain language understandable to a lay user and include:

(A) Consistent explanations of the risk of disease associated with all variants included in the test. If there are different categories of risk, the manufacturer must provide literature references that support the different risk categories. If there will be multiple test reports and multiple variants, the risk categories must be defined similarly among them. For example, ''increased risk'' must be defined similarly between different test reports and different variant combinations.

(B) Clear context for the user to understand the context in which the cited clinical performance data support the risk reported. This includes, but is not limited to, any risks that are influenced by ethnicity, age, gender, environment, and lifestyle choices.

(C) Materials that explain the main concepts and terminology used in the test that include:

(*1*) *Definitions:* Scientific terms that are used in the test reports.

(*2*) *Prepurchase page:* This page must contain information that informs the user about what information the test will provide. This includes, but is not limited to, variant information, the condition or disease associated with the variant(s), professional guideline recommendations for general genetic risk testing, the limitations associated with the test (*e.g.,* test does not detect all variants related to the disease) and any precautionary information about the test the user should be aware of before purchase. When the test reports the risk of a life-threatening or irreversibly debilitating disease or condition for which there are few or no options to prevent, treat, or cure the disease, a user opt-in section must be provided. This opt-in page must be provided for each disease that falls into this category and must provide specific information relevant to each test result. The opt-in page must include:

(*i*) An option to accept or decline to receive this specific test result;

(*ii*) Specification of the risk involved if the user is found to have the specific genetic test result;

(*iii*) Professional guidelines that recommend when genetic testing for the associated target condition is or is not recommended; and

(*iv*) A recommendation to speak with a health care professional, genetic counselor, or equivalent professional before getting the results of the test.

(*3*) *Frequently asked questions (FAQ) page:* This page must provide information that is specific for each variant/disease pair that is reported. Information provided in this section must be scientifically valid and supported by corresponding publications. The FAQ page must explain the health condition/disease being tested, the purpose of the test, the information the test will and will not provide, the relevance of race and ethnicity to the test results, information about the population to which the variants in the test is most applicable, the meaning of the result(s), other risk factors that contribute to disease, appropriate followup procedures, how the results of the test may affect the user's family, including children, and links to resources that provide additional information.

(iii) A technical information section containing the following information:

(A) Gene(s) and variant(s) the test detects using standardized nomenclature, Human Genome Organization nomenclature and coordinates as well as Single Nucleotide Polymorphism Database (dbSNP) reference SNP numbers (rs#).

(B) Scientifically established disease-risk association of each variant detected and reported by the test. This risk association information must include:

(*1*) Genotype-phenotype information for the reported variants.

(*2*) Table of expected frequency and risks of developing the disease in relevant ethnic populations and the general population.

(*3*) A statement about the current professional guidelines for testing these specific gene(s) and variant(s).

(*i*) If professional guidelines are available, provide the recommendations in the professional guideline for the gene, variant, and disease, for when genetic testing should or should not be performed, and cautionary information that should be communicated when a particular gene and variant is detected.

(*ii*) If professional guidelines are not available, provide a statement that the professional guidelines are not available for these specific gene(s) and variant(s).

(C) The specimen type (*e.g.,* saliva, capillary whole blood).

(D) Assay steps and technology used.

(E) Specification of required ancillary reagents, instrumentation, and equipment.

(F) Specification of the specimen collection, processing, storage, and preparation methods.

(G) Specification of risk mitigation elements and description of all additional procedures, methods, and practices incorporated into the directions for use that mitigate risks associated with testing.

(H) Information pertaining to the probability of test failure (*i.e.,* percentage of tests that failed quality control) based on data from clinical samples, a description of scenarios in which a test can fail (*i.e.,* low sample volume, low DNA concentration, etc.), how users will be notified of a test failure, and the nature of followup actions on a failed test to be taken by the user and the manufacturer.

(I) Specification of the criteria for test result interpretation and reporting.

(J) Information that demonstrates the performance characteristics of the test, including:

(*1*) Accuracy of study results for each claimed specimen type.

(*i*) Accuracy of the test shall be evaluated with fresh clinical specimens collected and processed in a manner consistent with the test's instructions for use. If this is impractical, fresh clinical samples may be substituted or supplemented with archived clinical samples. Archived samples shall have been collected previously in accordance with the instructions for use, stored appropriately, and randomly selected. In some limited circumstances, use of contrived samples or human cell line samples may also be appropriate and used as an acceptable alternative. The contrived or human cell line samples shall mimic clinical specimens as much as is feasible and provide an unbiased evaluation of the device accuracy.

(*ii*) Accuracy must be evaluated by comparison to bidirectional Sanger sequencing or other methods identified as appropriate by FDA. Performance criteria for both the comparator method and the device must be predefined and appropriate to the device's intended use. Detailed study protocols must be provided.

(*iii*) Test specimens must include all genotypes that will be included in the tests and reports. The number of samples tested in the accuracy study for each variant reported must be based on the variant frequency using either the minimum numbers of samples identified in this paragraph or, when determined appropriate and identified by FDA, a minimum number of samples determined using an alternative method. When appropriate, the same samples may be used in testing to demonstrate the accuracy of testing for multiple genotypes by generating sequence information at multiple relevant genetic locations. At least 20 unique samples representing the wild-type genotype must be tested. To test samples that are heterozygous for the reported variant(s), common variants (>0.1 percent variant frequency in the relevant population) must be tested with at least 20 unique samples. Rare variants (≤0.1 percent variant frequency in the relevant population) must be tested with at least three unique samples. To test samples that are homozygous for the reported variant(s), variants with ≥2 percent variant frequency in a relevant population must be tested with at least 20 unique samples. Variants with a frequency in the relevant population <2 percent and ≥0.5 percent must be tested with at least 10 unique samples. Variants with a frequency in the relevant population <0.5 percent must be tested with at least three unique samples. If variants with a frequency of <0.5 percent are not found within the relevant population and homozygous samples are not tested, then the test results for this homozygous rare variant must not be reported to the user.

(*iv*) Information about the accuracy study shall include the number and type of samples that were compared to bidirectional Sanger sequencing or other methods identified as appropriate by FDA. This information must either be reported in tabular format and arranged by clinically relevant variants or reported using another method identified as appropriate by FDA. As an example, for samples with different genotypes DD, Dd, and dd, the following table represents data from the accuracy study presented in tabular format:

		Comparator		
		DD	Dd	dd
Device	DD	A_1	B_1	C_1
	Dd	A_2	B_2	C_2
	Dd	A_3	B_3	C_3
	no calls or *invalid*	A_4	B_4	C_4
Total		N_{DD}	N_{Dd}	N_{dd}

where:

D and d = Variants; d = Risk variant;

A_1, A_2, A_3, A_4 are numbers of samples with DD result by the comparator and DD, Dd, dd, or 'no calls' or 'invalid' results by the device correspondingly and N_{DD} is the total number of samples with DD result by the comparator ($N_{DD}=A_1+A_2+A_3+A_4$);

B_1, B_2, B_3, B_4 are numbers of samples with Dd result by the comparator and DD, Dd, dd, or 'no calls' or 'invalid' results by the device correspondingly and N_{Dd} is the total number of samples with Dd result by the comparator ($N_{Dd}=B_1+B_2+B_3+B_4$);

C_1, C_2, C_3, C_4 are numbers of samples with dd result by the comparator and DD, Dd, dd, or 'no calls' or 'invalid' results by the device correspondingly and N_{dd} is the total number of samples with dd result by the comparator ($N_{dd}=C_1+C_2+C_3+C_4$);

(*v*) The accuracy represents the degrees of agreement between the device results and the comparator results. The accuracy must be evaluated by measuring different percent agreements (PA) of device results with the comparator results and percent of 'no calls' or 'invalid calls.' Calculate the rate of 'no calls' and 'invalid calls' for each comparator output as %Inv(DD) = A_4/N_{DD}, %Inv(Dd) = B_4/N_{Dd}, %Inv(dd) = C_4/N_{dd}. If 'no calls' or 'invalid calls' are required to be retested according to the device instructions for use, the percent of final 'no calls' or 'invalid calls' must be provided. In the table presenting the results of the accuracy study, use only the final results (*i.e.,* after retesting the initial 'no calls' or 'invalid calls', if required according to the instructions for use). Samples that resulted in a 'no call' or 'invalid call' after retesting must not be included in the final calculations of agreement. If the percentages of 'no calls' or 'invalid calls' for each comparator output are similar, combine these estimates as $(A_4 + B_4 + C_4)/(N_{DD} + N_{Dd} + N_{dd})$ and provide a 95 percent two-sided confidence interval. The percent of final 'no calls' or 'invalid calls' must be clinically acceptable.

(*vi*) Point estimates of percent agreement for each genotype must be calculated as the number of correct calls for that genotype divided by the number of samples known to contain that genotype excluding 'no calls' or 'invalid calls'. The calculations must be performed as follows:

$PA(DD|DD)=A_1/(A_1+A_2+A_3)$;

$PA(Dd|DD)=A_2/(A_1+A_2+A_3)$; and $PA(dd|DD)=1- PA(DD|DD)- PA(Dd|DD)$.

$PA(Dd|Dd)=B_2/(B_1+B_2+B_3)$;

$PA(DD|Dd)=B_1/(B_1+B_2+B_3)$; and $PA(dd|Dd)=1-PA(DD|Dd)-PA(Dd|Dd)$.

$PA(dd|dd)=C_3/(C_1+C_2+C_3)$;

$PA(Dd|dd)=C_2/(C_1+C_2+C_3)$ and $PA(DD|dd)=1-P(Dd|dd)-PA(dd|dd)$.

(*vii*) For percent agreements for DD, Dd and dd (PA(DD|DD), PA(Dd|Dd) and PA(dd|dd)) as described in paragraph (b)(3)(iii)(J)(*1*)(*vi*) of this section, the 95 percent two-sided confidence intervals must be provided. The accuracy point estimates for percent agreements for DD, Dd and dd must be ≥99 percent per reported variant and overall. Any variants that have a point estimate for either PA(DD|DD), PA(Dd|Dd), or PA(dd|dd) of <99 percent compared to bidirectional sequencing or other methods identified as appropriate by FDA must not be incorporated into test claims and reports. Accuracy results generated from clinical specimens versus contrived samples or cell lines must be presented separately. Results must be summarized and presented in tabular format by sample type and by genotype or must be reported using another method identified as appropriate by FDA (see paragraph (b)(3)(iii)(J)(*1*)(*iv*) of this section).

(*viii*) Information must be reported on the Technical Positive Predictive Value (TPPV) related to the analytical (technical) performance of the device for genotypes in each relevant subpopulation (*e.g.,* ethnicity, gender, age, geographical location, etc.). TPPV is the percentage of individuals with the genotype truly present among individuals whose test reports indicate that this genotype is present. The TPPV depends on the accuracy measures of percent agreements and on the frequency of the genotypes in the subpopulation being studied. The f(DD) is the frequency of DD and f(Dd) is the frequency of Dd in the subpopulation being studied; TPPV must be calculated as described in paragraphs (b)(3)(iii)(J)(*1*)(*ix*) through (*xi*) of this section.

(*ix*) For variants where the point estimates of PA(DD|DD), PA(Dd|Dd) and PA(dd|dd) are less than 100 percent, use these point estimates in TPPV calculations.

(*x*) Point estimates of 100 percent in the accuracy study may have high uncertainty about performance of the test in the population. If these variants are measured using highly multiplexed technology, calculate the random error rate for the overall device. The accuracy study described in paragraph (b)(3)(iii)(J) of this section in those cases is more to determine that there is no systematic error in such devices. In those cases, incorporate that rate in the estimation of the percent agreements as calculated in paragraph (b)(3)(iii)(J)(*1*)(*vi*) of this section and include it in TPPV calculations.

(*xi*) The TPPV for subpopulations with genotype frequencies of f(dd), f(Dd) and f(DD) = 1 − f(dd) − f(Dd) in the subpopulation is calculated as:

The TPPV for subpopulations with genotype frequencies of f(dd), f(Dd) and f(DD)=1-f(dd)-f(Dd) in the subpopulation is calculated as:

TPPV for a device result of dd = [PA(dd|dd)•f(dd)]/[PA(dd|dd)•f(dd)+PA(dd|Dd)•f(Dd)+PA(dd|DD)•f(DD)]

TPPV for a device result of Dd =[PA(Dd|Dd)•f(Dd)]/[PA(Dd|DD)•f(DD)+PA(Dd|Dd)•f(Dd)+PA(Dd|dd)•f(dd)]

(*2*) Precision and reproducibility data must be provided using multiple instruments and multiple operators, on multiple non-consecutive days, and using multiple reagent lots. The sample panel must either include specimens from the claimed sample type (*e.g.,* saliva) representing all genotypes for each variant (*e.g.,* wild type, heterozygous, and homozygous) or, if an alternative panel composition of specimens is identified by FDA as appropriate, a panel composed of those specimens FDA identified as appropriate. A detailed study protocol must be created in advance of the study and must include predetermined acceptance criteria for performance results. The percentage of samples that failed quality control must be indicated (*i.e.,* the total number of sample replicates for which a sequence variant cannot be called (no calls) or that fail sequencing quality control criteria divided by the total number of replicates tested). It must be clearly documented whether results were generated from clinical specimens, contrived samples, or cell lines. The study results shall report the variants tested in the study and the number of replicates for each variant, and what conditions were tested (*i.e.,* number of runs, days, instruments, reagent lots, operators, specimens/type, etc.). Results must be evaluated and presented in tabular format and stratified by study parameter (*e.g.,* by site, instrument(s), reagent lot, operator, and sample variant). The study must include all extraction steps from the claimed specimen type or matrix, unless a separate extraction reproducibility study for the claimed sample type is performed. If the device is to be used at more than one laboratory, different laboratories must be included in the reproducibility study and reproducibility across sites must be evaluated. Any no calls or invalid calls in the study must be listed as a part of the precision and reproducibility study results.

(*3*) *Analytical specificity data:* Data must be provided that evaluates the effect of potential endogenous and exogenous interferents on test performance, including specimen extraction and variant detection. Interferents tested must include those reasonably likely to be potentially relevant to the sample type used for the device.

(*4*) *Interfering variant data:* Nucleotide mutations that can interfere with the technology must be cited and evaluated. Data must be provided to demonstrate the effect of the interfering variant(s) on the performance of the correct calls. Alternatively, for each suspected interfering mutation for which data is not provided demonstrating the effect of the interfering variant, the manufacturer must identify the suspected interfering

variants in the labeling and indicate that the impact that the interfering variants may have on the assay's performance has not been studied by providing a statement that reads ''It is possible that the presence of [insert clearly identifying information for the suspected interfering variant] in a sample may interfere with the performance of this test. However, its effect on the performance of this test has not been studied.''

(*5*) *Analytical sensitivity data:* Data must be provided demonstrating the minimum amount of DNA that will enable the test to perform correctly in 95 percent of runs.

(*6*) *Reagent stability:* The manufacturer must evaluate reagent stability using wild-type, heterozygous, and homozygous samples. Reagent stability data must demonstrate that the reagents maintain the claimed accuracy and reproducibility. Data supporting such claims must be provided.

(*7*) *Specimen type and matrix comparison data:* Specimen type and matrix comparison data must be generated if more than one specimen type can be tested with this device, including failure rates for the different specimens.

(K) Clinical performance summary.

(*1*) Information to support the clinical performance of each variant reported by the test must be provided.

(*2*) Manufacturers must organize information by the specific variant combination as appropriate (*e.g.,* wild type, heterozygous, homozygous, compound heterozygous, hemizygous genotypes). For each variant combination, information must be provided in the clinical performance section to support clinical performance for the risk category (*e.g.,* not at risk, increased risk). For each variant combination, a summary of key results must be provided in tabular format or using another method identified as appropriate by FDA to include the appropriate information regarding variant type, data source, definition of the target condition (*e.g.,* disease), clinical criteria for determining whether the target disease is present or absent, description of subjects with the target disease present and target disease absent (exclusion or inclusion criteria), and technical method for genotyping. When available, information on the effect of the variant on risk must be provided as the risk of a disease (lifetime risk or lifetime incidences) for an individual compared with the general population risk.

(*i*) If odds ratios are available, using information about the genotype distribution either among individuals with the target disease absent, or in the general population, or information about the risk variant frequency and odds ratios, the likelihood ratios for the corresponding device results along with 95 percent confidence intervals must be calculated. Using information about pretest risk (π), an estimate of likelihood ratio (LR), and a relationship between post-test risk R as $R/(1-R) = LR \cdot \pi/(1-\pi)$, the post-test risk R must be calculated.

(*ii*) When available, likelihood ratios (LR) for different test results must be presented in a tabular format along with references to the source data or using another method identified as appropriate by FDA as stated in paragraph (b)(3)(iii)(K)(2) of this section. When these values are not directly available in published literature, likelihood ratios can be separately calculated along with the 95 percent confidence interval with references to the source data. Note that a minimum requirement for the presence of the variant's effect on the risk is that a corresponding LR is statistically higher than 1 (a lower bound of 95 percent two-sided confidence interval is larger than 1). It means that the post-test risk is statistically higher than the pretest risk (an observed value of the difference between the post-test and pretest risks).

(L) Materials that explain the main concepts and terminology used in the test that includes, but is not limited to:

(*1*) *Definitions:* Scientific terms that are used in the test reports.

(*2*) *Prepurchase page:* This page must contain information that informs the user about what the test will provide. This includes, but is not limited to, variant information, the condition or disease associated with the variant(s), professional guideline recommendations for general genetic risk testing, the limitations associated with the test (*e.g.,* test does not detect all variants related to the disease) and any precautionary information about the test the user should be aware of before purchase. When the test reports the risk of a life-threatening or irreversibly debilitating disease or condition for which there are few or no options to prevent, treat, or cure the disease, a user opt-in section must be provided. This opt-in page must be provided for each disease that falls into this category and must provide specific information relevant to each test result. The opt-in page must include:

(*i*) An option to accept or decline to receive this specific test result;

(*ii*) Specification of the risk involved if the user is found to have the specific genetic test result;

(*iii*) Professional guidelines that recommend when genetic testing for the associated target condition is or is not recommended; and

(*iv*) A recommendation to speak with a health care professional, genetic counselor, or equivalent professional before getting the results of the test.

(*3*) Frequently asked questions (FAQ) page: This page must provide information that is specific for each variant/disease pair that is reported. Information provided in this section must be scientifically valid and supported by corresponding publications. The FAQ page must explain the health condition/disease being tested, the purpose of the test, the information the test will and will not provide, the relevance of race and ethnicity on the test results, information about the population to which the variants in the test is most applicable, the meaning of the result(s), other risks factors that contribute to disease, appropriate followup procedures, how the results of the test may affect the user's family, including children, and links to resources that provide additional information.

(M) User comprehension study: Information on a study that assesses comprehension of the test process and results by potential users of the test must be provided.

(*1*) The test manufacturer must provide a genetic risk education module to naïve user comprehension study participants prior to their participation in the user comprehension study. The module must define terms that are used in the test reports and explain the significance of genetic risk reports.

(*2*) The test manufacturer must perform pre- and post-test user comprehension studies. The comprehension test questions must include directly evaluating a representative sample of the material being presented to the user as described in paragraph (b)(3)(ii) of this section.

(*3*) The manufacturer must provide a justification from a physician and/or genetic counselor that identifies the appropriate general and variant-specific concepts contained within the material being tested in the user comprehension study to ensure that all relevant concepts are incorporated in the study.

(*4*) The user study must meet the following criteria:

(*i*) The study participants must comprise a statistically sufficient sample size and demographically diverse population (determined using methods such as quota-based sampling) that is representative of the intended user population. Furthermore, the study participants must comprise a diverse

range of age and educational levels and have no prior experience with the test or its manufacturer. These factors shall be well defined in the inclusion and exclusion criteria.

(*ii*) All sources of bias must be predefined and accounted for in the study results with regard to both responders and non-responders.

(*iii*) The testing must follow a format where users have limited time to complete the studies (such as an onsite survey format and a one-time visit with a cap on the maximum amount of time that a participant has to complete the tests).

(*iv*) Users must be randomly assigned to study arms. Test reports in the user comprehension study given to users must define the target condition being tested and related symptoms, explain the intended use and limitations of the test, explain the relevant ethnicities in regard to the variant tested, explain genetic health risks and relevance to the user's ethnicity, and assess participants' ability to understand the following comprehension concepts: The test's limitations, purpose, appropriate action, test results, and other factors that may have an impact on the test results.

(*v*) Study participants must be untrained, be naïve to the test subject of the study, and be provided the labeling prior to the start of the user comprehension study.

(*vi*) The user comprehension study must meet the predefined primary endpoint criteria, including a minimum of a 90 percent or greater overall comprehension rate (*i.e.,* selection of the correct answer) for each comprehension concept. Other acceptance criteria may be acceptable depending on the concept being tested. Meeting or exceeding this overall comprehension rate demonstrates that the materials presented to the user are adequate for over-the-counter use.

(*vii*) The analysis of the user comprehension results must include results regarding reports that are provided for each gene/variant/ethnicity tested, statistical methods used to analyze all data sets, and completion rate, non-responder rate, and reasons for nonresponse/data exclusion. A summary table of comprehension rates regarding comprehension concepts (*e.g.,* purpose of test, test results, test limitations, ethnicity relevance for the test results, etc.) for each study report must be included.

(4) The intended use of the device must not include the following indications for use:

(i) Prenatal testing;

(ii) Determining predisposition for cancer where the result of the test may lead to prophylactic screening, confirmatory procedures, or treatments that may incur morbidity or mortality to the patient;

(iii) Assessing the presence of genetic variants that impact the metabolism, exposure, response, risk of adverse events, dosing, or mechanisms of prescription or over-the-counter medications; or

(iv) Assessing the presence of deterministic autosomal dominant variants.

Dated: November 1, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24159 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2015–N–3455]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Autosomal Recessive Carrier Screening Gene Mutation Detection System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing an order to exempt autosomal recessive carrier screening gene mutation detection systems from the premarket notification requirements, subject to certain limitations. This exemption from 510(k), subject to certain limitations, is immediately in effect for autosomal recessive carrier screening gene mutation detection systems. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. FDA is also amending the codified language for the autosomal recessive carrier screening gene mutation detection system devices classification regulation to reflect this final determination.

DATES: This order is effective November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–5866.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a device to submit and obtain FDA clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

On December 13, 2016, the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was signed into law. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(2) provides that, 1 calendar day after the date of publication of the final list under paragraph (1)(B), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon its own initiative or a petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 60-calendar-day comment period. Within 120 days of publication of such notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (referred to herein as the Class II 510(k) Exemption Guidance) (Ref. 1).

III. Device Description

On February 19, 2015, FDA completed its review of a De Novo request for classification of the 23andMe

EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR MSK-IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets)

DECISION SUMMARY

A. DEN Number:

DEN170058

B. Purpose for Submission:

De novo request for evaluation of automatic class III designation for the MSK-IMPACT

C. Measurand:

Somatic single nucleotide variants, insertions, deletions, and microsatellite instability in genes in human genomic DNA obtained from formalin-fixed, paraffin-embedded tumor tissue.

Refer to Appendix 1a for complete list of hotspot mutations and Appendix 1b for complete list of genes included in this assay.

D. Type of Test:

Next generation sequencing tumor profiling test

E. Applicant:

Memorial Sloan Kettering (MSK)

F. Proprietary and Established Names:

MSK-IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets)

G. Regulatory Information:

1. **Regulation section:**

   21 CFR 866.6080

2. **Classification:**

   Class II

3. **Product code:**

   PZM

4. **Panel:**

   Pathology

H. Indications for Use:

1. **Indications for Use:**
   The MSK-IMPACT assay is a qualitative in vitro diagnostic test that uses targeted next generation sequencing of formalin-fixed paraffin-embedded tumor tissue matched with normal specimens from patients with solid malignant neoplasms to detect tumor gene alterations in a broad multi gene panel. The test is intended to provide information on somatic mutations (point mutations and small insertions and deletions) and microsatellite instability for use by qualified health care professionals in accordance with professional guidelines, and is not conclusive or prescriptive for labeled use of any specific therapeutic product. MSK-IMPACT is a single-site assay performed at Memorial Sloan Kettering Cancer Center.

2. **Special conditions for use statement(s):**

   For prescription use.

   For in vitro diagnostic use.

3. **Special instrument requirements:**

   Illumina HiSeq™ 2500 Sequencer (qualified by MSK)

I. Device Description:

A description of required equipment, software, reagents, vendors, and storage conditions were provided, and are described in the product labeling (MSK-IMPACT manual). MSK assumes responsibility for the device.

1. **Sample Preparation**:
   The tumor volume and minimum tumor content needed to obtain sufficient DNA for testing to achieve the necessary quality performance are shown in the Table 1 below:

Table 1. Specimen Handling and Processing for Validated Specimen Types

Tissue Type	Volume	Minimum Tumor Proportion	Macrodissection requirements (Based on tumor proportion)	Limitations	Storage
FFPE sections	5-20 unstained sections, 10 microns thick	More than 10% of tumor cells; sections containing >20% viable tumor are preferred. For MSI testing, >25% tumor cells.	Yes, macrodissection to obtain non-neoplastic tissue for analysis	Archival paraffin-embedded material subjected to acid decalcification is unsuitable for analysis because acid decalcification severely damage nucleic acids.	Room temp

Genomic DNA is extracted from tissue specimens per protocol. DNA is quantified and concentrated if necessary. The amount of DNA required to perform the test is 100-250ng. DNA is run in singlicate. DNA shearing is conducted per protocol and a quality control check is performed. Average fragment size should be ~200bp. Sheared DNA is stored at -20°C if not proceeding directly to Library Preparation. The DNA can be stored at 37°C for 10-20 minutes, stored at 2–8°C for 24 hours, or at –20°C for longer periods.

2. **Library Preparation:**
Sequence libraries are prepared using KAPA Biosystems Library Preparation Reagents by first producing blunt-ended, 5'-phosphorylated fragments. To the 3' ends of the dsDNA library fragments, dAMP is added (A-tailing). Next, dsDNA adapters with 3'dTMP is ligated to the A-tailed library fragments. Library fragments with appropriate adapter sequences are amplified via ligation-mediated pre-capture PCR. A quality control check on the amplified DNA libraries is performed: Samples should be a smear; average fragment size with the peak at ~200bp; and concentration between 5-300ng/μL to ensure adequate hybridization for capture.

3. **Hybrid Capture NGS:**
Library capture is conducted using NimbleGen Capture reagents. Pooled sequencing libraries are hybridized to the vendor oligo pool. Capture beads are used to pull down the complex of capture oligos and genomic DNA fragments. Unbound fragments are washed away. The enriched fragment pool is amplified by ligation mediated-PCR. The success of the enrichment is measured as a quality control step: Samples should be a smear, average fragment size with the peak at ~300bp; the concentration of the amplified DNA library should be 5-45ng/μL; the LM-PCR yield should be ≥ 250ng. Reactions can be stored at 4°C until ready for purification, up to 72 hours.

4. **Sequencing and Data Analysis:**
Sequencing is conducted with the Illumina HiSeq2500 Sequencing Instruments and reagents and PhiX Control v3. The sequencing process uses multiple quality checks.

   a) **Data Management System (DMS):** Automated sample tracking and archival of run-associated metadata (barcode, run name, samples accession number, patient medical record number, source (class), specimen type, and panel version) is conducted with the following key functions: Tracking sample status through various stages of data analysis; tracking iterations of analysis applied to a given sample; recording versions of databases and algorithms used in analysis; archival of selected pipeline output files (FASTQ, BAM, VCF) and sequencing run statistics (e.g., cluster density, %clusters passing filter, unassigned read indices).

   b) **Demultiplexing and FASTQ generation:** The analysis pipeline uses software provided by Illumina. Two FASTQ files are generated per samples corresponding to full length forward and reverse reads. Demultiplexing quality control includes quality metrics for per-base sequence quality, sequence content, GC content and sequence length distribution, relative percentages of unmatched indices.

c) Indexing QC check: The potential for index contamination is managed by demultiplexing all sequencing reads for all possible barcodes. If the number of reads > 15,000 for any unused barcodes, then those reads are analyzed with the pipeline and the fingerprint SNPs are used to identify which of the barcodes used in the pool could be causing the appearance of extra reads.

d) Read alignment and BAM generation: Spurious adapter sequences are trimmed prior to read alignment. Reads are aligned in paired-end mode to the hg19 b37 version of the human genome. Aligned reads are written to a Sequence Alignment Map (SAM) file, which is then converted into Binary Alignment Map (BAM) format. PCR duplicates are removed. Each base within a read is assigned a base quality score by the sequencing software, which reflects the probability an error was made with the base call. To account for systemic biases that may not accurately reflect the actual error probabilities observed empirically, the analysis pipeline uses another tool to adjust the reported quality scores based on the selected covariates. Reassigned quality scores are subject to a threshold of 20, corresponding to a 1/100 chance of error.

e) Sample QC checks: The baits used for hybridization capture include custom intergenic and intronic probes targeting >1000 regions throughout the genome containing common single nucleotide polymorphisms (SNPs). The unique combination of SNPs specific to a given sample serves as a 'fingerprint' for the identity of the corresponding patient, and serves to identify potential sample mix-ups and contamination between samples and barcodes. QC checks involving the use of these 'fingerprint' SNPs are detailed below:

i. *Sample mix-up check:* The analysis pipeline computes the 'percent discordance' between a reference and query sample, defined as the percent of homozygous sites in the reference sample that are homozygous for the alternate allele in the query sample. The expected discordance between tumors and their respective matched normal should be low (<5%). Conversely, the expected discordance between samples from different patients should be high (~ 25%). Pairs of samples from the same patient with > 5% discordance ("unexpected mismatches") and from different patients with <5% discordance ("unexpected matches") are flagged.

ii. *Sample contamination checks*: Alternate alleles (percent heterozygous) at homozygous SNP sites (fingerprint SNPs) are assessed. A sample is flagged for review if the average minor allele frequency at these SNPs exceeds 2%.

iii. *Check for presence of tumor in normal:* Normal samples are expected to be free of known SNVs and insertions and deletions (indels) that are commonly (somatically) recurrent in tumor samples. As a first pass check, the pipeline genotypes normal samples at several known 'hotspot' locations derived from somatic mutation catalogs. If a known tumor-specific mutation (i.e. BRAF V600E) is detected with mutation frequency > 1% in a normal sample, the normal sample is flagged for review and possible exclusion from analysis. Tumor

samples with matched normal controls excluded due to possible tumor contamination will be considered as unmatched tumor samples for subsequent analyses.

f) Mutation calling – SNVs and Indels: The analysis pipeline identifies two classes of mutations: (1) single nucleotide variants (SNVs) and (2) indels. Paired sample mutation calling is performed on tumor samples and their respective matched normal controls. In instances where a matched normal sample is unavailable, or where the matched normal sample was sequenced with low coverage (< 50X), tumor samples will be considered as unmatched samples, and will be compared against a standard, in-batch pooled FFPE normal control for mutation calling. Filtering is performed to remove low quality sequence data, sources of sequencing artifacts, and germline results.

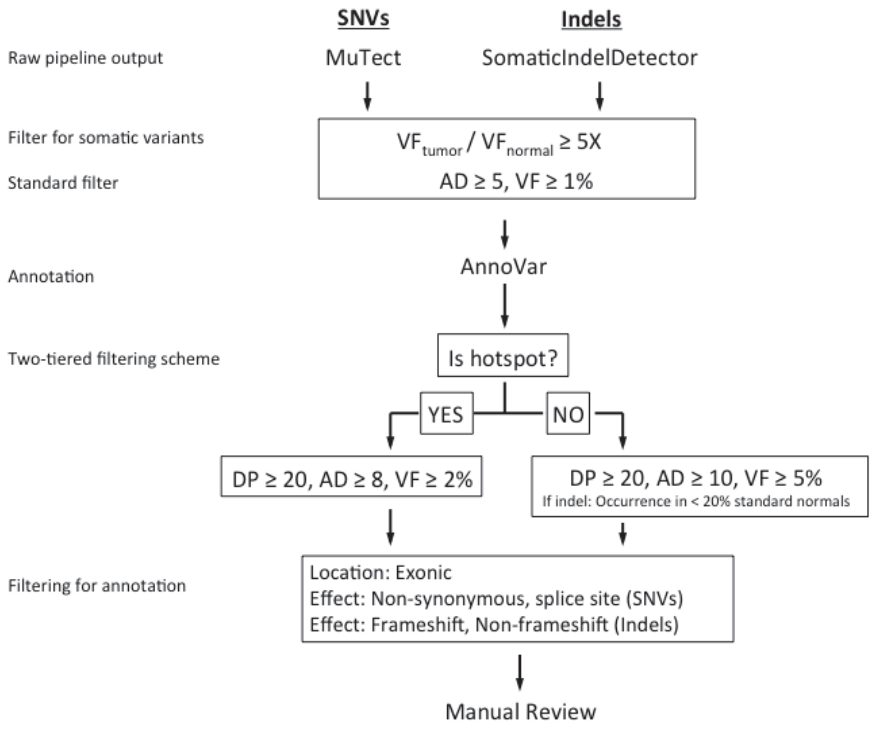
i. *Analysis of pooled FFPE positive and negative controls*: data from controls is used to confirm lack of contamination as well as analytical sensitivity.

ii. *Filters on sample coverage:* A sequence coverage ≥ 100X is required to achieve 95% power to detect mutations with underlying variant frequency of 10% or greater. To ensure that at least 98% of targeted exons meet this coverage, a per sample coverage requirement has been conservatively set at ≥ 200X. A lower coverage threshold for the matched normal is set at 50X.

iii. *Filtering for high confidence mutations:* Raw SNV and indel calls are subjected to a series of filtering steps to ensure only high-confidence calls are admitted to the final step of manual review. These parameters include (1) evidence of it being a somatic mutation (i.e., ratio between mutation frequencies in the tumor and normal samples to be ≥ 5.0); (2) whether the mutation is a known hotspot mutation (refer to Appendix 1a for details); (3) reference on in house ‘standard normal’ based on common artifacts; (4) technical characteristics that use coverage depth (DP), number of mutant reads (AD), mutation frequency (VF).

The filtering scheme and threshold are shown in Figure 1 below. The threshold values for the filtering criteria were established based on paired-sample mutation analysis on replicates of normal FFPE samples, and optimized to reject all false positive SNVs and almost all false positive indel calls from the reference dataset.

Figure 1. Summary of mutation filtering scheme



g) **Mutation annotation:** Predicted functional effect and clinical interpretation for each mutation is curated by automated software using information from several databases.

h) **Microsatellite Instability (MSI) status calling:** The somatic MSI status is inferred by interrogating all available genomic microsatellites covered by MSK-IMPACT within tumor samples against the matched normal DNA using the program MSIsensor (Nui B et al. 2014). Essentially, the sequencing results are analyzed via MSIsensor to assess the number and length of homo-polymers / microsatellites within the targeted regions of tumor-normal sample pair. This results in a continuous rather than categorical MSI score assignment for the tumor sample. Loci are considered unstable (somatic) if k-mer distributions are significantly different between the tumor and matched normal using a standard multiple testing correction of $\chi 2$ p-values. The percentage fraction of unstable sites is reported as the MSIsensor score. The assay uses a MSIsensor score threshold of 10 or greater to define MSI-H by MSIsensor.

5. Controls

a) **Matched normal control:** Genomic DNA is extracted from patient-matched normal tissue (when available) or peripheral blood, for use as a matched normal control. In the event a matched normal is unavailable, or where the matched normal sample was sequenced with low coverage (<50X), tumor samples will be compared against a standard, in-batch pooled FFPE normal control for mutation calling; mutations called under these circumstances may include rare germline mutations and cannot be guaranteed to be somatic.

b) Positive control: The positive control sample is a mixture of 3 tumor samples, each sample with a different confirmed SNV and at least one insertion or deletion, representing a range of mutation allele frequencies. Results are compared against a pooled FFPE negative control as an unmatched normal. Data generated from the mixed positive control sample are analyzed using the pipeline, and frequencies of the detected mutations are reviewed to determine if (1) the known mutations are among those called, and (2) the observed frequencies for the known mutations match their expected values within 5% of their values. The mixed FFPE positive control sample pools with expected variant frequency (VF) prior to pooling are shown in Table 2.

Table 2. Positive Controls and Expected Mutation Frequencies

Mixed Positive ID	Sample ID	VF	Known Mutation
M-1913-BF	M-1682-C3-T	17%	KRAS Q61H
	M-1791-8C-T	66%	EGFR L858R
	M-1754-DB-T	61%	KITexon9ins
M-1914-A2	M-1671-CE-T	25%	KITexon11del
	M-1693-5E-T	24%	PIK3CA H1047R
	M-1646-FC-T	41%	BRAF V600E
M-1915-CA	M-1612-28-3-T	32%	EGFR exon19 del
	M-1627-D9-T	52%	NRAS Q61H
	M-1625-1A-2A-T	28%	KRAS G12D

c) Negative control: The negative control sample is a mixture of FFPE normal samples verified in previous reruns to be free of tumor contamination and germline copy number mutations in target genes. Polymorphisms unique to each constituent normal sample in the pool have been identified in prior analyses and the expected frequencies for each polymorphism in the pooled negative control are confirmed. The observed mutation frequencies are compared against the expected mutation frequencies for the 862 common SNPs, and the degree of concordance is measured using Pearson's correlation. The correlation between expected and observed mutation frequencies is expected to be 0.9 or higher.

d) PCR reagent control [No Template Control (NTC)]: The NTC control should have a Qubit measurement of < 1.0ng/μL. Sequencing data from the NTC control sample will also be subjected to analysis using the pipeline, to verify that no known hotspot mutations are detected. Similar to the pooled FFPE negative control, if a hotspot mutation is detected, any samples containing that mutation in the pool will be reviewed to determine if a re-run is necessary.

6. <u>Result Reporting:</u>

- Oncopanel results are reported out under one of the two categories: "Cancer Mutations with Evidence of Clinical Significance" or "Cancer Mutations with

Potential Clinical Significance". The two categories are based on the supporting level of clinical evidence. Refer to the Clinical Performance Section for more information.

- Results are reported for point mutations and small insertions and deletions in protein-coding exons of the 468 gene panel. Refer to Appendix 1b for a list of genes.
- The MSK-IMPACT does not report mutations in 73 exons due to consistently low coverage in those exons. Refer to Appendix 1c for a list of excluded exons.
- Reporting takes in account the following quality metrics in the Table 3 below.

Table 3. Sample Level Quality Control Metrics

QC Metrics	Acceptance Criteria
Coverage	Average target coverage > 200X
Coverage Uniformity	≥ 98% target exons above 100X coverage
Base Quality	> 80% of bases with QS above > Q30
% Cluster passing	The percent cluster passing filter (Cluster PF) > 80%
% Reads passing filter	The percent reads passing filter (Reads PF) > 80%
Hotspot Mutation* calling threshold	Mutation Coverage (DP) ≥ 20, Number of Mutant Reads (AD) ≥ 8, Mutation Frequency (VF) ≥ 2%
Non-hotspot Mutation threshold**	DP ≥ 20, AD ≥ 10, VF ≥ 5%
Indels	Fewer than 20% of samples in an established 'standard normal'database
Positive Run Control	The difference between the observed and expected frequencies for the known mutations should be within 5%.
Negative Run Control	The correlation between expected and observed mutation frequencies should be 0.9 or higher
Sample-Mix up QC	Check over 1000 custom intergenic/intronic "fingerprint" SNPs. Flagged if pairs of samples from the same patient with > 5% discordance and from different patients with < 5% discordance
Major Contamination QC	% heterozygous sites at fingerprint SNPs < 55%; Average MAF at homozygous fingerprint SNPs < 2%
Criteria for calling test failure	If a sample presents with mean coverage across all exons < 50x and no mutations are detected due to the low overall coverage, the test is deemed "failed" for the sample.

*Defined as Hotspot SNVs in COSMICv68, mutation hotspots reported in TCGA, reported in Cheng *at. al.*(Nature Biotech, 2016) and indels in selected exons of established oncogenes.
**SNVs and Indels other than the ones defined as hotspot mutations above.

J. Standard/Guidance Document Referenced (if applicable):
Not applicable

K. Test Principle:
The MSK-IMPACT assay is a custom targeted sequencing platform, utilizing solution-phase exon capture and sequencing, to detect somatic alterations (point mutations, small insertions and deletions, and microsatellite instability) in tumor specimens. The MSK-IMPACT assay involves hybridization capture and deep sequencing of all protein-coding exons of 468 cancer-associated genes. The assay uses custom DNA probes corresponding to all exons and selected introns of oncogenes and tumor suppressor genes. Probes are synthesized by a secondary manufacturer and are biotinylated to enable sequence enrichment through capture by streptavidin-conjugated beads. Probes were designed to tile the entire length of each target sequence in an overlapping fashion, typically extending 20-50 base pairs beyond the boundaries of the target. In total, the probes target approximately 1.5Mb of the human genome.

Genomic DNA is extracted from tumor and patient-matched blood/normal tissue as a normal control when available. Sequence libraries are prepared through a series of enzymatic steps including shearing of double-stranded DNA, end repair, A-base addition, ligation of barcoded sequence adaptors, and low cycle PCR amplification. Multiple barcoded sequence libraries are pooled and captured using the custom-designed biotinylated probes. Captured DNA fragments are then sequenced on an Illumina HiSeq2500 as paired-end reads. Sequence reads are then aligned to the reference human genome. By comparing the identity of bases from the tumor DNA to the matched normal DNA and the reference human genome, somatic alterations are identified in the tumor.

L. Performance:

1. <u>Determination of pipeline thresholds:</u>

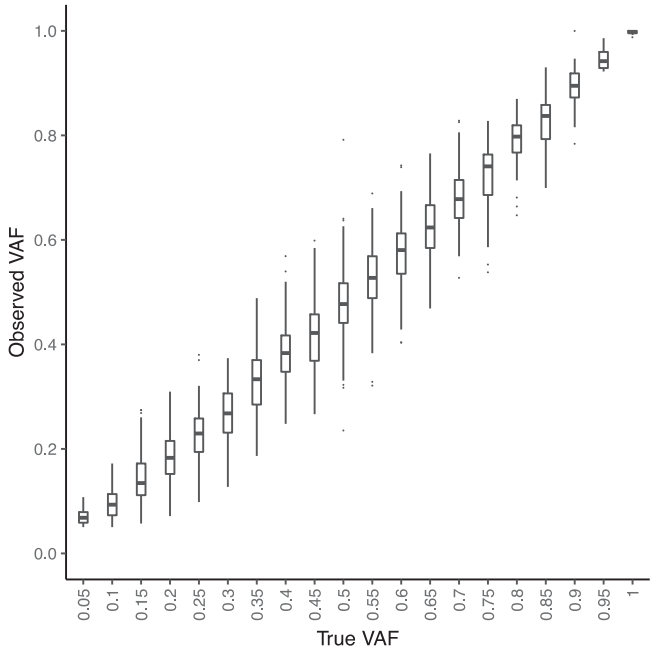
a) Requirements on exon coverage were established: A power analysis to compute the coverage or total number of reads needed to detect a mutation with true underlying mutation frequency 2% or greater, for varying levels of power (0.8 to 0.99), assuming a fixed alpha (Type I error rate) of 0.05 was conducted. Additionally, the 95% confidence interval ranges of observed mutation frequency as a function of coverage was also calculated. When the mutation is present at 10%, the 95% confidence interval with a coverage of 500X is expected to fall between 7.5% and 13%. When the overall coverage is 100X, the 95% CI for a mutation at 10% is estimated to fall between 5.0% and 17.6%.

To confirm these estimates, empirical data was obtained to measure the range of observed VF to expected VF using DNA from 10 normal FFPE samples from unrelated individuals which was mixed in equimolar parts so as to create a range of SNPs with expected frequencies as low as 5%. A total of 862 common SNPs were considered for this experiment.

A boxplot showing the observed mutation frequencies for the 862 common SNPs genotyped in the pooled normal sample binned by their true underlying mutation frequency is shown below. The results demonstrated that an observed VF range from 5.0% to 13.9% for a SNP with true underlying mutation frequency of 10% when the mean coverage of the sample was 480X. This range in values is roughly in line with what the theoretical statistical assessment for a coverage depth of 500X (7.5% to 13.0%). This data provided support for using a 5% as the lower limit for reporting mutations detected with true underlying frequency of 10%.

The boxplot in Figure 2 shows the correlation is 0.975, with a slope of 0.971 and intercept of -0.004. Consistent correlation is established as >0.9 as a QC metric for the whole pool analyzed.

Figure 2. Observed vs. Expected Variant Frequency



b) Requirements on sample coverage: Ten normal (diploid) FFPE samples were profiled in duplicate using the IMPACT assay (total = 20 replicates) to generate summary statistics across all targeted exons. The mean coverage across all targeted exons for the normal samples was 571X (SD = 373X). Summary statistics were also computed on coverage values per exon normalized by per-sample coverage. There were exons that presented with consistently low coverage values. None of the exons of the genes in the clinical validation are among those with consistently low coverage. It was determined the low coverage was due to sequence similarity with other loci, and high GC content. The exons were removed from the MSK-IMPACT assay. Of the remaining exons across all genes, 99.5% were sequenced to a depth of 100X or greater while 98.6% were sequenced to a depth of 250X or greater. This analysis of normal samples indicates that with a mean sample coverage of 571X, 98% of exons are sequenced with coverage greater than 306X, or with normalized coverage greater

than 0.54. (The ‘mean-normalized coverage’ is the coverage of the mutation divided by the mean coverage across all exons; it serves as a measure of how deeply the validation exon was sequenced relative to the overall coverage of the sample. A mean-normalized coverage below 1 indicates the exon coverage is below average; conversely if greater than 1, it indicates above average coverage.) The data are shown in Figures 3 and Figure 4

Figure 3. Distribution of mean coverage values for targeted exons. Dashed line indicates coverage at 100X.

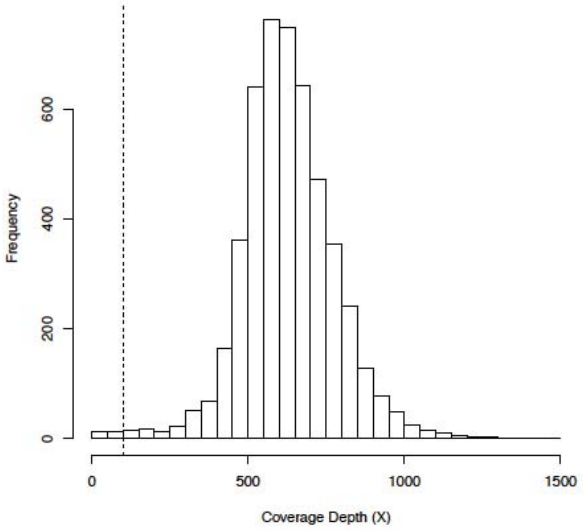
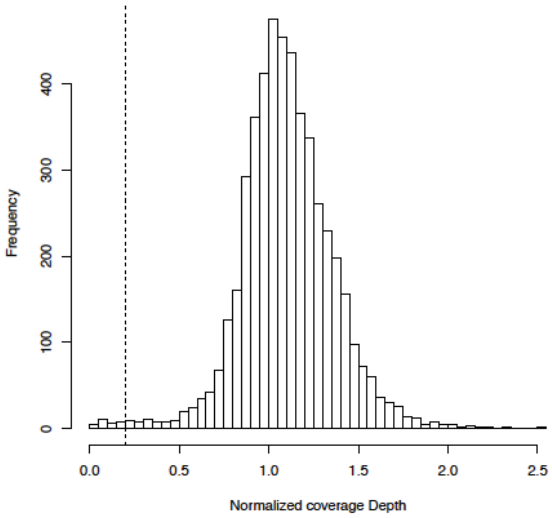


Figure 4. Distribution of mean coverage for targeted exons, normalized by per-sample coverage. Dashed line indicates 20% of mean sample coverage.



Based on the calculations, 98% of exons can be expected to be sequenced to coverage greater than 100X, when mean sample coverage is 185X (0.54* 185X = 100X). (A 100X minimum coverage threshold per exon is required based on the power

calculations, which showed 100X coverage was necessary to call mutations with true underlying mutation frequency 10% or greater, with 95% power at an alpha level of 0.05).

To be conservative, a threshold of 200X on mean sample coverage is used to determine if a sample is sequenced to sufficient depth for subsequent analysis. A sample is flagged as being at increased risk of false negatives if its mean coverage is below 200X.

To provide empirical data for these requirements, MSK utilizes the pool normal sample with known expected single nucleotide mutations (n = 2436) and the underlying mutation allele fractions (MAF). In silico downsampling analysis was conducted with a pool normal mix down to 45% where the sample coverage decreased from 452X to 203X. At this coverage level, 94% of the mutations with expected underlying VAF of 10% were called.

c) **Requirements on mutation coverage, allele depth and frequency for positive calls:** Permissive standard filters were used to intentionally generate false positives to identify suitable thresholds for parameters such as mutation coverage (DP), alternate allele depth (AD) and mutation frequency (VF) to optimize specificity. The following criteria allows optimal rejection of false positive SNVs (stratified by whether they are hotspots or not) and indel calls, while maintaining ability to detect true positive events with underlying frequency of 10% (5-17.6% observable). Potential strand-bias is also evaluated in the standard somatic mutation calling pipeline. An example of the number of false positive events detected pre and post filtering for coverage depth(DP), number of mutant reads (AD) and variant frequency (VF) is shown in Table 4.

Table 4. Sample error correction by DP/AD/VF filter

	Mutations –Cosmic database		**Mutations**	
Filter criteria	**DP ≥ 20X, AD ≥ 8,VF ≥ 2%**		**DP ≥ 20X, AD ≥ 10,VF ≥ 5%**	
	SNVs	Indels	SNVs	Indels
Pre-filter	1	24	342	40,793
Post-filter	0	0	0	8
Rejection Rate	1.00	1.00	1.00	0.999

2. **<u>Pre-Analytical performance:</u>**

Minimum DNA requirements were established by measuring assay performance based on different inputs from normal blood and FFPE tumor samples. DNA samples are normalized to yield 50 – 250 ng input and maximized to 55 ul prior to shearing. The normalization and DNA quantification are performed.

DNA extraction method was validated based on the invalid rates across multiple tumor types obtained from historical data. The data demonstrated that the DNA extraction has been optimized across tumor types to reasonably conclude that the analytical

performance presented is representative across FFPE tumor types. Table 5 shows the historical data for invalid rates from a retrospective chart review of >10,000 specimens tested with MSK-IMPACT. The range of invalid rates was 7.2% to 18.4%. The data shows that interference effects from different specimens are not significant across different tumor types supporting the performance of the pan-cancer specimen handling.

Table 5. Specimen Invalid Rates for 17 FFPE Tumor Types

			Pre-Run Invalids	Pre-Run Invalids	Post-Run Invalids	
Tumor Type	**Specimen Type**	**Number of Tests**	**Tumor Insufficient (Tumor % <20%)**	**DNA Insufficient (DNA yield <50ng)**	**Sequencing Failure (Coverage <50X)**	**Percent Invalids**
Non-Small Cell Lung Cancer	FFPE	1995	53	208	75	16.8
Breast Carcinoma	FFPE	1588	41	126	97	16.6
Colorectal Cancer	FFPE	1105	29	39	31	9.0
Prostate Cancer	FFPE	879	28	63	71	18.4
Glioma	FFPE	601	1	33	16	8.3
Pancreatic Cancer	FFPE	584	15	38	29	14.0
Soft Tissue Sarcoma	FFPE	479	3	21	13	7.7
Bladder Cancer	FFPE	480	12	20	25	9.8
Melanoma	FFPE	411	7	22	17	11.2
Renal Cell Carcinoma	FFPE	403	12	15	16	10.7
Hepatobiliary Cancer	FFPE	398	11	17	15	10.8
Esophagogastric Carcinoma	FFPE	374	5	12	16	8.8
Germ Cell Tumor	FFPE	332	9	13	30	8.1
Thyroid Cancer	FFPE	258	2	12	13	10.5
Ovarian Cancer	FFPE	244	4	8	8	8.2
Endometrial Cancer	FFPE	235	2	8	7	7.2
Head and Neck Carcinoma	FFPE	208	8	8	6	10.5
Cancer of Unknown Primary	FFPE	224	15	15	10	17.8

3. Analytical performance:

The hybridization-capture-based targeted re-sequencing assay is designed to detect point mutations [also referred to as single nucleotide variants (SNVs)] as well as small insertions/deletions (indels) < 30bp in length in the coding exons of 468 genes (Appendix 1b). A total of 6,357 exons are sequenced, 73 exons were excluded during assay development due to low sequence coverage and high GC content (Appendix 1c). A paired-sample analysis pipeline (tumor vs. matched normal) is used to identify somatic mutations in the targeted exons. MSK took a representative approach to validation of the SNVs and indels targeted in this panel, which is appropriate for variants of this type.[1]

a) Precision Studies: The objective of the precision studies was to assess between-run and within-run precision. Extracted DNA was run once per day for 3 days using different barcodes for inter-day assessment (n=3). For one run, a sample was run in triplicates for intra-day assessment, resulting in a total of 3+1+1=5 replicates. For each replicate tested, all observed mutations were reported and assessed for precision. Details of the study are described below.

i. Precision Panel: The precision of the MSK-IMPACT assay was assessed using 10 samples (9 FFPE specimens and one commercial cell line) to represent different tumor types, different mutation types, and the range of mutant allele frequencies. The panel included challenging specimens. The specimen panel was selected based on known mutations corresponding to "Cancer Mutations with Evidence of Clinical Significance" as well as the associated target tissue. The representative list of specimens is shown in Table 6.

Table 6: Summary of the Specimens and Allele Frequencies in the Precision Studies

Tissue type	Mutation type	Gene/ exon	cDNA change	Amino acid change	Mutation frequency
Glioblastoma	INS	EGFR exon20	C2290_2310dup TACGTGATGGCCAGC GTGGAC	p.Y764_D770dup	~ 5%
Cutaneous Melanoma	DNV	BRAF exon15	c.1798_1799delinsAA	V600K	~6.5%
Uterine Endometrial Cancer	SNV	KRAS exon2	C35G>C	G12A	~7%
Lung Adenocarcinoma	INS	ERBB2 exon 20	2310_2311ins GCATACGTGATG	E770_A771insAYVM	~15%
Lung Adenocarcinoma	SNV	EGFR exon 21	2573T>G	L858R	~20%

[1] For complex structural variations, such as genomic rearrangements (fusions) and copy number variations (CNVs), the expectation is that the representative approach should be demonstrated at the gene level.

Tissue type	Mutation type	Gene/ exon	cDNA change	Amino acid change	Mutation frequency
CRC	SNV	KRAS exon 2	C34G>T	G12C	~30%
Lung Adenocarcinoma	DEL (15bp)	EGFR exon 19	2236_2250delGAATTAAGAGAAGCA	E746_A750del	~30%
CRC	SNV	BRAF exon 15	c.1799T>A	V600E	~40%
GIST	DEL (6bp)	Kit exon 11	1667_1672delAGTGGA	Q556_K558del	~50%
FFPE Cell Line	DEL, SNV	Hotspot mutations in BRAF, EGFR, FLT3, GNA11, IDH1, KRAS, NRAS and PIK3CA genes			~2%-15%

ii. *Precision- Panel-Wide Reproducibility*: The precision analysis was performed for the known mutations (as listed in Table 6), and also performed for all additional mutations identified in each specimen in any of the test replicates. A total of 69 mutations in the clinical specimens and 13 mutations in the cell line were detected for a total of 82 mutations. In addition to SNV/MNVs, there were 9 deletions and 8 insertions.

The results showed that all mutations have 100% concordance in all replicates except for 4 mutations in the clinical specimens and 3 mutations in the commercial sample. In the clinical specimen discordance was observed for an SNV (pQ64K) and a frameshift mutation (pL54fs) in AR exon1, an insertion (pA445_P446insP) ARID1B exon1; and a frameshift mutation (pT319Kfs*24) in PTEN exon 8. The discordance on AR and ARID1B mutations were due to poor mapping quality in the highly repetitive regions.

The 3 mutations from the commercial control sample that were discordant were 2 SNVs and one deletion (IDH1 exon4 R132H; BRAF exon15 V600M; EGFR exon19 E746_A750del). These 3 mutations were believed to be discordant because they have low frequencies near 2%.

The coefficient of variation (%CV) for the mutation allele frequency was also calculated for all 5 replicates. Thirty-four (45) of the 69 mutations in the clinical specimens had %CV ≤10%, 17/69 were between 10 and 20% and 7/69 were >21%. All results are summarized in Table 7. Each specimen is separated by a dark gray line. Known mutation within each specimen are in **bold**. Discordant cases are denoted in light grey. All runs passed the quality metrics criteria.

Table 7. Panel-wide precision summary for all 5 replicates Abbreviations: NC (normalized coverage); MAF (Mutant allele frequency)

Gene Exon	Mutation (cDNA/Protein Changes)	NC range	MAF range	MAF mean	MAF median	MAF (SD)	MAF (%CV)	Positive /Total Calls	Positive Call Rate (two-sided 95% CI)
EGFR exon19	**c.2236_2250delGAATTAAGAGAAGCA 746_750del**	0.84-1	0.311-0.342	0.323	0.316	0.013	4.0%	5/5	100.0% (47.8%, 100.0%)
PTEN exon2	c.T83G I28S	0.62-0.73	0.502-0.569	0.543	0.544	0.027	5.0%	5/5	100.0% (47.8%, 100.0%)
TET2 exon3	c.C311G S104C	1.04-1.32	0.085-0.103	0.098	0.102	0.008	8.2%	5/5	100.0% (47.8%, 100.0%)
TP53 exon7	c.C742T R248W	0.97-1.22	0.648-0.664	0.66	0.663	0.007	1.1%	5/5	100.0% (47.8%, 100.0%)
BRAF exon15	**c.T1799A V600E**	1.26-1.44	0.415-0.454	0.431	0.425	0.015	3.5%	5/5	100.0% (47.8%, 100.0%)
BRCA2 exon14	c.A7388G N2463S	0.84-0.96	0.19-0.23	0.209	0.21	0.015	7.2%	5/5	100.0% (47.8%, 100.0%)
BRD4 exon19	c.G3922A A1308T	0.44-0.56	0.5-0.636	0.553	0.54	0.054	9.8%	5/5	100.0% (47.8%, 100.0%)
FBXW7 exon9	c.G1268T G423V	0.91-1.05	0.369-0.418	0.395	0.391	0.02	5.1%	5/5	100.0% (47.8%, 100.0%)
GRIN2A exon7	c.C1514A A505E	0.92-1.1	0.194-0.211	0.202	0.203	0.006	3.0%	5/5	100.0% (47.8%, 100.0%)
PTPRD exon12	c.G10A V4I	0.5-0.63	0.281-0.361	0.336	0.35	0.034	10.1%	5/5	100.0% (47.8%, 100.0%)
RUNX1 exon9	c.806-1G>A NA	1.01-1.23	0.185-0.21	0.202	0.207	0.01	5.0%	5/5	100.0% (47.8%, 100.0%)
SPEN exon12	c.C10445T P3482L	0.94-1.03	0.189-0.235	0.208	0.2	0.018	8.7%	5/5	100.0% (47.8%, 100.0%)
SYK exon13	c.C1768T R590W	1.13-1.22	0.233-0.292	0.273	0.279	0.023	8.4%	5/5	100.0% (47.8%, 100.0%)
TP53 exon6	c.G610T E204X	0.9-1.01	0.525-0.56	0.547	0.551	0.013	2.4%	5/5	100.0% (47.8%, 100.0%)
APC exon16	c.G3856T E1286X	0.8-1.05	0.326-0.39	0.351	0.349	0.026	7.4%	5/5	100.0% (47.8%, 100.0%)

APC exon7	c.C646T R216X	0.87-1.06	0.148-0.185	0.162	0.16	0.015	9.3%	5/5	100.0% (47.8%, 100.0%)
CREBBP exon29	c.G4837A V1613M	1-1.19	0.159-0.196	0.178	0.18	0.017	9.6%	5/5	100.0% (47.8%, 100.0%)
KRAS exon2	**c.G34T G12C**	1.13-1.31	0.289-0.352	0.314	0.305	0.024	7.6%	5/5	100.0% (47.8%, 100.0%)
NOTCH1 exon34	c.7541dupC P2514fs	1.28-1.5	0.144-0.211	0.184	0.189	0.025	13.6%	5/5	100.0% (47.8%, 100.0%)
SMAD4 exon11	c.C1333T R445X	0.76-0.95	0.206-0.238	0.223	0.229	0.014	6.3%	5/5	100.0% (47.8%, 100.0%)
ALOX12B exon11	c.G1406A R469Q	1.03-1.31	0.333-0.377	0.355	0.356	0.016	4.5%	5/5	100.0% (47.8%, 100.0%)
ARID1B exon1	c.1333_1334insCGC A445_P446insP	0.2-0.2	0.2-0.2	0.2	0.2	NA	NA	1/5	20.0% (0.5%, 71.6%)
CDK8 exon10	c.C1014A D338E	0.59-0.7	0.256-0.336	0.303	0.315	0.032	10.6%	5/5	100.0% (47.8%, 100.0%)
DNMT1 exon36	c.T4380G H1460Q	1.18-1.51	0.51-0.558	0.534	0.53	0.017	3.2%	5/5	100.0% (47.8%, 100.0%)
ERBB2 exon2	c.G140A R47H	1.16-1.59	0.596-0.712	0.656	0.666	0.045	6.9%	5/5	100.0% (47.8%, 100.0%)
ERBB2 exon20	**c.2310_2311insGCATACGTGATG E770_A771insAYVM**	1.02-1.38	0.142-0.199	0.173	0.171	0.023	13.3%	5/5	100.0% (47.8%, 100.0%)
ERCC2 exon21	c.C1904T A635V	1.19-1.47	0.363-0.466	0.409	0.423	0.045	11.0%	5/5	100.0% (47.8%, 100.0%)
IRS1 exon1	c.C3639A S1213R	0.42-0.49	0.384-0.494	0.449	0.455	0.04	8.9%	5/5	100.0% (47.8%, 100.0%)
MED12 exon37	c.5258_5282delCTCCTACCCTGCTAGAGCCTGAGAA A1753fs	1.08-1.36	0.141-0.187	0.164	0.17	0.019	11.6%	5/5	100.0% (47.8%, 100.0%)
MED12 exon43	c.6339_6340insCAGCAACACCAG Q2113_Q2114insQQHQ	0.96-1.43	0.37-0.422	0.4	0.399	0.021	5.3%	5/5	100.0% (47.8%, 100.0%)
NF1 exon51	c.C7595T A2532V	0.92-1.04	0.627-0.68	0.664	0.676	0.022	3.3%	5/5	100.0% (47.8%, 100.0%)

NTRK1 exon1	c.G53A G18E	0.28-0.55	0.6-0.668	0.631	0.63	0.027	4.3%	5/5	100.0% (47.8%, 100.0%)
PDGFRB exon7	c.G946A V316M	0.73-1.14	0.615-0.681	0.646	0.642	0.026	4.0%	5/5	100.0% (47.8%, 100.0%)
PIK3CB exon15	c.A2150G N717S	0.67-0.85	0.273-0.317	0.299	0.308	0.018	6.0%	5/5	100.0% (47.8%, 100.0%)
PTPRS exon32	c.C4822T R1608W	0.79-1.06	0.526-0.562	0.543	0.542	0.013	2.4%	5/5	100.0% (47.8%, 100.0%)
RB1 exon2	c.138-2A>G splicing mutation	0.51-0.75	0.231-0.345	0.291	0.284	0.047	16.2%	5/5	100.0% (47.8%, 100.0%)
TET1 exon4	c.G3476A R1159Q	0.86-1.34	0.499-0.606	0.533	0.522	0.044	8.3%	5/5	100.0% (47.8%, 100.0%)
TP53 exon5	c.G524A R175H	0.75-1.11	0.247-0.344	0.314	0.337	0.04	12.7%	5/5	100.0% (47.8%, 100.0%)
EGFR exon21	**c.T2573G L858R**	1.4-1.44	0.172-0.225	0.199	0.203	0.02	10.1%	5/5	100.0% (47.8%, 100.0%)
HNF1A exon4	c.C934T L312F	0.35-0.54	0.033-0.077	0.057	0.059	0.016	28.1%	5/5	100.0% (47.8%, 100.0%)
MLL3 exon42	c.G9671A R3224H	1.27-1.4	0.089-0.118	0.104	0.105	0.011	10.6%	5/5	100.0% (47.8%, 100.0%)
NTRK3 exon14	c.1401delC P467fs	0.49-0.54	0.062-0.086	0.074	0.077	0.01	13.5%	5/5	100.0% (47.8%, 100.0%)
TP53 exon10	c.A1051T K351X	0.74-0.84	0.075-0.116	0.103	0.108	0.016	15.5%	5/5	100.0% (47.8%, 100.0%)
AR exon1	c.161_171delTGC TGCTGCTG L54fs	0.34-0.39	0.079-0.097	0.088	0.087	0.009	10.2%	3/5	60.0% (14.7%, 94.7.0%)
AR exon1	c.C190A Q64K	0.25-0.29	0.134-0.135	0.134	0.134	0.001	0.7%	2/5	40.0% (5.3%, 85.3%)
KIT exon11	c.1667_1672delA GTGGA 556_558del	1.65-1.86	0.554-0.595	0.569	0.566	0.016	2.8%	5/5	100.0% (47.8%, 100.0%)
KIT exon17	c.T2467G Y823D	1.28-1.49	0.619-0.658	0.646	0.655	0.016	2.5%	5/5	100.0% (47.8%, 100.0%)
RPS6KB2 exon10	c.G840T K280N	0.93-1.19	0.435-0.473	0.462	0.468	0.015	3.2%	5/5	100.0% (47.8%, 100.0%)

CARD11 exon25	c.3382T>A p.V1128I	1.34-1.58	0.276-0.293	0.284	0.278	0.009	3.2%	5/5	100.0% (47.8%, 100.0%)
EGFR exon20	**c.2290_2310dupTACGTGATGGCCAGCGTGGAC p.Y764_D770dup**	14.36-15.46	0.05-0.06	0.055	0.055	0.004	7.3%	5/5	100.0% (47.8%, 100.0%)
EGFR exon7	c.874G>T p.V292L	21.51-21.82	0.934-0.939	0.937	0.939	0.002	0.2%	5/5	100.0% (47.8%, 100.0%)
NOTCH3 exon22	c.3646G>A p.A1216T	1.35-1.52	0.247-0.318	0.281	0.281	0.026	9.3%	5/5	100.0% (47.8%, 100.0%)
PTEN exon5	c.395G>C p.G132A	0.6-0.72	0.605-0.667	0.635	0.631	0.029	4.6%	5/5	100.0% (47.8%, 100.0%)
RUNX1 exon8	c.899C>T p.T300M	0.81-0.92	0.244-0.274	0.26	0.266	0.015	5.8%	5/5	100.0% (47.8%, 100.0%)
STAG2 exon17	c.1544_1547delATAG p.D515Gfs*6	0.19-0.27	0.677-0.842	0.753	0.741	0.067	8.9%	5/5	100.0% (47.8%, 100.0%)
TERT Promoter	g.1295228C>T non-coding	0.55-0.67	0.388-0.467	0.421	0.417	0.033	7.8%	5/5	100.0% (47.8%, 100.0%)
AKT3 exon2	c.134T>G p.V45G	1.14-1.36	0.05-0.078	0.066	0.067	0.012	18.2%	5/5	100.0% (47.8%, 100.0%)
BRAF exon15	**c.1798_1799delinsAA p.V600K**	1.04-1.32	0.065-0.095	0.072	0.067	0.013	18.1%	5/5	100.0% (47.8%, 100.0%)
KIT exon11	c.1735_1737delGAT p.D579del	1.08-1.22	0.051-0.056	0.053	0.054	0.002	3.8%	5/5	100.0% (47.8%, 100.0%)
CTCF exon3	c.610dupA p.T204Nfs*26	0.68-0.86	0.041-0.072	0.057	0.061	0.014	24.6%	5/5	100.0% (47.8%, 100.0%)
EGFR exon20	c.2317_2319dupCAC p.H773dup	1.15-1.19	0.067-0.093	0.078	0.079	0.011	14.1%	5/5	100.0% (47.8%, 100.0%)
KDM5C exon23	c.3755G>A p.R1252H	0.88-1.17	0.064-0.13	0.088	0.084	0.026	29.5%	5/5	100.0% (47.8%, 100.0%)
KRAS exon2	c.35G>C p.G12A	0.78-0.94	0.044-0.106	0.076	0.074	0.023	30.3%	5/5	100.0% (47.8%, 100.0%)
PIK3R1 exon13	c.1672_1683delGAAATTGACAAA p.E558_K561del	0.43-0.52	0.067-0.116	0.085	0.081	0.019	22.4%	5/5	100.0% (47.8%, 100.0%)

PIK3R1 exon9	c.1023dupA p.E342Rfs*4	0.41-0.58	0.056-0.102	0.083	0.086	0.017	20.5%	5/5	100.0% (47.8%, 100.0%)
PIK3R1 exon9	c.1024G>T p.E342*	0.42-0.59	0.064-0.108	0.093	0.095	0.017	18.3%	5/5	100.0% (47.8%, 100.0%)
PTEN exon6	c.493-1G>A p.X165_splice	0.53-0.64	0.173-0.208	0.192	0.187	0.015	7.8%	5/5	100.0% (47.8%, 100.0%)
PTEN exon8	c.956_959delCTTT p.T319Kfs*24	0.28-0.48	0.006-0.079	0.049	0.052	0.029	59.2%	3/5	60.0% (14.7%, 94.7.0%)
SOX17 exon1	c.287C>G p.A96G	1.16-1.51	0.061-0.074	0.069	0.069	0.005	7.2%	5/5	100.0% (47.8%, 100.0%)
BRAF exon15	**c.1798G>A V600M**	0.97-1.06	0.016-0.041	0.027	0.027	0.01	37.0%	3/5	60.0% (14.7%, 94.7.0%)
BRAF exon15	**c.1799T>A V600E**	0.97-1.06	0.051-0.08	0.064	0.067	0.012	18.8%	5/5	100.0% (47.8%, 100.0%)
EGFR exon18	**c.2155G>A G719S**	1.23-1.33	0.125-0.179	0.158	0.164	0.022	13.9%	5/5	100.0% (47.8%, 100.0%)
EGFR exon19	**c.2235_2249delGGAATTAAGAGAAGC E746_A750del**	1.01-1.19	0.009-0.043	0.023	0.019	0.013	56.5%	2/5	40.0% (5.3%, 85.3%)
FLT3 exon20	**c.2503G>T D835Y**	0.97-1.02	0.037-0.059	0.045	0.043	0.008	17.8%	5/5	100.0% (47.8%, 100.0%)
GNA11 exon5	**c.626A>T Q209L**	1.41-1.48	0.036-0.054	0.046	0.044	0.008	17.4%	5/5	100.0% (47.8%, 100.0%)
IDH1 exon4	**c.395G>A R132H**	0.5-0.53	0.038-0.049	0.035	0.044	0.020	57.1%	4/5	80.0% (28.4%, 99.5%)
KRAS exon2	**c.34G>A G12S**	0.9-1.03	0.026-0.057	0.041	0.039	0.011	26.8%	5/5	100.0% (47.8%, 100.0%)
KRAS exon2	**c.38G>A G13D**	0.91-1.06	0.217-0.249	0.231	0.229	0.012	5.2%	5/5	100.0% (47.8%, 100.0%)
KRAS exon4	**c.436G>A A146T**	0.82-0.88	0.031-0.055	0.042	0.044	0.009	21.4%	5/5	100.0% (47.8%, 100.0%)
NRAS exon3	**c.183A>T Q61H**	1.01-1.14	0.039-0.065	0.051	0.051	0.01	19.6%	5/5	100.0% (47.8%, 100.0%)
PIK3CA exon10	**c.1624G>A E542K**	0.67-0.87	0.038-0.047	0.042	0.042	0.004	9.5%	5/5	100.0% (47.8%, 100.0%)
PIK3CA exon21	**c.3140A>G H1047R**	0.62-0.72	0.222-0.331	0.276	0.258	0.05	18.1%	5/5	100.0% (47.8%, 100.0%)

iii. Per Specimen Precision: Results of the precision studies were combined and precision across all reportable genes was determined for each specimen. The positive call rate based on the total number of mutations along with the 2-sides 95% confidence interval were calculated. Results are summarized in Table 8.

Table 8. Precision per specimen across all reportable mutations (N – 5 replicates)

Specimen	Total No unique mutations detected across all 5 replicates*	*Positive call rate per mutation	Positive call rate* (two-sided 95% CI)	Negative call rate (two-sided 95% CI)
M15-22924	5	5/5 for all	25/25 100.0% (86.3%, 100.0%)	-
M15-3038	3	5/5 for all	15/15 100.0% (78.2%, 100.0%)	-
M16-19000	10	5/5 for 9 4/5 for 1	49/50 98.0% (89.4%, 99.9%)	-
M1688-5C	18	5/5 for 17 1/5 for 1	86/90 95.6% (89.0%, 98.8%)	4/5 80.0% (28.4%, 99.5%)
M-1698-A9	5	5/5 for all	25/25 100.0% (86.3%, 100.0%)	-
M-1654-CA	6	5/5 for all	30/30 100.0% (88.4%, 100.0%)	-
M-1612-28	4	5/5 for all	20/20 100.0% (83.2%, 100.0%)	-
M1648-D5	10	5/5 for all	50/50 100.0% (92.9%, 100.0%)	-
M-1707-12	5	5/5 for 3 3/5 for 1; 2/5 for 1	20/25 80.0% (59.3%, 93.2%)	3/5 60.0% (14.7%, 94.7%)
Commercial sample	13	5/5 for 10; 4/5 for 1; 3/5 for 1; 2/5 for 1	59/65 90.8% (81.0%, 96.5%)	3/5 60.0% (14.7%, 94.7%)

*Positive call rate is calculated based on variants with majority call detected as positive
#Negative call rate is calculated based on variants detected at least once, but with majority call as negative. For all other locations, the negative call rates are 100%.

The precision study was also evaluated for the intra-assay repeatability (within-run). All results were concordant except for ARID1B exon 2 insertion from clinical specimen M-1688, and BRAF V600M point mutation in the commercial control sample as described previously. Additionally, performance with respect to quality metrics (i.e., total depth of coverage and mutant allele coverage) in all replicates was also summarized and shown to meet the pre-specified acceptance criteria (data not shown).

iv. *Precision - Well-characterized reference material:* The precision of MSK-IMPACT was assessed through repeated measurements of a well characterized reference standard (HapMap cell line NA20810). To determine sequencing error rates for the reference sample, DNA extracted from the HapMap cell line was included in each run tested in the accuracy study. The study investigated whether the SNPs in the targeted exons were detected at their expected frequencies. Reference genotypes for 11,767 SNPs in the targeted exons using a whole genome sequencing BAM file for NA20810, were obtained from the 1000 Genomes database. A total of 11,443 SNPs (97.2%) were homozygous for the major allele (relative to the hg19 reference genome), 212 SNPs (1.8%) were heterozygous and 112 SNPs (0.95%) were homozygous for the minor allele. The strong bias towards alleles matching the reference genome was expected, given that these SNPs occur in coding exons and there is likely strong selective pressure against deviations from the reference sequence. NA20810 was profiled with the assay multiple times across different runs, for a total of 23 replicates. Zygosity results were 100% concordant and high levels of concordance – specifically, the difference between the expected and mean observed mutation frequencies was very small (absolute difference = 0.09%±0.45%). The data provide additional supplemental evidence of the reproducibility of the assay.

v. *Precision for Microsatellite Instability (MSI):* Precision of the MSI calling by MSIsensor was demonstrated with a total of 12 specimens: 6 MSI-H specimens (at three MSI-score levels, 3 replicates per sample) and 6 MSS specimens. Each DNA extracted sample was tested with 3 inter- and 3 intra-run replicates. Multiple barcodes were included. All samples had 100% agreement between calls**.** The total number of unstable loci relative to the total number of sites surveyed along with the mean, median and standard deviation (SD) and coefficient of variance (%CV) was also presented for each specimen and score. The results supported the precision of the MSIsensor scores greater than 0.5 Results are shown in Table 9.

Table 9. Precision of the MSIsensor Score Using 12 Specimens

N	Total Sites_ range	Unstable Loci_range	Mean	Median	SD	%CV	Positive Call Rate (two-sided 95% CI)
5	1227-1458	518-650	43.00	43.00	1.22	2.8%	100%(47.8%, 100.0%)
5	1158-1477	483-646	43.00	43.00	0.71	1.7%	100%(47.8%, 100.0%)
5	1187-1429	500-613	42.00	42.00	0.71	1.7%	100%(47.8%, 100.0%)
5	1287-1400	303-359	24.80	25.00	0.84	3.4%	100%(47.8%, 100.0%)
5	1251-1303	240-318	23.40	24.00	2.51	10.7%	100%(47.8%, 100.0%)
5	1154-1379	153-175	12.60	12.00	0.89	7.1%	100%(47.8%, 100.0%)

N	Total Sites_ range	Unstable Loci_range	Mean	Median	SD	%CV	Positive Call Rate (two-sided 95% CI)
5	1321-1545	46-58	3.60	4.00	0.55	15.3%	100%(47.8%, 100.0%)
5	1535-1604	44-64	3.40	3.00	0.55	16.2%	100%(47.8%, 100.0%)
5	1411-1612	28-38	2.20	2.00	0.45	20.5%	100%(47.8%, 100.0%)
5	1438-1528	6-9	0.48	0.50	0.08	16.7%	100%(47.8%, 100.0%)
5	1315-1487	0-2	0.02	0.00	0.04	223.6%	100%(47.8%, 100.0%)
5	1312-1532	0-1	0.01	0.00	0.03	223.6%	100%(47.8%, 100.0%)

b) Analytical Sensitivity – Limit of Detection (LoD): The LoD of the IMPACT assay is defined as the mutant allele fraction at which 95% of replicates across all replicates for a variant type are reliably detected. Studies were conducted to demonstrate a putative LoD for each variant type. In the first part, a dilution series was conducted to identify the lowest reliable mutant fraction. In part 2, the putative LoD was confirmed with multiple replicates.

i. Part 1: Dilution Series: The mean normalized coverage for all exons was determined for 10 normal FFPE specimens and the LoD was assessed with samples containing mutations in 5 validation exons (defined as representative exons harboring cancer mutations with evidence of clinical significance assessed in the accuracy study) with the lowest and highest coverage.

- The 5 validation exons with lowest coverage correspond to 3 exons harboring SNVs, (ERBB2 exon 20 (V777L), PDGFRA exon 18 (D842V), PIK3CA exon 10 (E545K), and 2 exons harboring indels (EGFR exon 19 and KIT exon 9).
- The 5 validation exons with highest coverage correspond to 3 exons harboring SNVs (BRAF exon 15 (V600E), KRAS exon 2 (G12D) and PIK3CA exon 2 (R88Q) and 2 exons harboring indels (KIT exon 11 and EGFR exon 20).

Five to eight serial dilutions were prepared using patient samples positive for the mutations listed above, where tumor samples were either diluted with their respective matched FFPE normal sample (when available) or a previously sequenced, unmatched normal FFPE sample. One replicate at each dilution was tested and the ability to detect the mutation of interest was measured. All results were called at the lowest dilution except for PIK3CA which was called wild-type at the lowest dilution. Results are shown in Tables 10A-J.

Table 10A. Limit of Detection –Part 1

SNV BRAF Exon 15 (Sample M-1648-D5-T)						
Dilution	**cDNAchange**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.1799T>A	V600E	1018	410	0.4	Called
1:2			1044	319	0.31	Called
1:4			888	173	0.19	Called
1:8			999	91	0.09	Called
1:16			783	26	0.03	Called
1:32			845	20	0.02	Called

Table 10B

SNV KRAS Exon 2 (sample M-1807-ED-T)						
Dilution	**cDNA change**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.35G>A	G12D	907	405	0.45	Called
1:2			820	298	0.36	Called
1:4			400	97	0.24	Called
1:8			660	121	0.18	Called
1:16			665	59	0.09	Called
1:32			632	41	0.06	Called

Table 10C

SNV PIK3CA Exon 2 (Sample M-1729-E1-T)						
Dilution	**cDNAchange**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.263G>A	R88Q	2029	629	0.31	Called
1:2			1008	211	0.21	Called
1:4			1140	145	0.13	Called
1:8			997	62	0.06	Called
1:16						WT

Table 10D

Kit exon 11 Deletion (Sample M-1621-AC-T)						
Dilution	**cDNAchange**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.1667_1681delAGTGGAAGGTTGTTG	556_561del	2503	922	0.37	Called
1:2			1986	688	0.35	Called
1:4			1513	430	0.28	Called
1:8			1049	250	0.24	Called
1:16			792	138	0.17	Called
1:32			761	66	0.09	Called
1:64			618	37	0.06	Called
1:125			736	18	0.02	Called

Table 10E

EGFR exon 20 Insertion (sample M-1674-10-T)						
Dilution	**cDNAchange**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.2308_2309insACT	D770_N771insY	1484	400	0.27	Called
1:2			777	166	0.21	Called
1:4			566	105	0.19	Called
1:8			595	55	0.09	Called
1:16			581	33	0.06	Called
1:32			608	21	0.03	Called

Table 10F

SNV ERBB2 exon 20 (sample M-1801-98-T)						
Dilution	**cDNAchange**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.2525A>T	D842V	1471	408	0.28	Called
1:2			1482	240	0.16	Called
1:4			864	73	0.08	Called
1:8			903	38	0.04	Called
1:16			873	24	0.03	Called

Table 10G

SNV PDGFRα Exon 18 (sample M-1670-A6-T						
Dilution	**cDNAchange**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.1633G>A	E545K	448	236	0.53	Called
1:2			636	142	0.22	Called
1:4			962	95	0.1	Called
1:8			647	45	0.07	Called
1:16			707	16	0.02	Called

Table 10H

SNV PK3CA exon 10 (sample M-1434-A5-T)						
Dilution	**cDNAchange**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.1633G>A	E545K	448	236	0.53	Called
1:2			636	142	0.22	Called
1:4			962	95	0.1	Called
1:8			647	45	0.07	Called
1:16			707	16	0.02	Called

Table 10I

EGFR exon 19 deletion (sample M-1809-C4-T)						
Dilution	**cDNAchange**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.2236_2250delGAATTAAGAGAAGCA	746_750del	1278	790	0.62	Called
1:2			1137	484	0.43	Called
1:4			792	207	0.26	Called
1:8			666	94	0.14	Called
1:16			622	49	0.08	Called
1:32			499	17	0.03	Called

Table 10J

Kit Exon 9 insertion (sample M-1754-DB-T)						
Dilution	**cDNA change**	**AA Change**	**DP**	**AD**	**VF**	**Result**
Neat	c.1502_1503insTGCCTA	S501_A502insAY	517	314	0.61	Called
1:2			512	187	0.37	Called
1:4			641	89	0.14	Called
1:8			486	27	0.06	Called
1:16			447	17	0.04	Called
1:32			521	14	0.03	Called

ii. *Part 2: Confirmation of the LoD.* A total of 5 replicates were tested for each of the 3 deletions, 4 insertions and 6 SNVs at 5% minor allele frequency. All variants have 100% positive call rates except for one replicate for a deletion on PTEN exon 6. This replicate also failed the mutation read depth and was below the estimated LoD of 5%. The results are shown in Table 11.

Table 11. Limit of Detection– Part 2

Type	Mutation	GeneExon	Range DP	Range AD	Range MAF	Range NormDP	Positive Call Rate
DEL	In_Frame_Del c.1735_1737delGAT p.D579del	KIT exon11	509-693	26-38	0.051-0.056	1.08-1.22	100.0%
DEL	Frame_Shift_Del c.956_959delCTTT p.T319Kfs*24	PTEN exon8	197-242	7-19	0.036-0.079	0.31-0.48	80.0%
DEL	In_Frame_Del c.1672_1683delGAAATT GACAAA p.E558_K561del	PIK3R1 exon13	216-313	18-36	0.067-0.116	0.43-0.52	100.0%
INS	In_Frame_Ins c.2317_2319dupCAC p.H773dup	EGFR exon20	587-749	46-65	0.067-0.093	1.15-1.19	100.0%
INS	Frame_Shift_Ins c.1023dupA p.E342Rfs*4	PIK3R1 exon9	236-345	15-32	0.056-0.102	0.41-0.58	100.0%
INS	Frame_Shift_Ins c.610dupA p.T204Nfs*26	CTCF exon3	344-540	14-36	0.041-0.072	0.68-0.86	100.0%
INS	In_Frame_Ins c.2290_2310dupTACGTG ATGGCCAGCGTGGAC p.Y764_D770dup	EGFR exon20	8601-9836	441-572	0.05-0.06	14.36-15.46	100.0%
SNV	Missense_Mutation c.134T>G p.V45G	AKT3 exon2	535-813	28-63	0.05-0.078	1.14-1.36	100.0%
SNV	Missense_Mutation c.1798_1799delinsAA p.V600K	BRAF exon15	489-747	33-71	0.065-0.095	1.04-1.32	100.0%
SNV	Missense_Mutation c.287C>G p.A96G	SOX17 exon1	672-805	45-59	0.061-0.074	1.16-1.51	100.0%
SNV	Missense_Mutation c.35G>C p.G12A	KRAS exon2	445-571	20-55	0.044-0.106	0.78-0.94	100.0%
SNV	Missense_Mutation c.3755G>A p.R1252H	KDM5C exon23	475-733	40-68	0.064-0.13	0.88-1.17	100.0%
SNV	Nonsense_Mutation c.1024G>T p.E342*	PIK3R1 exon9	242-355	18-37	0.064-0.108	0.42-0.59	100.0%

iii. *Microsatellite instability (MSI):* The minimum tumor proportion required to support the MSIsensor score robustness was assessed using CRC specimens. Five (5) replicates were run using multiple barcodes and runs. The data showed that qualitatively, the assay and score are reproducible to 8% tumor proportion, though a decreasing trend in the quantitative score was observed. Therefore, the minimum tumor proportion required for the assay was established as 25% with an average coverage of 200X. Separately, regardless of the tumor proportion, data showed that the score is robust across the MSIsensor score range (refer to Table 9 above and Table 12).

Table 12. Replicate Testing of the MSI Sensor Score at 8% Tumor Purity

Tumor Purity	Coverage	# Total site	# Unstable loci	MSIsensor Score (%)
Diluted to 8%	517	1420	182	13
Diluted to 8%	562	1389	175	13
Diluted to 8%	555	1352	185	14
Diluted to 8%	502	1361	135	10
Diluted to 8%	378	1273	152	12

iv. *DNA-Input:* The validated DNA concentration is the amount at which the average read depth over the exon regions was maintained at the criteria established (e.g., ≥20 reads per base), and have 100% positive mutation call rate. The optimized and recommended DNA concentration for the assay is 250ng. The DNA input range 50-250ng. was assessed for accuracy and sequencing failures as a function of the input DNA concentration. The results show that assay performance in terms of sequencing failures is a function of genomic DNA input values as shown in Table 13.

Table 13. Sequencing Failures Relative to DNA Input

DNA Input	Success	Sequencing Failure
250ng	97%	3%
201-249ng	87%	13%
151-200ng	87%	13%
101-150ng	81%	19%
50-100ng	78%	22%

c) Linearity/assay reportable range:
Not applicable

d) Traceability (controls, calibrators, or methods):
The MSK-IMPACT is not traceable to any known standard. Controls and quality metrics are described in the device description section.

e) Stability:

Reagent stability is based on manufacturer expiration dating, and supported by MSK verification. Stability of the reagents is monitored through the use of consistent controls.

f) Expected values:

The laboratory follows protocols for the use of controls consistent with CLIA regulation. The MSK-IMPACT does not use calibrators; however, the verification of mutant allele frequency is maintained by analysis of a pooled control with expected allele frequencies.

g) Analytical specificity:

High analytical specificity is maintained by paired tumor/matched normal sequencing, and was established during assay optimization.

Interference:

The MSK-IMPACT assay pre-analytic steps are designed to minimize interference. The invalid rates in the historical testing from >10,000 samples support that any interference from any challenging tissues is minimized.

h) Assay cut-off*:*

The MSK-IMPACT does not report mutations below 2% for known hotspot mutations and 5% for non-hotspot mutations.

i) Comparison studies:

i. Method comparison:

The MSK-IMPACT assay is designed to detect SNVs and small indels in 6284 exons from 468 genes. The accuracy of the MSK-IMPACT was assessed by comparison of the MSK-IMPACT result to the original results obtained with the validated orthogonal methods. Testing was conducted per protocol. A total of 267 unique mutations in 433 FFPE tumor specimens representing 48 exons in 20 genes were tested and are listed in Table 14 below.

Table 14. Mutations Represented in the Accuracy Summary Per Gene

Gene (n=20)	#Samples (n=433)	Exon (n=48)	Type	Mutations Assessed
AKT	10	exon3	SNV	E17K
ALK	3	exon23	SNV	F1174V/L;S1205F
	4	exon25	SNV	R1275Q;R1260T
BRAF	11	exon11	SNV	G466V/R;S467L;G469*
	19	exon15	SNV	D594G;V600*;K601I
EGFR	10	exon18	SNV	G719A/S; G724S
	12	exon19	**DEL**	745_750del; 746_748del; 746_750del; 747_753del; K754fs

Gene (n=20)	#Samples (n=433)	Exon (n=48)	Type	Mutations Assessed
	10	exon20	SNV	T790M
	16	exon20	**INS**	M766_A767insASV; V769_D770insDNP; D770_N771ins*;P772_H773ins*; H773_V774insY/H
	9	exon21	SNV	L858R
ERBB2	7	exon19	SNV	L755S;I767M;D769Y
	16	exon20	**INS**	E770_A771insAYVM; A771_Y772insYVMA;G776_G778ins*
	3	exon20	SNV	V777L;G776V
	7	exon8	SNV	S310F/Y; S305C
FGFR2	1	exon12	SNV	L528H
	1	exon7	SNV	S252W
	1	exon9	SNV	Y375C
FGFR3	2	exon18	SNV	P797L
	1	exon7	SNV	A261V;A265V
	5	exon9	SNV	F384L
	1	exon9	**INS**	G370_S371insH
GNA11	7	exon5	SNV	Q209L
GNAQ	5	exon5	SNV	Q209P/L
GNAS	5	exon8	SNV	R201C/H
HRAS	3	exon2	SNV	G10A; G13D/V
	5	exon3	SNV	A59V; Q61R/L/K
IDH1	8	exon4	SNV	R132G/C/H
IDH2	5	exon4	SNV	R172*;R140Q
	1	exon4	**DEL**	T146Lfs*15
KIT	9	exon11	**INS; DEL**	K550fs; 552_557del; 556_558del; 556_561del; 558_565del; 559_566del; P573_T574insTQLPS
	9	exon11	SNV	V555L; W557G;V559D; D572G;L576P.
	6	exon13	SNV	V654A; K642E
	5	exon17	SNV	D816H; D820E; N822K
	10	exon9	**INS**	S501_A502insAY; A502_Y503dup
KRAS	16	exon2	SNV	G12*; G13D
	13	exon3	SNV	Q61*
	10	exon4	SNV	K117N;G138E;A146*
MET	13	exon14	SNV	D1010*; Exon14 skipping
	19	exon14	**DEL**	Exon14 skipping; Other splicing defects
NRAS	4	exon2	SNV	G13*
	12	exon 3	SNV	Q61*
PDGFRA	12	exon18	SNV	D842V/I
	1	exon12	SNV	V561D
PIK3CA	4	exon10	SNV	E545A/K; E542K
	2	exon21	SNV	H1047R/Y
	1	exon21	**INS**	X1069delinsFL
	8	exon2	SNV/MNV	F83L;R88Q;R93Q;K111E/N
	2	exon2	**DEL**	E110del; 112_113del
	9	exon5	SNV	V344M;N345I/K
	9	exon8	SNV	E418K;C420R;P449R;E453K/Q
	1	exon8	**DEL**	E453_D454del
TP53	9	exon4	SNV/MNV	W53X;W91X;Q100X;G105V/C; S106R; F113C
	6	exon4	DEL	L35fs;P67fs;A84fs;109_109del;G108fs;

Gene (n=20)	#Samples (n=433)	Exon (n=48)	Type	Mutations Assessed
				R110fs
	3	exon4	INS	V73fs;L114fs;C124fs
	6	exon5	SNV	K132Q;W146X; Y163C; R175H; R158H
	3	exon5	INS	P153fs; M160_A161insRA; Q167_M170dup
	9	exon5	DEL	K132fs;A138fs;P152fs; R156fs; V157_R158del; K164fs; H178fs;D184fs
	2	exon6	SNV	R213L/X
	8	exon6	**DEL**	G187fs; L188fs; P191_Q192del; R196_L201del; D207fs; R209fs; F212fs
	10	exon7	SNV/MNV	Y234C; Y236C; M237I; R248G/Q; R249S; T256P
	3	exon7	**INS**	S241dup; R249fs; T253dup
	6	exon7	**DEL**	S241fs; M243X; G244fs; M246X; I255del; L257fs
	4	exon8	SNV/MNV	V272K; C275X; R282W; T284K
	4	exon8	**INS**	C275fs; N288fs; G302fs
	5	exon8	**DEL**	N263_N268del; N263fs; R267fs; P278fs; P301fs
	6	exon10	SNV	R337L; R342X; R337C
	1	exon10	**INS**	L344fs

Of the 433 specimens, 418 met the criteria of ≥200X coverage, 15 samples (3.5%) failed to achieve average coverage above 200X. The known mutation associated with each sample was successfully detected in 432 out of 433 cases (99.8% with two-sided 95% CI of (98.7%, 100.0%)). One discordant case was observed in sample M-1994-BC-T, which was used for the validation of insertions in EGFR exon 20. The known mutation for this sample was a 12bp duplication which began in the intron 5' of EGFR exon 20, potentially creating an alternative splice site acceptor for the exon. This duplication event was detected by the indel calling pipeline but was incorrectly filtered out because of the calling algorithm. (The filtering algorithm was modified to improve the detection accuracy for such mutations.)

The MSK-IMPACT accuracy study included 159 unique SNV/MNVs from 20 genes (45 exons), 49 unique deletions from 6 genes (11 exons), and 39 unique insertions from 6 genes (10 exons). Performance was stratified by mutation type and gene for percent positive agreement (PPA) with 95% confidence interval (CI). Results are shown in Table 15A-C.[2]

[2] Performance may be overestimated because specimens were selected based on the availability of results by the orthogonal methods (i.e., the specimen set may lack challenging specimens).

Table 15A.Percent Positive Agreement for SNV/MNVs by Gene

Gene	Number of exons	Number of unique mutations	Number of samples	PPA (95% CI)
AKT1	1	1	10	**100.0% (69.2%, 100.0%)**
ALK	2	5	7	**100.0% (59.0%, 100.0%)**
BRAF	2	13	30	**100.0% (88.4%, 100.0%)**
EGFR	3	6	30	**100.0% (88.4%, 100.0%)**
ERBB2	3	12	17	**100.0% (80.5%, 100.0%)**
FGFR2	3	3	3	**100.0% (29.2%, 100.0%)**
FGFR3	3	3	8	**100.0% (63.1%, 100.0%)**
GNA11	1	1	7	**100.0% (59.0%, 100.0%)**
GNAQ	1	2	5	**100.0% (47.8%, 100.0%)**
GNAS	1	2	5	**100.0% (47.8%, 100.0%)**
HRAS	2	7	8	**100.0% (63.1%, 100.0%)**
IDH1	1	3	8	**100.0% (63.1%, 100.0%)**
IDH2	1	4	6	**100.0% (54.1%, 100.0%)**
KIT	3	13	20	**100.0% (83.2%, 100.0%)**
KRAS	3	15	39	**100.0% (91.0%, 100.0%)**
MET	1	9	13	**100.0% (75.3%, 100.0%)**
NRAS	2	6	16	**100.0% (79.4%, 100.0%)**
PDGFRA	2	3	13	**100.0% (75.3%, 100.0%)**
PIK3CA	4	19	32	**100.0% (89.1%, 100.0%)**
TP53	6	32	37	**100.0% (90.5%, 100.0%)**

Table 15B. Percent Positive Agreement for insertions by gene

Gene	Number of exons	Number of unique mutations	Number of samples	PPA (95% CI)
EGFR	1	12	16	**93.8% (69.8%, 100.0%)**
ERBB2	1	8	16	**100.0% (79.4%, 100.0%)**
FGFR3	1	1	1	**100.0% (2.5%, 100.0%)**
KIT	1	3	10	**100.0% (69.2%, 100.0%)**
PIK3CA	1	1	1	**100.0% (2.5%, 100.0%)**
TP53	5	14	14	**100.0% (76.8%, 100.0%**

Table 15C. Percent Positive Agreement for deletions by gene

Gene	Number of exons	No. unique mutations	Number of samples	PPA (95% CI)
EGFR	1	6	12	**100.0% (73.5%, 100.0%)**
IDH2	1	1	1	**100.0% (2.5%, 100.0%)**
KIT	1	7	9	**100.0% (66.4%, 100.0%)**
MET	1	18	19	**100.0% (82.4%, 100.0%)**
PIK3CA	2	3	3	**100.0% (29.2%, 100.0%)**
TP53	5	14	14	**100.0% (76.8%, 100.0%)**

ii. Supplemental Method Comparison Study for Wildtype Calls:
A supplemental study was conducted to assess accuracy for 33 "hotspots" within 10 genes. A total of 95 specimens were tested and the accuracy of

MSK-IMPACT results at all 33 positions was compared to results obtained with a single orthogonal method. Within the 95 specimens, there were 109 mutations across samples and 3026 wild-type calls. Variant-level concordance (PPA and NPA) was 100% for all results with two-sided 95% confidence intervals of (96.7%, 100.0%) for mutations (PPA) and (99.9%, 100.0%) for wild-type locations (NPA).

iii. *Method Comparison of the MSK-IMPACT MSIsensor:*
The somatic MSI status is inferred by interrogating all available genomic microsatellites covered by MSK-IMPACT within tumor samples against the matched normal DNA using the MSIsensor program as described in the Device Description section above. An MSIsensor score assigned to each tumor sample is used to distinguish MSS from MSI-H by MSIsensor.

The cutoff was first established using a training specimen dataset consisting of 138 colorectal cancer (CRC) and 40 endometrial carcinoma (EC) specimens with matched normal and having MSI status results from a validated MSI-PCR or MMR IHC test. MSIsensor scores ranged from 0 to 47.7 for CRC and 0 to 43.7 for EC. Based on concordance to either mismatch repair immunohistochemistry (MMR IHC) for MLH1, MSH2, MSH6 and PMS2 expression, or a commercially available PCR assay that detects 5 mononucleotide microsatellite loci including MR-21, BAT-25, MONO-27, NR-24 and BAT-26, a MSIsensor cut-off of 10 was established to delineate microsatellite stable (MMS) from high microsatellite instability (MSI-H).

A separate data set was obtained to validate this cut-off. A retrospective-prospective chart review of 135 CRC patients was conducted to identify cases that had both MSK-IMPACT MSI results and results by a validated IHC panel (MLH1, MSH2, MSH6 and PMS2). A total of 66 specimens had both sets of results. Of these, there were two discordant cases. The estimated positive predictive value (PPV) was 92.3% (12/13) with two-sided 95% confidence interval of 64.0%-99.8% and the estimated negative predictive value (NPV) was 98.1%. (52/53) with two-sided 95% confidence interval of 90.0%, 100.0%. The results are shown in Table 16 below.

Table 16. MSIsensor Results Compared to IHC MMR for CRC

CRC/EC Concordance with IHC		**MMR-D***	**MMR-P***	**Total**
MSI Sensor	**MSI-H ≥ 10**	12	1	13
	MSS < 10	1	52	53
Total		13	53	66
PPV = 92.3% (12/13) 95% CI 64.0%-99.8%				
NPV = 98.1%. (52/53) 95% CI 90.0%, 100.0%				

*MMR-D refers to deficient in mismatch repair proteins and MMR-P indicates not deficient

To evaluate the ability of the MSIsensor to determine MSI status in cancer types other than CRC or EC cancer types, 119 unique non-CRC and non-EC tumor-normal pair samples covering 25 tumor types were assessed for MSI by both MSIsensor and a validated MSI-PCR test. The results are shown in Table 17. Excluding the specimens without a MSI-PCR result from the total number of specimens analyzed, PPV is 46/49=93.9% (83.1%, 98.7%), and NPV is 58/60=96.7% (88.5%, 99.6%). When including all missing data in the analysis (i.e., consider all PCR unknown data as discordant results), the PPV=46/59=78.0% (65.3%, 87.7%), NPV= 58/60=96.7% (88.5%, 99.6%). (The MSIsensor MSI-H/MSS definition is based on genome wide analysis of over 1000 microsatellite markers and not based on the 5 or 7 MSI loci described in current clinical practice guidelines.)

Table 17. MSIsensor Results Compared to PCR 5 Loci MSI Panel for Other Cancer Types

Non CRC/EC concordance with MSI-PCR		**PCR Results**			
		MSI-H	**MSI-L/MSS**	**Unknown***	**Total**
MSIsensor	MSI-H (≥10)	46	3	10	59
	MSS (≥2 & <10)	2	58	0	60
	Total	48	61	10	119
Excluding missing specimens with 95%CI	PPV is 46/49=93.9% 95%CI (83.1%, 98.7%)				
	NPV is 58/60=96.7% (88.5%, 99.6%)				
Accounting for missing specimens with 95%CI	PPV=46/59=78.0% (65.3%, 87.7%)				
	NPV= 58/60=96.7% (88.5%, 99.6%)				

* In exploratory analysis, the 10 without PCR results were all MMR-D by IHC, consistent with the MSI-H by MSIsensor findings.

MSI Supplemental Information:
The mean, median and range of MSIsensor score was determined in a large cohort of 10,900 patients with 66 different types advanced solid tumor. The MSIsensor scores ranged from 0 to 48.5, mean 1.2, median 0.4. The prevalence of MSI-H by MSIsensor was also determined, and the findings are consistent with the MSI-H prevalence as described in the literature (data not shown).

3. Clinical Performance:

MSK-IMPACT assay is a molecular profiling platform using next generation sequencing to detect somatic alterations (point mutations and small insertions and deletions and microsatellite instability) in tumor specimens using a 468 gene panel. The genes in the panel were selected for their role in cancer pathogenesis and tumor

suppression, or for clinical or mechanistic information of relevance in the management of cancer patients. The assay reports mutations under two categories: "Cancer mutations with evidence of clinical significance" and "Cancer mutations with potential clinical significance" consistent with the intended use clinical settings. Mutations with evidence of clinical significance are represented in professional guidelines as established by consensus opinion of experts in the health care community.

Clinical Evidence Curation:
MSK-IMPACT uses a clinical evidence curation resource (OncoKB) to facilitate the clinical interpretation of detected mutations. OncoKB is a knowledge base that includes biologic, clinical and therapeutic information curated from multiple information resources including professional guidelines and recommendations, therapeutic labeling, disease specific expert and advocacy group recommendations, and medical literature. OncoKB information is publicly available through an interactive web site. Classification criteria were developed by MSK to communicate the level of clinical evidence available for individual mutations in the test report. The mutations are reported under two categories (i.e., cancer mutations panel with evidence of clinical significance and cancer mutations panel with potential clinical significance) based on the pre-specified classification criteria. OncoKB undergoes periodic updates through the review of new information by a panel of experts.

4. Clinical cut-off:

Not applicable.

5. Expected values:

The prevalence of somatic mutations was explored through a large-scale, prospective clinical sequencing initiative using a comprehensive assay, MSK-IMPACT, through which tumor and matched normal sequence data from a cohort of more than 10,000 patients with advanced cancer and available pathological and clinical annotations was compiled. The prevalence of mutations and cancer type via the link to the publicly accessible data on cohort of tested patients and available pathological and clinical annotations was published by Zehir, A. et al., "Mutational landscape of metastatic cancer revealed from prospective clinical sequencing of 10,000 patients." 2017. 23(6):703-713. This information is also available at the following website. (http://www.cbioportal.org/study?id=msk_impact_2017#summary)

N. Instrument Name
Illumina HiSeq 2500 (qualified by MSK)

O. System Descriptions:

1. Modes of Operation:
The Illumina HiSeq2500 is a high throughput sequencing system using Sequencing-By-Synthesis chemistry.

2. Software:
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes _X_ or No ___

3. Level of Concern:
Moderate

4. Specimen Handling
Refer to Device Description section above.

5 Calibration and Quality Controls:
Refer to Device Description section above.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section Above:

To support the continuous implementation of process improvements to the existing 468 gene panel, protocols with specific procedures and acceptance criteria for modifications that could be anticipated at the time of submission were provided, reviewed by FDA, and cleared as part of this marketing authorization. Future modifications by MSK for the specified types of changes below that are made in accordance with the applicable validation strategy and the pre-specified success criteria would not require a new 510(k) submission. Significant changes such as adding new genes or variant types to the panel would require a new submission with appropriate validation.

Type of change	**Validation Strategy**	**Pre-specified success criteria**
New pre-analytical protocol, kits or reagents	Sequence at least 10 specimens with known mutations. Measure sequence coverage distribution, and call somatic mutations in all samples.	For cases sequenced to >200x, ensure that 95% of exons are covered to 100x or more. Concordance for known mutations should be >95%.
New library preparation protocol, kits, or reagents	Sequence at least 40 DNA specimens (tumor / normal pairs) or three pools previously sequenced by MSK-IMPACT. Measure sequence coverage distribution, and call	For cases sequenced to >200x, ensure that 95% of exons are covered to 100x or more. Concordance for calling somatic mutations with variant allele fraction >10% should be >98%.

Type of change		Validation Strategy	Pre-specified success criteria
		somatic mutations in all samples.	
Changes to probes for already analytically validated genes		Re-capture existing sequence libraries from at least 3 runs (at least 40 samples) with new probes, sequence, and analyze.	For cases sequenced to >200x, ensure that 95% of exons in analytically validated genes are covered to 100x or more. Concordance for calling somatic mutations with variant allele fraction >10% should be >98%.
New sequencing instrument or reagents using similar chemistry and technology, and the sequence depth and read length are not changed from previous platform.		Re-sequence existing captured libraries from at least 3 runs, and call somatic mutations in all samples.	Sequence coverage distribution and GC bias across targeted regions should be within 5% of prior sequencing runs. Concordance for calling somatic mutations with variant allele fraction >10% should be >98%.
Bioinformatics pipeline	Update to underlying annotation database or transcript isoforms	Reanalyze FASTQ files (raw sequencing reads) from at least 3 runs (at least 40 samples). Compare variants calls between the clinical analysis results and the current modified results	Confirm the changes do not change the variant call results. Confirm the annotations for the unaffected transcripts do not change. Confirm the annotations for the affected transcripts are modified as expected.
	Update to data management system and system database	Reanalyze FASTQ files (raw sequencing reads) from at least 3 runs (at least 40 samples) in production mode. Compare variants calls between the clinical analysis results and the current modified results	Ensure that all previously called mutations are recovered and the variants in the database of results are concordant with the variants in the pipeline output files

Type of change		Validation Strategy	Pre-specified success criteria
	Modification to an existing component of the analysis pipeline (e.g., tool or algorithm) where the underlying algorithm or main parameter settings (e.g. minimal coverage/VAF threshold for SNV/indel calling; MSIsensor score cut-off for MSI-H calling, etc.) are not changed.	Reanalyze FASTQ files (raw sequencing reads) from at least 3 runs (at least 40 samples). Compare variants calls between the clinical analysis results and the current modified results	Ensure that all previously called mutations are recovered and that newly detected mutations can be explained by pipeline modifications.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable, and the special controls for this device type.

R. Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

S. Identified Risks to Health and Identified Mitigations:

Identified Risks to Health	Identified Mitigations
Incorrect performance of the test leading to false positives, false negatives	General controls and special control (b)(1)
Incorrect interpretation of test results	General controls and special controls (b)(1)(iii)(E) and (b)(2)

T. Benefit/Risk Determination

Summary of the Benefit(s)	The MSK-IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets) test provides comprehensive genomic profiling of tumor samples (point mutations, small insertions and deletions and microsatellite instability), in previously diagnosed cancer patients, for use by qualified health professionals in accordance with professional guidelines. There is probable clinical benefit of the device based on evidence from peer-reviewed clinical literature and analytical performance of the device in identifying genomic alterations.
Summary of the Risk(s)	Erroneous device results could adversely influence clinical interpretation and consultation for patients. The risk of an erroneous test result is mitigated by the analytical performance of this device. The accuracy of the test was demonstrated using clinical specimens covering a variety of clinically relevant variants across multiple tumor types and variant categories (i.e., point mutations, small insertions and deletions and microsatellite instability). The output of this device demonstrated a high degree of analytical concordance to comparator assays across multiple tumor types. Thus, the probable risk of this device is mitigated by the supportive analytical performance for the device, when clinical limitations and the established special controls, in combination with general controls, are considered.
Summary of Other Factors	Limitations statements in the test report and the established special controls, in combination with general controls, serve to mitigate the risks associated with the use of this device.
Conclusions Do the probable benefits outweigh the probable risks?	The probable clinical benefits of this device, which allows for detection of somatic mutations and MSI status in patients previously diagnosed with cancer, outweigh the probable risks that are mitigated by the special controls established for this device type, in combination with general controls.

U. Conclusion:

The information provided in this *de novo* submission is sufficient to classify this device into class II under regulation 21 CFR 866.6080. FDA believes that special controls, along with the applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type. The device is classified under the following:

Product Code:	PZM
Device Type:	Next Generation Sequencing Based Tumor Profiling Test.
Class:	II (special controls)
Regulation:	21 CFR 866.6080

(a) *Identification.* A next generation sequencing (NGS) based tumor profiling test is a qualitative in vitro diagnostic test intended for NGS analysis of tissue specimens from malignant solid neoplasms to detect somatic mutations in a broad panel of targeted genes to aid in the management of previously diagnosed cancer patients by qualified health care professionals.

(b) *Classification.* Class II (special controls). A next generation sequencing based tumor profiling test must comply with the following special controls:

(1) Premarket notification submissions must include the following information:

(i) A detailed description of all somatic mutations that are intended to be detected by the test and that are adequately supported in accordance with paragraph (b)(1)(v) of this section and reported in the test results in accordance with paragraph (b)(2)(iv) of this section, including:

(A) A listing of mutations that are cancer mutations with evidence of clinical significance.

(B) As appropriate, a listing of mutations that are cancer mutations with potential clinical significance.

(ii) The indications for use must specify the following:

(A) The test is indicated for previously diagnosed cancer patients.

(B) The intended specimen type(s) and matrix (e.g., formalin-fixed, paraffin-embedded tumor tissue).

(C) The mutation types (e.g., single nucleotide variant, insertion, deletion, copy number variation or gene rearrangement) for which validation data has been provided.

(D) The name of the testing facility or facilities, as applicable.

(iii) A detailed device description including the following:

(A) A description of the test in terms of genomic coverage, as follows:

(*1*) Tabulated summary of all mutations reported, grouped according to gene and target region within each gene, along with the specific cDNA and amino acid positions for each mutation.

(*2*) A description of any within-gene targeted regions that cannot be reported and the data behind such conclusion.

(B) Specifications for specimen requirements including any specimen collection devices and preservatives, specimen volume, minimum tumor content, specimen handling, DNA extraction, and criteria for DNA quality and quantity metrics that are prerequisite to performing the assay.

(C) A detailed description of all test components, reagents, instrumentation, and software required. Detailed documentation of the device software including but not limited to, software applications and hardware-based devices that incorporate software.

(D) A detailed description of the methodology and protocols for each step of the test, including description of the quality metrics, thresholds, and filters at each step of the test that are implemented for final result reporting and a description of the metrics for run-failures, specimen-failures, invalids, as applicable.

(E) A list of links provided by the device to the user or accessed by the device for internal or external information (e.g., decision rules or databases) supporting clinical significance of test results for the panel or its elements in accordance with paragraphs (b)(1)(v) and (b)(2)(vi) of this section.

(F) A description of internal and external controls that are recommended or provided and control procedures. The description must identify those control elements that are incorporated into the testing procedure.

(iv) Information demonstrating analytical validity of the device according to analytical performance characteristics, evaluated either specifically for each gene/mutation or, when clinically and practically justified, using a representative approach based on other mutations of the same type, including:

(A) Data that adequately supports the intended specimen type (e.g., formalin-fixed, paraffin-embedded tumor tissue), specimen handling protocol, and nucleic acid purification for specific tumor types or for a pan-tumor claim.

(B) A summary of the empirical evidence obtained to demonstrate how the analytical quality metrics and thresholds were optimized.

(C) Device precision data using clinical samples to adequately evaluate intra-run, inter-run, and total variability. The samples must cover all mutation types tested (both positive and negative samples) and include samples near the limit of detection of the device. Precision must be assessed by agreement within replicates on the assay final result for each representative mutation, as applicable, and also supported by sequencing quality metrics for targeted regions across the panel.

(D) Description of the protocols and/or data adequately demonstrating the interchangeability of reagent lots and multiplexing barcodes.

(E) A description of the nucleic acid assay input concentration range and the

evidence to adequately support the range.

(F) A description of the data adequately supporting the limit of detection of the device

(G) A description of the data to adequately support device accuracy using clinical specimens representing the intended specimen type and range of tumor types, as applicable.

(*1*) Clinical specimens tested to support device accuracy must adequately represent the list of cancer mutations with evidence of clinical significance to be detected by the device.

(*2*) For mutations that are designated as cancer mutations with evidence of clinical significance and that are based on evidence established in the intended specimen type (e.g., tumor tissues) but for a different analyte type (e.g., protein, RNA) and/or a measurement (e.g., incorporating a score or copy number) and/or with an alternative technology (e.g., IHC, RT-qPCR, FISH), evidence of accuracy must include clinically adequate concordance between results for the mutation and the medically established biomarker test (e.g., evidence generated from an appropriately sized method comparison study using clinical specimens from the target population).

(*3*) For qualitative DNA mutations not described in paragraph (b)(1)(iv)(G)(*2*) of this section, accuracy studies must include both mutation-positive and wild-type results.

(H) Adequate device stability information.

(v) Information that adequately supports the clinical significance of the panel must include:

(A) Criteria established on what types and levels of evidence will clinically validate a mutation as a cancer mutation with evidence of clinical significance versus a cancer mutation with potential clinical significance.

(B) For representative mutations of those designated as cancer mutations with evidence of clinical significance, a description of the clinical evidence associated with such mutations, such as clinical evidence presented in professional guidelines, as appropriate, with method comparison performance data as described in paragraph (b)(1)(iv)(G) of this section.

(C) For all other mutations designated as cancer mutations with potential clinical significance, a description of the rationale for reporting.

(2) The 21 CFR 809.10 compliant labeling and any product information and test report generated, must include the following, as applicable:

(i) The intended use statement must specify the following:

(A) The test is indicated for previously diagnosed cancer patients.

(B) The intended specimen type(s) and matrix (e.g., formalin-fixed, paraffin-embedded tumor tissue).

(C) The mutation types (e.g., single nucleotide variant, insertion, deletion, copy number variation or gene rearrangement) for which validation data has been provided.

(D) The name of the testing facility or facilities, as applicable.

(ii) A description of the device and summary of the results of the performance studies performed in accordance with paragraphs (b)(1)(iii), (b)(1)(iv), and (b)(1)(v) of this section.

(iii) A description of applicable test limitations, including, for device specific mutations validated with method comparison data to a medically established test in the same intended specimen type, appropriate description of the level of evidence and/or the differences between next generation sequencing results and results from the medically established test (e.g., as described in professional guidelines).

(iv) A listing of all somatic mutations that are intended to be detected by the device and that are reported in the test results under the following two categories or equivalent designations, as appropriate: "cancer mutations panel with evidence of clinical significance" or "cancer mutations panel with potential clinical significance."

(v) For mutations reported under the category of "cancer mutations panel with potential clinical significance," a limiting statement that states "For the mutations listed in [cancer mutations panel with potential clinical significance or equivalent designation], the clinical significance has not been demonstrated [with adequate clinical evidence (e.g., by professional guidelines) in accordance with paragraph (b)(1)(v) of this section] or with this test."

(vi) For mutations under the category of "cancer mutations panel with evidence of clinical significance," or equivalent designation, link(s) for physicians to access internal or external information concerning decision rules or conclusions about the level of evidence for clinical significance that is associated with the marker in accordance with paragraph (b)(1)(v) of this section.

Appendix 1a:
List of hotspot mutations (i.e., commonly somatically mutated in cancers) for all genes in the MSK-IMPACT panel

Gene	Codons
ABL1	G250, Q252, Y253, E255, T315, F317, M351, F359, H396R
AKT1	E17,Q124,G171,E170
AKT2	V140
ALK	K1062,D1091,C1156,M1166,I1171,F1174,L1196,A1234,F1245,I1250,R1275,Y1278
APC	S1234,I1307,E1309,E1317,P1319,G1339,S1341,P1361,P1372,P1373,R1399,S1400, S1407,S1411,V1414,S1415,S1421,T1438,P1439,P1440,T1445,P1453,N1455,E1464, S1465,T1487,L1488,F1491,T1493,E1494,T1537,K1555,T1556,I1557,C1578
AR	T878,T8782,Q581
ARAF	S214
ARID1A	D1850,G2087
ARID2	R314,S297,R285,A1773
ASXL1	Y591,E635,G645,G646,E1102D
ASXL2	R591
ATM	D1853,R3008,R3376,E2164
ATRX	K1936,E625
BARD1	P24
BCL6	R594,R618
BCOR	N1425,N14591
BRAF	G464,G466,G469,Y472,N581,D594,F595,G596,L597,A598_T599,V600,V600_K601, K601,V60010,K6010,G4694,N5810,G4660
CARD11	R170
CBL	Y371,L380,C384,C404,R420Q
CDH1	T263
CDK4	R24
CDKN2A	S43,P48,A57,A68,D74,L78,P81,H83,D84,L97,D108,P114,H831,D1081,P1140
CEBPA	P23,H24,Q83,K304_Q305,E309_T310,Q312_K313,K313_V314,K313_V314,K313, E316_L317,E316_L317insQ
CHEK2	K373,K3732
CIC	R215
CREBBP	R1446,S1680,R14460
CRLF2	F232C
CSF1R	Y969C
CTCF	R377
CTNNB1	D32,S33,G34,I35,H36,S37,T40,T41,T42,A43,P44,S45,G48,K49,E53,K335,S376, S334,D324,T412,G349,S455,C619

DICER1	E1813
DIS3	R382,D488
DNMT1	E432
DNMT3A	G543,R635,S714,F731,R882,R8820
DOT1L	G1386
EGFR	R108,A289,G598,R677,E709,G719,K745_E749,K745_E746,E746_A750,E746_S752,E746_T751,E746_E749,E746_T751,L747_P753,L747_A750,L747_T751,L747_S752,L747_T751,L747_E749,L747,T751,S752_I759,D761,S768,V769_D770,D770_N771,H773_V774,R776,T790,L833,H835,T847,P848,T854,L858,L861,G863,L8587,A2898,R252,R222
EP300	D1399,D13990,C1164
EPHB1	R170
ERBB2	S310,L755,D769,A775_G776,G776,V777,V842,S3108,L7553,E930,R678
ERBB3	V1043,D297,M91
ERBB4	R711
ERCC2	D312
ESR1	Y537
ETV1	R187
ETV6	R369
EZH2	Y646,R690
FBXW7	G423,R465,R479,R505,S582,R689,R4652,R5054,R4792
FGFR2	S252,P253,C382,N549,N550,K659
FGFR3	R248,S249,G370,S371,Y373,G380,A391,K650,G697,S2492,Y3730
FGFR4	V550
FLT3	D835,I836,D8358
FOXL2	C134W
FUBP1	R430
GATA1	M1,S30,V74I
GATA2	G320,L321,L359,R362Q
GNA11	R183,Q209,R256
GNAQ	R183,Q209
GNAS	R201,Q227,R8448
GRIN2A	R1067
HIST1H3B	E74
HNF1A	W206,P291,G292
HRAS	G12,G13,Q61,E62,Q614,G136,G122
IDH1	G70,V71,R132,V178,R13239,P33
IDH2	R140,R172,V294,R1402,R1721
IL7R	K395
IRS2	G1057

JAK1	R873
JAK2	F537_K539,H538_K539,K539,I540_E543,R541_E543,N542_E543,E543_D544, V617, R683
JAK3	A572,A573,R657Q
KDR	S1100,E759
KEAP1	R470
KIT	D52,D419,Y503_F504,K509,M541,K550_K558,P551_V555,P551_E554,P551_M552, Y553_K558,E554_K558,Q556_V560,W557_K558,W557,W557_V559,W557_E561, W557_V559,K558_E562,K558,K558_V560,V559,V559_V560,V559_E561,V560,E56 Y570_L576,D572,L576,D579,K642,V654,T670,S715,D816,K818,D820,N822,Y823,V 25, D8160
KMT2C	V656
KRAS	G10_A11,G12,G13,V14,L19,Q22,T58,A59,Q61,K117,A146,G1242,G133,Q619, A146
LATS2	A3243,G3630
MAP2K1	Q56,K57,D67,P124,P1240,F53,E203
MAP2K4	R134
MAP3K1	S1330,S939
MAPK1	E322
MAX	R600
MED12	L36,Q43,G44,L1224,L12240
MEF2B	D83V
MET	T1010,Y1248,Y1253,M1268,K1360
MLL3	K2797
MPL	S505,W515,W515R
MSH6	F1088,T1219I
MTOR	S22152,F1888
MYC	T58
MYCN	P44
MYD88	S219,S243,L265P
NF1	L844
NFE2L2	D29,L30,G31,R34,E79,T80,G81,E82,E794,D294,R342
NOTCH1	L1574,L1575,V1578,L1585,L1586,F1592,L1593,L1594,R1598,R1599,L1600, L1601,L1678,L1679,Q2460,P2514,A1944
NOTCH2	E385,N463
NPM1	W288,W290
NRAS	G12,G13,A18,G60,Q61,Q6193,G128,G138
NTRK1	T264
PAK7	E144
PARP1	I562
PAX5	P80R

PDGFRA	V561,S566_E571,N659,D842,I843_D846,D1071N
PIK3C2G	S670
PIK3CA	R38,E81,R88,R93,G106,R108,K111,G118,V344,N345,C378,E418,C420,E453, P539,E542,E545,Q546,E547,S553,K567,H701,E726,C901,G1007,Y1021,T1025, M1043,N1044,D1045,A1046,H1047,G1049,T1052,A1066,N1068,E54534,H104715, E54217,Q5467,R887,N3453,C4209,G1187,E7265,E4535, K1113, R932, R382, R1080, E39
PIK3R1	G376,D560,N564,K567
POLE	P2864,V4111
PPP2R1A	P179,R182,R183,S256,W257,R258,R1832
PREX2	G233C
PTCH1	P1315
PTEN	K6,P38,L42,H61,Y68,Y76,Y88,H93,I101,C105,L112,H123,A126,G129,R130,C136, A151,Y155,R159,K164,G165,S170,R173,N184,E242,P246,P248,C250,K267,V290, L318,T319,T321,N323,F347,R1309,R1730,K128
PTPN11	G60,D61,E69,A72,T73,E76,S502,G503,Q510
PTPRD	S431,P666
RAC1	P295
RAF1	S2570
RET	E632_T636,E632_L633,C634,M918T
RHOA	E40,Y42
RICTOR	S1101
RIT1	M90
RUNX1	L56,R107,D198,R201,R204,R162,R205
SDHA	S4560,A466,R465
SF3B1	E622,R625,H662,K666,K700,K7002
SMAD4	A118,D351,R361,G386,R3619,D537,P356
SMARCA4	T910,G1232
SMARCB1	R377,A382,P383
SMO	W535L
SPOP	F133,F1338,W131,F102
SRSF2	P95,P95_R102,P107H
STAG2	R370
STK11	D194,P281,F354L
TET2	C25,C262,Q764,F868,R1261,H1380,V1718L
TNFAIP3	L324
TP53	E11,D49,P82,T102,G105,Y107,R110,L111,F113,K120,T125,Y126,Y126_K132,S127, P128,L130,N131,K132,M133,F134,C135,A138,K139,T140,C141,P142,V143,Q144, L145,V147,S149,P151,P152,P153,G154,T155,R156,V157,R158,A159,M160,A161,

	I162,Y163,K164,S166,H168,M169,T170,E171,V172,V173,R174,R175,C176,P177, P177_C182,H178,H179,E180,R181,C182,D184,D186,G187,P190,P191,Q192,H193, L194,I195,R196,V197,E198,G199,N200,R202,V203,Y205,D208,R209,T211,F212,R21 , ,S215,V216,V217,V218,Y220,E224,G226,S227,D228,C229,T230,I232,Y234,N235,Y2 6, M237,C238,N239,S240,S241,C242,M243,G244,G245,M246,N247,R248,R249,P250 I251,L252,T253,I254,I255,L257,E258,D259,G262,L265,G266,R267,F270,E271,V272, R273,V274,C275,A276,C277,P278,G279,R280,D281,R282,R283,T284,E285,E286,E28 7, N288,R290,K291,K292,E294,P300,P301,S303,K320,G334,R337,R27328,R24892, R17538,R2820,G2451,Y2202,H1938,H1797,R1583,C1763,P2783,Y1633,R2800, G2660,I1950,S2419,R2499,V1577,C2386,E2856,R3375,G2445,V1733,P1512,C2752, K1321,Y2050,V2720,C1359,D2818,E2718,V2168,M2378,Y2347,E2867,L1946, A1596,R2675,S1275,C2425,Y2364,C1414,F2704,A1613,V2743,S2153,R2132,H2142, R1101,N2390,T1550,P1520,P2500,G1050,L1300,Q136,F109
TP63	R379
TSC2	N1515
TSHR	M453,I486,L512,I568,D619,A623,L629,I630,T632,D633,D633E
U2AF1	S34,Q157,S347
VHL	V62,S65,S72,V74,F76,N78,S80,P81,L85,P86,L89,N90,S111,G114,H115,L118,D121, L128,V130,G144,F148,I151,L153,V155,L158,E160,C162,V166,R167,L169,L184
WT1	V303,R312,A314,R394,D396,R462
XPO1	E571,R749

Appendix 1b: List of genes/transcripts included on the MSK-IMPACT panel

Gene Name	Transcript ID
ABL1	NM_005157
ACVR1	NM_001111067
AGO2	NM_012154
AKT1	NM_001014431
AKT2	NM_001626
AKT3	NM_005465
ALK	NM_004304
ALOX12B	NM_001139
AMER1	NM_152424
ANKRD11	NM_013275
APC	NM_000038
AR	NM_000044
ARAF	NM_001654
ARID1A	NM_006015
ARID1B	NM_020732
ARID2	NM_152641
ARID5B	NM_032199
ASXL1	NM_015338
ASXL2	NM_018263
ATM	NM_000051
ATR	NM_001184
ATRX	NM_000489
AURKA	NM_003600
AURKB	NM_004217
AXIN1	NM_003502
AXIN2	NM_004655
AXL	NM_021913
B2M	NM_004048
BABAM1	NM_001033549
BAP1	NM_004656
BARD1	NM_000465
BBC3	NM_001127240
BCL10	NM_003921
BCL2	NM_000633
BCL2L1	NM_138578
BCL2L11	NM_138621
BCL6	NM_001706
BCOR	NM_001123385
BIRC3	NM_182962
BLM	NM_000057
BMPR1A	NM_004329
BRAF	NM_004333
BRCA1	NM_007294
BRCA2	NM_000059
BRD4	NM_058243
BRIP1	NM_032043
BTK	NM_000061
CALR	NM_004343
CARD11	NM_032415
CARM1	NM_199141
CASP8	NM_001080125
CBFB	NM_022845
CBL	NM_005188
CCND1	NM_053056
CCND2	NM_001759
CCND3	NM_001760
CCNE1	NM_001238
CD274	NM_014143
CD276	NM_001024736
CD79A	NM_001783
CD79B	NM_001039933
CDC42	NM_001791
CDC73	NM_024529

CDH1	NM_004360
CDK12	NM_016507
CDK4	NM_000075
CDK6	NM_001145306
CDK8	NM_001260
CDKN1A	NM_078467
CDKN1B	NM_004064
CDKN2Ap14ARF	NM_058195
CDKN2Ap16INK4A	NM_000077
CDKN2B	NM_004936
CDKN2C	NM_078626
CEBPA	NM_004364
CENPA	NM_001809
CHEK1	NM_001274
CHEK2	NM_007194
CIC	NM_015125
CREBBP	NM_004380
CRKL	NM_005207
CRLF2	NM_022148
CSDE1	NM_001242891
CSF1R	NM_005211
CSF3R	NM_000760
CTCF	NM_006565
CTLA4	NM_005214
CTNNB1	NM_001904
CUL3	NM_003590
CXCR4	NM_003467
CYLD	NM_001042355
CYSLTR2	NM_020377
DAXX	NM_001141970
DCUN1D1	NM_020640
DDR2	NM_006182
DICER1	NM_030621
DIS3	NM_014953
DNAJB1	NM_006145
DNMT1	NM_001379
DNMT3A	NM_022552
DNMT3B	NM_006892
DOT1L	NM_032482
DROSHA	NM_013235
DUSP4	NM_001394
E2F3	NM_001949
EED	NM_003797
EGFL7	NM_201446
EGFR	NM_005228
EIF1AX	NM_001412
EIF4A2	NM_001967
EIF4E	NM_001130678
ELF3	NM_004433
EP300	NM_001429
EPAS1	NM_001430
EPCAM	NM_002354
EPHA3	NM_005233
EPHA5	NM_004439
EPHA7	NM_004440
EPHB1	NM_004441
ERBB2	NM_004448
ERBB3	NM_001982
ERBB4	NM_005235
ERCC2	NM_000400
ERCC3	NM_000122
ERCC4	NM_005236
ERCC5	NM_000123
ERF	NM_006494
ERG	NM_182918
ERRFI1	NM_018948

ESR1	NM_001122740
ETV1	NM_001163147
ETV6	NM_001987
EZH1	NM_001991
EZH2	NM_004456
FAM175A	NM_139076
FAM46C	NM_017709
FAM58A	NM_152274
FANCA	NM_000135
FANCC	NM_000136
FAT1	NM_005245
FBXW7	NM_033632
FGF19	NM_005117
FGF3	NM_005247
FGF4	NM_002007
FGFR1	NM_001174067
FGFR2	NM_000141
FGFR3	NM_000142
FGFR4	NM_213647
FH	NM_000143
FLCN	NM_144997
FLT1	NM_002019
FLT3	NM_004119
FLT4	NM_182925
FOXA1	NM_004496
FOXL2	NM_023067
FOXO1	NM_002015
FOXP1	NM_001244814
FUBP1	NM_003902
FYN	NM_153047
GATA1	NM_002049
GATA2	NM_032638
GATA3	NM_002051
GLI1	NM_005269
GNA11	NM_002067
GNAQ	NM_002072
GNAS	NM_000516
GPS2	NM_004489
GREM1	NM_013372
GRIN2A	NM_001134407
GSK3B	NM_002093
H3F3A	NM_002107
H3F3B	NM_005324
H3F3C	NM_001013699
HGF	NM_000601
HIST1H1C	NM_005319
HIST1H2BD	NM_021063
HIST1H3A	NM_003529
HIST1H3B	NM_003537
HIST1H3C	NM_003531
HIST1H3D	NM_003530
HIST1H3E	NM_003532
HIST1H3F	NM_021018
HIST1H3G	NM_003534
HIST1H3H	NM_003536
HIST1H3I	NM_003533
HIST1H3J	NM_003535
HIST2H3C	NM_021059
HIST2H3D	NM_001123375
HIST3H3	NM_003493
HLA-A	NM_001242758
HLA-B	NM_005514
HNF1A	NM_000545
HOXB13	NM_006361
HRAS	NM_001130442
ICOSLG	NM_015259

ID3	NM_002167
IDH1	NM_005896
IDH2	NM_002168
IFNGR1	NM_000416
IGF1	NM_001111285
IGF1R	NM_000875
IGF2	NM_001127598
IKBKE	NM_014002
IKZF1	NM_006060
IL10	NM_000572
IL7R	NM_002185
INHA	NM_002191
INHBA	NM_002192
INPP4A	NM_001134224
INPP4B	NM_001101669
INPPL1	NM_001567
INSR	NM_000208
IRF4	NM_002460
IRS1	NM_005544
IRS2	NM_003749
JAK1	NM_002227
JAK2	NM_004972
JAK3	NM_000215
JUN	NM_002228
KDM5A	NM_001042603
KDM5C	NM_004187
KDM6A	NM_021140
KDR	NM_002253
KEAP1	NM_203500
KIT	NM_000222
KLF4	NM_004235
KMT2A	NM_001197104
KMT2B	NM_014727
KMT2C	NM_170606
KMT2D	NM_003482
KNSTRN	NM_033286
KRAS	NM_033360
LATS1	NM_004690
LATS2	NM_014572
LMO1	NM_002315
LYN	NM_002350
MALT1	NM_006785
MAP2K1	NM_002755
MAP2K2	NM_030662
MAP2K4	NM_003010
MAP3K1	NM_005921
MAP3K13	NM_004721
MAP3K14	NM_003954
MAPK1	NM_002745
MAPK3	NM_002746
MAPKAP1	NM_001006617
MAX	NM_002382
MCL1	NM_021960
MDC1	NM_014641
MDM2	NM_002392
MDM4	NM_002393
MED12	NM_005120
MEF2B	NM_001145785
MEN1	NM_000244
MET	NM_000245
MGA	NM_001164273
MITF	NM_198159
MLH1	NM_000249
MPL	NM_005373
MRE11A	NM_005591
MSH2	NM_000251

MSH3	NM_002439
MSH6	NM_000179
MSI1	NM_002442
MSI2	NM_138962
MST1	NM_020998
MST1R	NM_002447
MTOR	NM_004958
MUTYH	NM_001128425
MYC	NM_002467
MYCL1	NM_001033082
MYCN	NM_005378
MYD88	NM_002468
MYOD1	NM_002478
NBN	NM_002485
NCOA3	NM_181659
NCOR1	NM_006311
NEGR1	NM_173808
NF1	NM_001042492
NF2	NM_000268
NFE2L2	NM_006164
NFKBIA	NM_020529
NKX2-1	NM_001079668
NKX3-1	NM_006167
NOTCH1	NM_017617
NOTCH2	NM_024408
NOTCH3	NM_000435
NOTCH4	NM_004557
NPM1	NM_002520
NRAS	NM_002524
NSD1	NM_022455
NTHL1	NM_002528
NTRK1	NM_002529
NTRK2	NM_006180
NTRK3	NM_001012338
NUF2	NM_031423
NUP93	NM_014669
PAK1	NM_002576
PAK7	NM_177990
PALB2	NM_024675
PARK2	NM_004562
PARP1	NM_001618
PAX5	NM_016734
PBRM1	NM_018313
PDCD1	NM_005018
PDCD1LG2	NM_025239
PDGFRA	NM_006206
PDGFRB	NM_002609
PDPK1	NM_002613
PGR	NM_000926
PHOX2B	NM_003924
PIK3C2G	NM_004570
PIK3C3	NM_002647
PIK3CA	NM_006218
PIK3CB	NM_006219
PIK3CD	NM_005026
PIK3CG	NM_002649
PIK3R1	NM_181523
PIK3R2	NM_005027
PIK3R3	NM_003629
PIM1	NM_002648
PLCG2	NM_002661
PLK2	NM_006622
PMAIP1	NM_021127
PMS1	NM_000534
PMS2	NM_000535
PNRC1	NM_006813

POLD1	NM_002691
POLE	NM_006231
PPARG	NM_015869
PPM1D	NM_003620
PPP2R1A	NM_014225
PPP4R2	NM_174907
PPP6C	NM_002721
PRDM1	NM_001198
PRDM14	NM_024504
PREX2	NM_024870
PRKAR1A	NM_212471
PRKCI	NM_002740
PRKD1	NM_002742
PTCH1	NM_000264
PTEN	NM_000314
PTP4A1	NM_003463
PTPN11	NM_002834
PTPRD	NM_002839
PTPRS	NM_002850
PTPRT	NM_133170
RAB35	NM_006861
RAC1	NM_018890
RAC2	NM_002872
RAD21	NM_006265
RAD50	NM_005732
RAD51	NM_002875
RAD51B	NM_133509
RAD51C	NM_058216
RAD51D	NM_133629
RAD52	NM_134424
RAD54L	NM_001142548
RAF1	NM_002880
RARA	NM_000964
RASA1	NM_002890
RB1	NM_000321
RBM10	NM_001204468
RECQL	NM_032941
RECQL4	NM_004260
REL	NM_002908
RET	NM_020975
RFWD2	NM_022457
RHEB	NM_005614
RHOA	NM_001664
RICTOR	NM_152756
RIT1	NM_006912
RNF43	NM_017763
ROS1	NM_002944
RPS6KA4	NM_003942
RPS6KB2	NM_003952
RPTOR	NM_020761
RRAGC	NM_022157
RRAS	NM_006270
RRAS2	NM_012250
RTEL1	NM_032957
RUNX1	NM_001754
RXRA	NM_002957
RYBP	NM_012234
SDHA	NM_004168
SDHAF2	NM_017841
SDHB	NM_003000
SDHC	NM_003001
SDHD	NM_003002
SESN1	NM_014454
SESN2	NM_031459
SESN3	NM_144665
SETD2	NM_014159

SETD8	NM_020382
SF3B1	NM_012433
SH2B3	NM_005475
SH2D1A	NM_002351
SHOC2	NM_007373
SHQ1	NM_018130
SLX4	NM_032444
SMAD2	NM_001003652
SMAD3	NM_005902
SMAD4	NM_005359
SMARCA4	NM_003072
SMARCB1	NM_003073
SMARCD1	NM_003076
SMO	NM_005631
SMYD3	NM_001167740
SOCS1	NM_003745
SOS1	NM_005633
SOX17	NM_022454
SOX2	NM_003106
SOX9	NM_000346
SPEN	NM_015001
SPOP	NM_001007228
SPRED1	NM_152594
SRC	NM_198291
SRSF2	NM_003016
STAG2	NM_001042749
STAT3	NM_139276
STAT5A	NM_003152
STAT5B	NM_012448
STK11	NM_000455
STK19	NM_004197
STK40	NM_032017
SUFU	NM_016169
SUZ12	NM_015355
SYK	NM_003177
TAP1	NM_000593
TAP2	NM_018833
TBX3	NM_016569
TCEB1	NM_005648
TCF3	NM_001136139
TCF7L2	NM_001146274
TEK	NM_000459
TERT	NM_198253
TET1	NM_030625
TET2	NM_001127208
TGFBR1	NM_004612
TGFBR2	NM_001024847
TMEM127	NM_001193304
TMPRSS2	NM_001135099
TNFAIP3	NM_006290
TNFRSF14	NM_003820
TOP1	NM_003286
TP53	NM_000546
TP53BP1	NM_001141980
TP63	NM_003722
TRAF2	NM_021138
TRAF7	NM_032271
TSC1	NM_000368
TSC2	NM_000548
TSHR	NM_000369
U2AF1	NM_006758
UPF1	NM_002911
VEGFA	NM_001171623
VHL	NM_000551
VTCN1	NM_024626
WHSC1	NM_001042424

WHSC1L1	NM_023034
WT1	NM_024426
WWTR1	NM_001168280
XIAP	NM_001167
XPO1	NM_003400
XRCC2	NM_005431
YAP1	NM_001130145
YES1	NM_005433
ZFHX3	NM_006885

Appendix 1c: List of genes/exons excluded from reporting due to consistently low coverage.

Gene	Transcript ID	Chromosome Coordinates	Exon	cDNA	Amino Acid
AGO2	NM_012154	8:141645584-141645605	1	1_22	1_8
ANKRD11	NM_013275	16:89334886-89335071	13	7807_7992	2603_2664
CD276	NM_001024736	15:73995113-73995427	4	419_733	140_245
CD276	NM_001024736	15:73996517-73996813	6	1073_1369	358_457
CHEK2	NM_007194	22:29085123-29085203	14	1462_1542	488_514
FAM58A	NM_152274	X:152864420-152864529	1	1176_1	392_1
FLT3	NM_004119	13:28674605-28674647	1	1_43	1_15
H3F3A	NM_002107	1:226259052-226259180	4	283_411	95_137
HIST2H3C	NM_021059	1:149812319-149812729	1	411_1	137_1
HIST2H3D	NM_001123375	1:149784826-149785236	1	1_411	1_137
HLA-A	NM_001242758	6:29911899-29912174	4	620_895	207_299
INSR	NM_000208	19:7293803-7293902	1	1_100	1_34
KMT2C	NM_170606	7:151970790-151970952	7	850_1012	284_338
KMT2C	NM_170606	7:151962123-151962294	8	1013_1184	338_395
KMT2C	NM_170606	7:151935792-151935911	15	2533_2652	845_884
KMT2C	NM_170606	7:151932902-151933018	16	2653_2769	885_923
KMT2C	NM_170606	7:151927008-151927112	18	2872_2976	958_992
KMT2C	NM_170606	7:151921520-151921701	19	2977_3158	993_1053
KMT2C	NM_170606	7:151921100-151921264	20	3159_3323	1053_1108
KMT2C	NM_170606	7:151919658-151919767	21	3324_3433	1108_1145
KMT2C	NM_170606	7:151904385-151904513	24	3713_3841	1238_1281
MST1	NM_020998	3:49726031-49726124	1	1_94	1_32
MST1	NM_020998	3:49724380-	6	608_728	203_243

		49724500			
MST1	NM_020998	3:49724117-49724235	7	729_847	243_283
MST1	NM_020998	3:49723746-49723914	8	848_1016	283_339
MST1	NM_020998	3:49723495-49723625	9	1017_1147	339_383
MST1	NM_020998	3:49722695-49722815	13	1424_1544	475_515
MST1	NM_020998	3:49722445-49722522	14	1545_1622	515_541
MST1	NM_020998	3:49721983-49722089	16	1770_1876	590_626
MST1	NM_020998	3:49721747-49721886	17	1877_2016	626_672
MYCL1	NM_001033082	1:40367480-40367560	1	1_81	1_27
NOTCH2	NM_024408	1:120611948-120612020	1	1_73	1_25
NOTCH2	NM_024408	1:120572529-120572610	2	74_155	25_52
NOTCH2	NM_024408	1:120547952-120548211	3	156_415	52_139
NOTCH2	NM_024408	1:120539620-120539955	4	416_751	139_251
NOTCH3	NM_000435	19:15311599-15311716	1	1_118	1_40
PDPK1	NM_002613	16:2588114-2588137	1	1_24	1_8
PDPK1	NM_002613	16:2607704-2607964	2	25_285	9_95
PDPK1	NM_002613	16:2611481-2611523	3	286_328	96_110
PDPK1	NM_002613	16:2611772-2611909	4	329_466	110_156
PDPK1	NM_002613	16:2615554-2615698	5	467_611	156_204
PDPK1	NM_002613	16:2616357-2616454	6	612_709	204_237
PDPK1	NM_002613	16:2627426-2627501	7	710_785	237_262
PDPK1	NM_002613	16:2631296-2631364	8	786_854	262_285
PDPK1	NM_002613	16:2631608-2631704	9	855_951	285_317
PDPK1	NM_002613	16:2633413-2633586	10	952_1125	318_375
PIK3CA	NM_006218	3:178937737-178937840	13	1912_2015	638_672
PIK3R2	NM_005027	19:18272089-18272305	6	599_815	200_272
PMS2	NM_000535	7:6022455-6022622	12	2007_2174	669_725
PMS2	NM_000535	7:6018227-6018327	13	2175_2275	725_759
PMS2	NM_000535	7:6017219-6017388	14	2276_2445	759_815
PMS2	NM_000535	7:6013030-6013173	15	2446_2589	816_863
PPP4R2	NM_174907	3:73096337-73096507	3	117_287	39_96

PTEN	NM_000314	10:89725044-89725229	9	1027_1212	343_404
PTPRT	NM_133170	20:41818286-41818373	1	1_88	1_30
RECQL	NM_032941	12:21623128-21623280	16	1798_1950	600_650
RECQL4	NM_004260	8:145743085-145743168	1	1_84	1_28
SDHA	NM_004168	5:254508-254621	14	1795_1908	599_636
SDHC	NM_003001	1:161332119-161332223	6	406_405	136_135
SDHD	NM_003002	11:111965529-111965694	4	315_480	105_160
SETD8	NM_020382	12:123873980-123874101	2	11_132	4_44
SETD8	NM_020382	12:123892040-123892250	8	849_1059	283_353
STAT5A	NM_003152	17:40452148-40452299	8	682_833	228_278
STAT5A	NM_003152	17:40452733-40452888	9	834_989	278_330
STAT5B	NM_012448	17:40371330-40371481	7	682_833	228_278
STAT5B	NM_012448	17:40370741-40370896	8	834_989	278_330
STK19	NM_004197	6:31948781-31948826	8	1050_1095	350_365
SUZ12	NM_015355	17:30267305-30267351	2	275_321	92_107
SUZ12	NM_015355	17:30267441-30267505	3	322_386	108_129
SUZ12	NM_015355	17:30274636-30274704	4	387_455	129_152
SUZ12	NM_015355	17:30300165-30300250	6	506_591	169_197
SUZ12	NM_015355	17:30310018-30310123	9	918_1023	306_341
TGFBR1	NM_004612	9:101867488-101867584	1	1_97	1_33

FDA News Release

FDA unveils a streamlined path for the authorization of tumor profiling tests alongside its latest product action

Newly authorized test detects genetic cancer mutations in 468 unique genes

For Immediate Release

November 15, 2017

Summary

FDA unveils streamlined path for the authorization of tumor profiling tests alongside its latest product action

Release

The U.S. Food and Drug Administration today authorized Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets) tumor profiling test (assay), an in vitro diagnostic test that can identify a higher number of genetic mutations (biomarkers) that may be found in various cancers than any test previously reviewed by the agency. The IMPACT test uses next-generation sequencing (NGS) to rapidly identify the presence of mutations in 468 unique genes, as well as other molecular changes in the genomic makeup of a person's tumor. Cancer profile tests are gaining wider acceptance. By identifying what genetic mutations are present in a particular tumor, the test results can provide patients and health care professionals with useful insight that may help inform how best to treat the cancer.

Today's action advances a policy framework that paves the way for the efficient review and availability of other NGS-based cancer profiling tools. The FDA is also announcing the recent accreditation of the **New York State Department of Health (NYSDOH) as an FDA third-party reviewer (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/Accredit.CFM?party_key=9)** of in vitro diagnostics, including tests similar to the IMPACT test. Moving forward, laboratories whose NGS-based tumor profiling tests have been approved by NYSDOH do not need to submit a separate 510(k) application to the FDA. Instead, developers may choose to request that their NYSDOH application, as well as the state's review memorandum and recommendation be forwarded to the FDA for possible 510(k) clearance. Other accredited, third-party FDA reviewers also may become eligible to conduct such reviews and make clearance recommendations to the agency.

"The goal of allowing NGS-based tumor profiling tests to undergo review by accredited third-parties is to reduce the burden on test developers and streamline the regulatory assessment of these types of innovative products. As this field advances, we are modernizing the FDA's approach to the efficient authorization of laboratory tests from developers that voluntarily seek 510(k) clearance," said FDA Commissioner Scott Gottlieb, M.D. "This is another example of where the FDA is working to find creative and flexible approaches to regulation that spurs development and efficient delivery of innovative technology. We'll continue to look for opportunities to create regulatory efficiencies where possible to drive broader access to tools that improve American health, while maintaining the safety and efficacy standards that patients should expect from their FDA-reviewed products."

According to the National Cancer Institute at the National Institutes of Health, approximately 38.5 percent of American men and women will be diagnosed with a form of cancer at some point during their lifetime. Unlike many cancer diagnostics that are designed to detect one cancer biomarker for use with a single drug, the IMPACT test works by comparing tumor tissue to a

“normal” sample of tissue or cells from the same patient to detect genetic alterations that might help guide treatment options. While the test is intended to provide information on cancer biomarkers, its results are not conclusive for choosing a corresponding treatment.

“NGS technologies can examine hundreds, if not millions, of DNA variants at a time; and we are only at the beginning of realizing the true potential for these devices to assist patients and their health care providers in learning about the genetic underpinnings of their disease,” said Jeffrey Shuren, M.D., director of the FDA’s Center for Devices and Radiological Health. “Recognizing the significant effect information about an individual’s biomarkers can have on their care planning and outcomes, the FDA worked closely with NYSDOH and MSK to help ensure that the IMPACT test is accurate, reliable and clinically meaningful. This collaboration is an excellent example of how the FDA can partner with the medical and development communities to review innovative tests as quickly as possible.”

The IMPACT test was reviewed by the FDA through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk devices that are novel and for which there is no legally marketed device (predicate device). Its ability to detect genetic mutations (analytical performance) was evaluated for precision, accuracy and limit of detection. Results indicated that the assay is highly accurate (greater than 99 percent) and capable of detecting a mutation at a frequency of approximately 5 percent (range of 2-5 percent). Additionally, detection of certain molecular changes (microsatellite instability) using the IMPACT test was concordant more than 92 percent of the time across multiple cancer types in 175 cases, when compared to traditional methods of detection.

Specific to the IMPACT test’s authorization, the NYSDOH previously conducted its own review and approved it for use on samples coming from patients in the state of New York. However, MSK had not previously submitted the test for the FDA’s review because it is a laboratory-developed test, for which the agency has generally not enforced premarket review and other applicable requirements. MSK submitted a de novo application for the IMPACT test to the FDA, including and extending the information submitted for NYSDOH’s prior review, to inform and expedite today’s FDA authorization.

Along with this authorization, the FDA is also establishing a Class II regulatory pathway for the review of other NGS-based tumor profiling tests for use in patients diagnosed with cancer. Class II designation allows these types of tests to be eligible to use the FDA’s 510(k) clearance process, either by submitting the application to the FDA directly or through an accredited third-party reviewer, like NYSDOH.

The FDA granted marketing authorization for the IMPACT tumor profiling assay to Memorial Sloan Kettering Cancer Center.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- FDA: MSK-IMPACT Decision Summary (https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170058.pdf)
- FDA: CDRH's Approach to Tumor Profiling Next Generation Sequencing Tests (PDF - 177KB) (/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/UCM584603.pdf)
- FDA: Medical Devices (http://www.fda.gov/MedicalDevices/default.htm)
- FDA: De Novo Pathway (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm462775.htm)
- FDA: Premarket Notification 510(k) (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotifica
- FDA: Third-Party Review (https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/thirdparyreview/def
- FDA: Laboratory-Developed Tests (https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/laboratorydevelopedtests/default.htm)
- FDA: CDRH Office of In Vitro Diagnostics and Radiological Health (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115904.htm)

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