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# Health Law Journal

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of the New York State Bar Association

## THE MEDICAL RESEARCH AND BIOTECHNOLOGY ISSUE

## Inside

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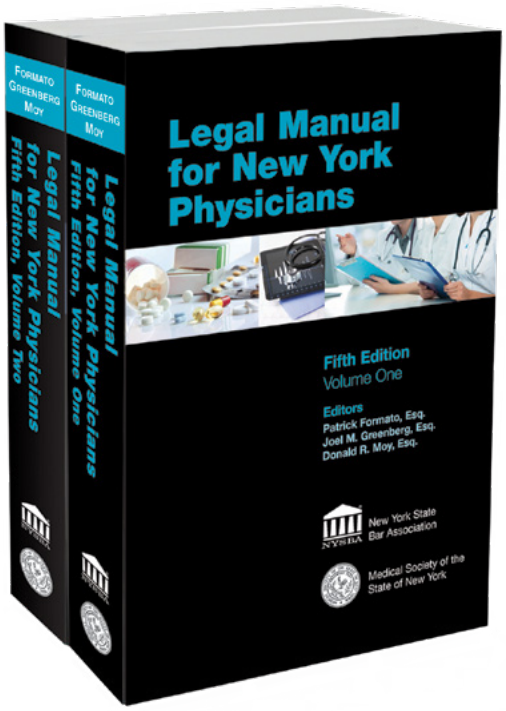


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# HEALTH LAW JOURNAL

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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# Message from the Chair

*"For a mentor, the mentoring relationship can re-energize the mentor's career through a solid connection to the next generation of lawyers with a different perspective and perhaps a fresh approach."*

All health care attorneys undoubtedly know the long learning curve one must follow to excel in one or more of the vast array of practice specialties. There is certainly no substitute for rolling up one's sleeves and studying, analyzing and digesting relevant materials. However, this purposeful experience of delving into the depths of the library in a particular area of law cannot replace the value of learning through the experiences of other attorneys. This is especially true for new attorneys who have the opportunity to seek guidance from those who have traveled down (or further down) a similar path.

At its core, mentoring consists of a mentor's commitment to providing guidance and advice to assist the mentee in their professional development. Quality mentoring relationships have powerful positive impacts on both the mentor and mentee's personal and professional experiences. A mentoring relationship provides a mentee with access to meaningful practical experiences and assistance with identifying and navigating the various career options and paths that are available. Questioning mentees about their interests and skills helps them gain greater insight into their vision for their future, and a mentor can help guide the mentee in the best direction to fulfill their potential. For a mentor, the mentoring relationship can re-energize the mentor's career through a solid connection to the next generation of lawyers with a different perspective and perhaps a fresh approach. Mentors also have the opportunity to learn, or be reminded, of the difficulties and pitfalls that confront new lawyers. The relationship also allows the mentor to reflect on their own experiences and share beneficial insight into what was successful, or not so successful, at various points in their career, and can lead to great personal satisfaction from assisting new lawyers to navigate those challenges.

In addition to the benefits that mentoring provides mentors and mentees, strong mentoring relationships serve to strengthen the value of lawyers' membership in the Health Law Section. As mentoring relationships blossom, mentees will be exposed to members of the mentor's network, and vice versa, creating a strong bond between members of our Section. Section meetings then become places were relationships are enhanced rather than simply created. Open discussions between mentors and mentees result in mentees having greater confidence in their ability and willingness to provide valuable contributions to the Section. Vibrant mentoring relationships will also instill in the Section a culture that will result in today's mentees seamlessly transitioning into tomorrow's mentors.

In my previous article, I discussed the profound and lasting impact that my mentors had on my professional development and career. It is my hope that beginning lawyers in the Health Law Section will enjoy a positive mentoring experience similar to the one that I enjoyed. To increase that possibility, the Health Law Section has implemented a mentoring program within the Section. Our Section has and will continue to provide a "Call for Mentors." Seasoned health care attorneys are encouraged to sign up and share their time and experience with someone new to our practice area. If you are someone who is in the fledgling stages of your career, whether as a new lawyer or as a lawyer new to health care, please take advantage of this opportunity to connect with a colleague who can help facilitate your development.

I hope you will consider participating in this rewarding initiative. If you are interested in partaking but have not received additional details on how to become involved, or have anything else you would like to discuss, please feel free to reach out to me at any time.

Warmest regards,

**Bob Hussar**
**Section Chair**
**Partner, Barclay Damon, LLP**
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# In the New York State Courts

By Leonard M. Rosenberg

## Court of Appeals Affirms Appellate Division Ruling Striking Down "Soft Cap" on Non-Profit Health Care Executive Compensation

***LeadingAge New York, Inc. v. Shah*, 2018 WL 5046104 (N.Y. 2018)**

Petitioners brought hybrid Article 78 proceedings and declaratory judgment actions seeking to invalidate portions of 10 N.Y.C.R.R. Part 1002, which impose limitations on executive compensation and administrative costs for covered health care providers. Such regulations were promulgated by the New York Department of Health (DOH) in accordance with Executive Order 38 (EO38), issued by Governor Cuomo in January 2012. Prompted by media coverage and subsequent task force findings concerning excessive executive compensation in non-profit health care organizations, EO38 provides specific directives to multiple state agencies charged with distributing state funds.

The challenged regulations include two "hard cap" provisions and one "soft cap" provision. The first hard cap limits the proportion of state funds or state-authorized payments that a provider can direct toward administrative expenses to 15 percent. The second hard cap prohibits the use of state funds or state-authorized payments for executive compensation to any "covered executive" in excess of $199,000 per year. The soft cap subjects covered providers to penalties if their executive compensation exceeds $199,000 per year from any source—public or private—and (1) such compensation exceeds the 75th percentile for comparable executives, as identified in a DOH-recognized survey; or (2) the compensation was not reviewed and approved by the covered provider's governing body upon consideration of "appropriate comparability data." The regulations permit covered entities to apply for a waiver of the hard cap and soft cap

limits on a showing of good cause.

In challenging the hard cap and soft cap regulations, Petitioners argued, *inter alia*, that (1) DOH exceeded its regulatory authority and violated the separation of powers doctrine, and (2) the regulations are arbitrary and capricious. The Supreme Court, Albany County denied the petitions with respect to the hard cap provisions, but granted the petitions with respect to the soft cap provision. The supreme court found that the hard caps were consistent with DOH's statutory mandate to administer taxpayer-funded programs and were not arbitrary and capricious, but that the soft cap was promulgated in excess of DOH's authority because it "reaches beyond state funds and state- authorized funds expended for executive compensation." All parties appealed to the Appellate Division, Third Department, which affirmed. All parties appealed to the Court of Appeals.

Reviewing applicable law, the Court of Appeals stated that it is the role of the legislature to make critical policy decisions, and that state agencies, as creatures of the legislature, may only promulgate rules based on specific grants of authority. The Court noted that while an agency need not be given "rigid marching orders," it cannot "resolve—under the guise of regulation—matters of social or public policy reserved to legislative bodies." The Court then noted that the four-factor test set forth in *Boreali v. Axelrod*, 71 N.Y.2d 1 (1987) serves as "guidance for finding 'the difficult-to-determine line between administrative rule-making and legislative policy-making.'" The four *Boreali* factors include (1) whether the agency simply balanced costs and benefits according to preexisting guidelines or made value judgments as to broad policy goals; (2) whether the agency merely filled in the details of a broad policy or created its own comprehensive set of rules without any legislative guidance; (3) whether the challenged regulation resolves an issue on which the legislature has unsuccessfully attempted to reach an agreement (which would weigh against the agency's rulemaking authority); and (4) whether the agency used special expertise in the field in order to develop the challenged regulation.

The Court of Appeals then began its analysis by examining the role and function of DOH. The court noted that DOH has broad authority to maintain New York's Medicare program, to implement related regulations, and to contract with private companies for the provision of state-funded health care services. Reading various provisions of the Public Health Law and the Social Services Law together, the Court found that the legislature's broad goal in delegating such authority to DOH was to ensure that "the limited public funding available be directed as efficiently as possible toward high-quality services for New Yorkers in need."

**Compiled by Leonard Rosenberg, Esq.** Mr. Rosenberg is a shareholder in the firm of Garfunkel Wild, P.C., a full service health care firm representing hospitals, health care systems, physician group practices, individual practitioners, nursing homes and other health-related businesses and organizations. Mr. Rosenberg is Chair of the firm's litigation group, and his practice includes advising clients concerning general health care law issues and litigation, including medical staff and peer review issues, employment law, disability discrimination, defamation, contract, administrative and regulatory issues, professional discipline, and directors' and officers' liability claims.

Applying the four *Boreali* factors to the hard cap provisions, the Court of Appeals held that they were promulgated within DOH's regulatory authority. First, the Court asserted that the hard caps are directly tied to the specific legislative goal of ensuring the efficient use of state funds for health care services. Second, the Court held that the DOH did not write on a clean slate, but that the hard cap regulations merely filled in the details of the legislature's broad policy. Third, the Court found the hard cap regulations did not encroach on an area of legislative deadlock. Fourth, the Court held that DOH relied on its specialized expertise of the health care industry in crafting the hard cap regulations, including "detailed definitional, waiver, and exemption provisions tailored to that sector."

The Court of Appeals then rejected Petitioners' argument that the hard cap regulations were arbitrary and capricious. The Court found that Petitioners failed to meet their "heavy burden" to establish that the regulations were invalid on their face. The Court also noted that the regulations were not irrational, as they were promulgated upon findings by the Governor's task force that providers were paying excessive executive compensation, and because rising health care costs in New York have led to per capita Medicaid spending at nearly twice the national average.

Finally, the Court of Appeals held that that the soft cap regulation violated the separation of powers doctrine. The Court noted that the soft cap provision "stands in stark contrast" to the hard cap provisions, as it limits executive compensation from private sources as well as taxpayer dollars. The Court held that in promulgating the soft cap provision, DOH impermissibly ventured beyond the legislature's enabling legislation and "wrote on a clean slate." The Court further observed that the exceptions to the soft cap—which are not clearly related to the quality or affordability of health care services—"reflect a choice between competing policy interests, rather than mere implementation of the Legislature's chosen goal relating to the efficient use of state funds." The Court rejected DOH's argument that the State Finance Law requires it to ensure that services be purchased from responsible vendors based upon their "financial ability, legal capacity, integrity, and past performance," finding that "DOH has not shown a connection between a provider's decision to use private funds to compensate its executive staff handsomely or even excessively and the absence of any of these essential contractor characteristics."

## Court of Appeals Rules That OMIG Is Permitted to Recoup Full Amount of Estimated Medicaid Overpayments Against Clinic Operator

***West Midtown Mgt. Group, Inc. v. State of N.Y., Dep't of Health, Office of the Medicaid Inspector Gen.*, 31 N.Y.3d 533, 81 N.Y.S.3d 343 (2018)**

Petitioner is the operator of two methadone clinics in Manhattan and an authorized provider of Medicaid-covered services. Respondent, the Office of the Medicaid Inspector General (OMIG), is an independent office within the New York Department of Health that is charged with, *inter alia*, the civil and administrative recovery of improperly expended Medicaid funds. OMIG is authorized to perform on-site audits of providers and to determine, through review of a random sampling of claims, the amount of any overpayments made to the provider by the Medicaid program. Upon finding an overpayment, OMIG issues a report to the provider that includes an estimated overpayment amount. Within 20 days of issuing its final audit report, and upon five days' notice, OMIG is authorized to recoup such estimated overpayment by withholding all or part of the Medicaid payments due and owing to the provider. Providers are given the opportunity, within 60 days of the issuance of the final audit report, to request an administrative hearing to challenge OMIG's estimate.

In January 2010, OMIG completed an audit of Petitioner's Medicaid claims for the years 2003 through 2007 and determined that Petitioner had received substantial overpayments. On June 16, 2010, OMIG issued its final audit report (FAR), which estimated, based upon a statistical analysis of Petitioner's claims, that the total amount of overpayments during this period was $1,857,401. In the FAR, OMIG offered to settle with Petitioner for $1,460,914, representing the "lower confidence limit" estimate of the overpayments. OMIG indicated that if Petitioner did not accept this offer within 20 days, it would seek to recoup this lesser amount against Petitioner by withholding a percentage of future Medicaid payments due and owing to it. Nevertheless, the FAR reserved OMIG's "other remed[ies] allowed by law," and indicated that if Petitioner were to request an administrative hearing, OMIG would seek to recover the extrapolated point estimate of $1,857,401. Petitioner did not accept OMIG's settlement offer, nor did it timely seek an administrative hearing challenging the FAR.

On July 12, 2010 and December 9, 2010, OMIG sent two notices to Petitioner that it would be withholding a portion of its current and future Medicaid claims in order to recoup the estimated overpayments. Both of those notices referenced the lower amount of $1,460,914 and not the full estimate of $1,857,401. Thereafter, Petitioner learned that OMIG intended to seek reimbursement for the full estimated overpayment.

Petitioner brought an Article 78 proceeding in the Supreme Court, New York County, seeking to prohibit OMIG from withholding more than the "lower confidence" amount. The Supreme Court dismissed the petition, holding that Petitioner was "well aware of its ultimate liability for $1.8 million." Petitioner appealed to the Appellate Division, Second Department, which reversed the judgment based upon the clear reference, in the two notices of with-

holding, to "an overpayment totaling $1,460,914." OMIG appealed.

Before the Court of Appeals, Petitioner made two separate arguments: First, Petitioner asserted that the FAR failed to "clearly advise" that OMIG intended to withhold the full estimated amount of $1,857,401, in contravention of applicable regulations. Second, Petitioner claimed that OMIG "acquiesced" to the lower payment of $1,460,914 based upon its reference to this amount in both notices of withholding.

The Court of Appeals rejected Petitioner's first argument, finding that it "ignores clear statements" in the FAR and the cover letter to the FAR, which indicated that $1,857,401 was Petitioner's estimated liability and that $1,460,914 was a lower amount that was offered as a settlement if accepted within 20 days. The Court held that Petitioner's reading of the FAR would render this 20-day period meaningless. Furthermore, the Court found it reasonable for OMIG to take the "conservative approach" to pursue an initial recoupment at the lower amount, as Petitioner still had time, when then notices were sent, to request an administrative hearing challenging the estimate. The Court noted that the language of the FAR reserved OMIG's other remedies at law, and thus OMIG was permitted to recoup the remainder of the estimated overpayment at a later time.

The Court of Appeals also rejected Petitioner's second argument. As a threshold, the Court noted that the applicable regulations do not require OMIG to indicate the total amount that it seeks to withhold. To the extent that the two notices of withholding limited OMIG to recoupment of the lower amount of $1,460,914, the Court asserted that OMIG could simply provide a new notice to Petitioner to recoup the remainder of the estimated overpayments. Finally, the court held that OMIG could not be estopped from seeking the full estimated overpayment liability. The Court stated that, except in rare circumstances, estoppel is not available to bar a government agency from carrying out its statutory duties. The Court found that Petitioner was clearly put on notice that OMIG was entitled to seek the full estimated overpayment liability against it, and thus Petitioner was not entitled to "seize[] on references to the lower confidence limit amount in the FAR provider rights section and subsequent notices of withholding."

## Appellate Division Dismisses Neurosurgeon's Suit for Injunction to Obtain Clinical Privileges

***Karim v. Raju*, 165 A.D.3d 504, 84 N.Y.S.3d 471 (1st Dep't, 2018)**

Dr. Karim, a neurosurgeon, applied for medical staff membership and clinical privileges at Lincoln Hospital and Mental Health Center, which is part of NYC H+HC. Lincoln denied the physician's application for clinical privileges based on two negative references that were received from out-of-state facilities, which indicated that the physician had poor interpersonal skills and difficulties working with subordinates. The physician filed an administrative grievance with the New York State Public Health and Health Planning Council pursuant to Public Health Law Section 2801-b. 2801-b provides that it is improper for a hospital to deny privileges without stating the reasons, or for reasons that are not related to patient care, patient welfare, the objectives of the institution or the character or competency of the applicant.

The Council ruled in the physician's favor, stating that the reasons were not sufficiently related to the 2801-b criteria. However, the Council did not make any findings of fact and gave no reasons for its ruling. It directed Lincoln to reconsider its decision. On reconsideration, Lincoln adhered to its decision to deny the application.

The physician sued for damages and for an injunction to obtain privileges, pursuant to Public Health Law Section 2801-c. The trial court granted defendants' motion to dismiss the damages claim, but denied their motion to dismiss the injunction claim, on the ground that defendants had not met their "heavy summary judgment burden," through admissible evidence, to prove that Lincoln acted in good faith.

The Appellate Division for the First Department unanimously reversed and dismissed the suit. The court first noted that in an action under PHL 2801-c, any findings of the Council are prima facie evidence of any fact found; however, in this case the Council made no factual findings. The court found that the decision to deny privileges was made in good faith and on reasonable grounds, as it was based on admissible evidence of the neurosurgeon's poor interpersonal skills and difficulties in working with subordinates, which are reasonably related to the statutory factors of "patient care, patient welfare, the objectives of the institution or the character or competency of the applicant." The court noted that good faith was shown by defendants' efforts to obtain clarification of the negative references, and on subsequent review, considering positive references that the physician had obtained.

[Ed. Note: Leonard Rosenberg of Garfunkel, Wild P.C. represented the defendants in this suit]

## Court of Appeals Holds That Hearsay Can Constitute Substantial Evidence in Administrative Proceeding Even if Contradicted by Live Testimony

***Haug v. State University of New York at Potsdam*, 32 N.Y.3d 1044, 87 N.Y.S.3d 146 (N.Y. 2018)**

Petitioner, a former public university student, brought an Article 78 proceeding to review SUNY's determination that he was guilty of sexual misconduct in violation of its code of conduct, which ultimately resulted in his expulsion.

While a freshman at SUNY, Petitioner had a sexual encounter with

a female fellow student with whom he had been friends for several years. Following the encounter, the student reported to campus police that, while she had not declined to engage in sex and gave no gesture indicating that the encounter was unwelcome, she had been sexually assaulted. She refused to identify her assailant or submit to a sexual assault examination, but an anonymous tip subsequently suggested Petitioner as the assailant. SUNY then charged Petitioner with sexual misconduct in violation of its code of conduct, which provides that consent to sexual activity cannot be inferred from silence, and must stem from "spoken words or behavior that indicates, without doubt to either party, a mutual agreement to" proceed.

During the disciplinary hearing, Complainant did not testify and, instead, her account was relayed only by third parties with whom she had spoken, including a campus police officer. The Hearing Board also assessed written notes prepared by SUNY's Director of Student Conduct and Community Standards. Complainant had reported to others that Petitioner was a friend whom she invited to her dormitory room, and that the two began kissing on her bed. Complainant communicated that while she did not verbally consent when Petitioner suggested they have sex, she did begin to remove her clothing. She also reported that she "froze up" and did "not respond" to Petitioner's advances. Conversely, Petitioner testified at the hearing that Complainant began removing both of their clothes after they were kissing and talking, and that, following the encounter, during which Complainant straddled Petitioner from above, Complainant asked if he had fun. Petitioner also testified that he asked Complainant whether she had any condoms, to which she replied that she did not but that it was "fine."

The Hearing Board determined that Complainant did not affirmatively consent to having sex and that, as a result, Petitioner engaged in sexual misconduct. The Board recommended that Petitioner be, among other things, suspended for the remainder of the term and directed to complete an alcohol evaluation and treatment program as well as a reflective paper on consent and appropriate sexual conduct. Petitioner then appealed to SUNY's Appellate Board, which rejected his contentions and recommended, without explanation, that the penalty be increased to expulsion.

The Supreme Court, Lawrence County, transferred Petitioner's Article 78 proceeding to the Appellate Division, which granted the petition and annulled SUNY's determination. Noting that hearsay must be "sufficiently relevant and probative if it is to constitute substantial evidence," the Appellate Division held that hearsay which is seriously controverted should not constitute substantial evidence as a matter of "common sense and elemental fairness." Because the accounts of Complainant and Petitioner differed regarding the "critical issue" of consent, the Appellate Division held that the hearsay evidence of Complainant's account of the interaction was insufficient to constitute substantial evidence. The Appellate Division also noted that it was "troubled" by the absence of any clear articulation in SUNY's Code of Conduct that an enhanced penalty such as expulsion might result from a student's decision to appeal the Hearing Board's determination. 149 A.D.3d 1200, 51 N.YS. 3d 663 (3d Dep't, 2017).

The Court of Appeals reversed, holding that sufficiently relevant, probative hearsay is admissible as competent evidence in an administrative proceeding, satisfying the substantial evidence standard, even if contradicted by live testimony on credibility grounds. In so holding, the Court emphasized that neither the Appellate Division nor the Court of Appeals has power to disturb an agency's determination regarding a factual issue, and that the courts may not review the weight of the evidence, other than to confirm that substantial evidence has been presented. Where substantial evidence does exist, the Court held, the reviewing court may not substitute its judgment for that of the agency, even if the court would have decided the matter differently, and even if a similar quantum of evidence is available to support other varying conclusions. The Court further emphasized that the substantial evidence standard is a minimal one, lower than a preponderance of the evidence standard, and demands only that a given inference be "reasonable and plausible, not necessarily the most probable."

The Court noted that it was the province of the hearing board to resolve any conflicts in the evidence and to make any credibility determinations. According, it held that the Appellate Division improperly re-weighed the evidence when it substituted its own factual findings for those of respondents. [Ed. note—Although this decision is not health law per se, it has broad application to the many types of administrative hearings that health care providers and entities engage in].

## Federal Court Holds That Protected Health Information Has Value Sufficient to Sustain Alleged Violation of the New York False Claims Act

***State of New York v. MedImmune, Inc.*, 2018 WL 6567648 (S.D.N.Y. 2018)**

In this an action brought by the Attorney General of the State of New York against drug manufacturer MedImmune under the New York False Claims Act (NYFCA) and other state laws, the district court denied a motion filed by MedImmune to dismiss the complaint. The Attorney General alleged in its complaint that MedImmune violated the NYFCA by entering into a kickback scheme with Trinity Pharmacy to induce Medicaid patients or their physicians to use a prescription drug, Synagis, manufactured by MedImmune. Synagis is used to treat infants who are in a weakened state due to premature birth of other illnesses, and it acts to

prevent the onset of serious respiratory ailments that these infants are particularly susceptible to.

According to the complaint, MedImmune's employees curried favor with employees of local hospitals with Neonatal Intensive Care Units, in order to gain access to the units. Once there, the MedImmune employees would surreptitiously obtain materials containing detailed confidential information regarding infants born prematurely, who would be natural candidates for Synagis. Included in the materials obtained was contact information for the infants' mothers. The MedImmune employees then passed that information to Trinity Pharmacy, a Medicaid provider, and Trinity contacted the infants' parents or their pediatrician and persuaded them to use Synagis. Many of the patients who followed Trinity's recommendation were Medicaid patients, and Trinity billed and was paid by the New York Medicaid program for the Synagis it distributed to them.

The Attorney General alleged that this scheme violated the federal Anti-Kickback statute (AKS), which prohibits the payment of any type of "remuneration" in exchange for the referral of Medicaid or Medicare business, and that it therefore violated the NYFCA, because claims for payment that arise out of a prohibited kickback relationship are necessarily false claims. According to the Attorney General, MedImmune's provision of confidential medical information to Trinity was remuneration that induced Trinity to solicit orders for Synagis, to the benefit of MedImmune.

MedImmune sought dismissal of the Complaint on multiple grounds. MedImmune argued that the confidential information MedImmune supposedly provided to Trinity could not constitute the remuneration required for a kickback because it had no actual monetary value. While not disputing that the information was Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA), and that it was unlawful to share it, MedImmune insisted that sharing it, even in exchange for referrals, was not a kickback. MedImmune also argued that Trinity's marketing of Synagis to patients' families and physicians was not a referral to MedImmune. It also argued that the alleged kickback scheme did not render Trinity's claims for payment from the Medicaid program false, because compliance with the AKS was not material to the program's decision to pay Trinity for the Synagis. MedImmune further asserted that it could not be liable under the FCA because MedImmune itself did not submit any claims for reimbursement to the Medicaid program.

The court rejected all of MedImmune's arguments. First, the court found that the PHI did have a value to Trinity because it "was instrumental in developing leads targeting particular doctors and patients," something that increased the volume of Trinity's business. Thus, even though it was not possible to ascribe a "fair market value" to the information, that did not mean it had no value or that it could not consitute an inducement to refer. The court also held that while Trinity did not refer patients directly to MedImmune, it did recommend that patients and physicians use MedImmune products, products which were paid for by Medicaid. The AKS prohibits the payment of remuneration in exchange for referring or "recommending the purchase of any good or item" that will be paid for by the Medicaid program. The court also noted that Trinity's participation in the kickback scheme was material because it is settled that the government will not pay claims for goods or services if it is aware that the order for the good or services arises out of a kickback violation. Finally, the court dismissed MedImmune's argument that it was not liable because Trinity, not MedImmune submitted the claims to Medicaid, given that courts have consistently held that the NYFCA extends to anyone who renders a claim false, even if another person actually submits the claim.

## Qui Tam Suit Dismissed Based on Prior Public Disclosure and Because Relator Was Not the Original Source

### *USA Ex. rel. Susan Vierczhalek, M.D. v. MedImmune, Inc.*, 2018 WL 6539469 (S.D.N.Y. 2018)

The relator in this *qui tam* suit is a pediatrician and attending physician at Bellevue Hospital, and co-director of the hospital's premature infant follow-up clinic.

MedImmune manufactures Synagis, a drug used to reduce the severity of lung infections in at-risk children. In 2009, the relator filed a *qui tam* complaint against MedImmune, Trinity Homecare, and OptionCare. Trinity's services include dispensing home-delivered drugs, such as Synagis. OptionCare operates various treatment locations, all of which dispense Synagis.

The 2009 complaint alleged that the defendants violated the False Claims Act by promoting off-label use of Synagis, which influenced physicians to prescribe it even though it was not medically necessary. The federal government declined to intervene. In 2015, New York State intervened as to Trinity and Option Care, and announced a settlement under which Trinity and OptionCare paid $22.4 million. Relator received $4 million as the original *qui tam* whistleblower.

New York continued to investigate MedImmune's involvement, and in March 2017, filed a complaint-in-intervention under the New York State False Claims Act and other state laws. In contrast to the relator's 2009 complaint, New York alleged that MedImmune engaged in a kickback scheme with Trinity. Under this alleged scheme, MedImmune gained access protected health information (PHI) of infants in hospitals who

would be candidates for treatment with Synagis. MedImmune allegedly passed this information to Trinity, which used it as patient leads.

In November 2017, the relator filed an amended complaint, alleging that the kickback scheme set forth in New York's complaint violated the federal False Claims Act and various state false claim acts.

Specifically, the amended complaint alleged that to curry favor with doctors, nurses, and other hospital staff, MedImmune provided "services" to various hospitals, such as "(i) helping the staff track discharged babies that were likely candidates for Synagis; (ii) reviewing and completing required paper work … needed to prescribe Synagis; (iii) providing lunches to physicians and their staff … (iv) providing binders and forms … and (v) paying neonatologists … for speaking about RSV and Synagis."

By cultivating relationships with nurses, discharges nurses, neonatologists, and other hospital staff, MedImmune gained access to neonatal intensive care unit logbooks, and identified infants who would be good candidates for Synagis. MedImmune then passed the PHI to Trinity and OptionCare, which used it like referrals or sales leads, with the objective of increasing the sales of Synagis.

According to the amended complaint, MedImmune focused its efforts on premature babies born to low-income families by targeting hospitals that served Medicaid populations; thus the Synagis treatments were ultimately paid for by Medicaid.

MedImmune moved to dismiss the relator's amended complaint on the ground that because the alleged fraud was already publicly disclosed in New York's complaint, it is precluded by the FCA's public disclosure bar [31 U.S.C. § 3730(e)(4)(A)]. The bar requires dismissal if the relevant information has entered the public domain. The court noted the purpose of the bar is to strike a balance between encouraging private persons to root out fraud and "stifling parasitic lawsuits" in which a relator seeks a "free ride" by merely repeating previously disclosed information.

The statute requires dismissal "if substantially the same allegations or transactions as alleged… were publicly disclosed…in a federal criminal, civil or administrative hearing in which the government…is a party…unless the person bringing the action is an original source of the information."

The court held that New York's complaint, filed eight months prior to the relator's amended complaint, was a prior public disclosure. The court noted that the relator's amended complaint "is a virtual carbon copy" of New York's complaint, repeatedly cites to it, and quotes it for over 11 consecutive pages. The court also held that relator's additional allegations that the scheme violated various state false claim acts did not negate substantial similarity, as the same theory of fraud "permeat[ed] the two complaints."

The court next addressed whether the relator was an original source of the allegations in New York's complaint. The court held that because the original complaint focused on off-label promotion of Synagis, was devoid of any allegations of violations by MedImmune of anti-kickback statutes, and the relator never identified MedImmune's role in the scheme and was concededly unaware of it, she was not an original source.

In that regard, the court held that relator's allegations that MedImmune engaged in similar misconduct in other states was insufficient to satisfy the original source rules, as "merely expanding the geographic scope of the potential fraud" was simply derivative of New York's allegations. The Court noted that the central question is whether the information adds significantly to "the who, what, when, where and how" of the events, and that relator "had not contributed an iota to the who, what or how" of the scheme alleged in New York's complaint.

In dismissing the amended complaint, and noting that the relator had already received $4 million, the court held that the "public disclosure bar prevents her from potentially receiving a second payday simply by amending her complaint to mirror New York's very different theory of fraud."

## Law Firm Disqualified From Representing Physician in Suit Against Hospital at Which Firm Partner Is a Member of the Board of Trustees

*In re Blackman; Boca Raton Regional Hospital, Inc. v. Tim Williams*, 165 A.D.3d 654, 83 N.Y.S.3d 628 (2d Dep't, 2018)

In New York the Hospital brought an action for construction of a deceased patient's trust that included a charitable gift to the Hospital valued at $75 million. Dr. Williams, an oncologist who had treated the patient at the Hospital, was named as a defendant. In Florida, Dr. Williams sued the Hospital, alleging that it was seeking to terminate Williams' relationship with the Hospital in order to gain control over the gift. The law firm Fox Rothschild represented Dr. Williams in both suits.

The Hospital moved to disqualify Fox Rothschild from representing Dr. Williams on the grounds that at the time both actions were commenced, a partner of the firm was a member of the Hospital's Board of Trustees.

The Appellate Division unanimously affirmed disqualification on two grounds. First, as a trustee, the partner owned a fiduciary duty to the Hospital, which created a potential conflict of interest arising from Fox Rothschild's representation of Dr. Williams in litigation against the Hospital. Second, the Hospital established that as a member of the Board of Trustees, the partner had access to confidential information regarding the gift and the ongoing dispute with

Dr. Williams. Accordingly, disqualification was warranted under Rule 1.7 of the Rules of Professional Conduct.

## Appellate Division Orders Disclosure of Privileged Medical Records in Whistleblower Case

***McMahon v. New York Organ Donor Network*, 161 A.D.3d 680, 78 N.Y.S.3d 61 (1st Dep't, 2018)**

In this suit under New York Labor Law § 740, Plaintiff alleged that defendant, a federally designated organ procurement organization, fired him in retaliation for complaining that defendant's employees obtained organs without performing legally required tests, and from individuals who still showed signs of life. In his complaint, plaintiff named four individuals whose organs were allegedly procured improperly by defendant.

To prevail on his claim, plaintiff must prove that the defendant fired him because he objected to or threatened to disclose a practice that was in violation of a law or regulation. Plaintiff argued that the medical records of the four individuals would show that defendant, in violation of Department of Health regulations, pressured physicians to declare patients dead. Plaintiff moved to compel production of the records. The Supreme Court, New York County, ordered production, and the defendant appealed, arguing that the medical records were confidential under HIPAA and the physician- patient privilege.

The court noted that although defendant is not a covered entity under HIPAA, it is required by New York Public Health Law § 4351(8) to abide by HIPAA's privacy protections to the same extent as a hospital or its employees. The court also noted that plaintiff's requested disclosure, made in the course of a judicial proceeding and subject to a protective order, is authorized under HIPAA. However, Public Health Law § 4351(8) renders the medical records subject to the protections of physician-patient privilege set forth in CPRL 4504, which privilege does not terminate with a patient's death.

Nonetheless, the court held that the medical records were material and necessary to plaintiff's claim, and that allowing discovery of the records is consistent with the public policy of the whistleblower statute, which is to encourage employees to report hazardous practices to supervisors and the public. Accordingly, the court affirmed the order directing production of the medical records, but to protect patient confidentiality, modified it to require redaction of all identifying patient information.

## Appellate Division Rules That Document Presented at Quality Assurance Review Meeting Is Privileged Under Education Law § 6527(3) but Is Discoverable Under the Medical Malpractice Exception

***Drum v. Collure*, 161 A.D. 3d 1509, 75 N.Y.S. 3d 746 (4th Dep't, 2018)**

Plaintiff, a stroke victim, was treated at two hospitals that are part of Kaleida Health's hospital network, Millard Fillmore Suburban Hospital and Buffalo General Medical Center. While at the second hospital, Buffalo General Medical Center, Plaintiff alleged that his treating physician showed him a slide show that described his treatment. It is undisputed that the treating physician also showed the same slide show to a hospital quality assurance review committee meeting at Millard Fillmore Suburban Hospital that concerned, *inter alia*, Plaintiff's care.

Plaintiff sued the operator of Kaleida Health's hospital network, his treating physician, and other related parties, alleging medical malpractice beginning with his treatment at Millard Fillmore Suburban Hospital. When Plaintiff sought the production of the slide show that he saw at Buffalo General Medical Center, Defendants moved for a protective order on the grounds that the slide show was privileged under, *inter alia*, Education Law § 6527 (3). As a part of their motion, Defendants submitted an affirmation by the treating physician, in which the treating physician outlined the hospital's quality assurance review procedure and explained why the slide show was created for the quality assurance meeting. The Supreme Court of New York, Erie County denied the motion, and Defendants appealed.

The Appellate Division affirmed, and directed disclosure of the slide show. The court found, as a threshold matter, that Defendants met the initial burden necessary to invoke the privilege under Education Law § 6527 (3) because the treating physician's affidavit showed that the slide show was generated in connection with a quality assurance review function. However, the court held that the slide show was nevertheless discoverable under an exception to the privilege. Statements, including written materials, made by a person in attendance at a quality assurance review meeting may be disclosed where the quality assurance review meeting concerned the same subject matter as the malpractice action, and the statements were made by a defendant in the action. In this instance, the court held that the exception applied because Plaintiff alleged malpractice beginning with his treatment at Millard Fillmore Suburban Hospital, the treating physician was a defendant the malpractice case, and the treating physician admitted that the quality assurance review meeting, at which he presented the slide show, concerned, *inter alia*, Plaintiff's care.

## Appellate Division Holds That Charges Brought by OPMC Eight to Nine Years After Alleged Misconduct Occurred Was Not Prejudicial to Physician

***St. Hill v. New York State Board for Professional Medical Conduct*, 166 A.D.3d 1092, 86 N.Y.S.3d 661 (3d Dep't, 2018)**

Petitioner, a physician who specializes in physical medicine and rehabilitation, was the sole director and officer of her professional

medical corporation. In August 2015, the Office of Professional Medical Conduct (OPMC) charged Petitioner with 30 specifications of professional misconduct resulting from the treatment of seven patients during 2006 and 2007. Following a hearing, the Hearing Committee sustained 22 specifications, including fraudulent practice of medicine, negligent practice of medicine, ordering excessive tests, and failure to maintain accurate medical records. Petitioner's license was suspended for 90 days, she was placed on probation for five years, and she was ordered to permanently limit her practice to a Public Health Law Article 28 facility.

Petitioner appealed the decision to the Administrative Review Board (ARB). The ARB sustained the charges, but modified the penalty. Rather than limiting Petitioner's practice to an Article 28 facility, the ARB prohibited her from owning a professional corporation, engaging in solo medical practice, and operating her own office. Thereafter, Petitioner commenced an Article 78 proceeding in the Appellate Division, Third Department, pursuant to Public Health Law § 230-c(5), seeking to annul the ARB's decision.

The court noted that its review was limited to determining whether the ARB's decision was arbitrary and capricious, or affected by error of law or an abuse of discretion. In making such a determination, the court stated it would not disturb the ARB decision as long as it had a rational basis and was supported by the facts on record, and resolution of issues such as credibility and weight of testimony are solely within the province of the ARB.

The court first addressed the issue of the alleged delay in the investigation and bringing of disciplinary charges. The court held that despite the charges being brought in 2015 for misconduct that occurred during 2006 and 2007, there was no statute of limitations regarding these charges, and the doctrine of laches did not apply to physician disciplinary proceedings. Therefore, the ARB's decision could only be annulled if the Petitioner demonstrated that she suffered actual prejudice from the delay.

Petitioner argued she was prejudiced because the Hearing Committee did not have the entire medical record for each patient. However, the court noted that the OPMC had requested "a certified copy of the complete medical record[s]," and Petitioner's billing clerk replied, attesting that the records provided were the "complete, true and exact copies" of the requested records.

Further, the OPMC advised Petitioner by letter in April 2010 that she was under investigation and had the opportunity to be interviewed in connection with this investigation. This letter also advised Petitioner that the investigation included the alleged failure to maintain accurate medical records, the excessive and unnecessary testing of the seven patients involved with the charges, and the staffing of her professional corporations.

Petitioner replied to this letter by sending the OPMC another set of the subject patients' medical records. However, these records were nearly identical to those sent by Petitioner in 2008. Although Petitioner claimed that she provided only billing excerpts because she was under the impression that the investigation related only to billing practices, the Hearing Committee had not found her explanations to be credible and concluded that the complete set of records had in fact been provided. Therefore, the court held that Petitioner was not prejudiced in this case.

The court also disagreed with Petitioner's contention that the OPMC erred in its decision on the charge of fraudulent practice of medicine. The court noted that the OPMC did not find that the Petitioner failed to perform EMGs on patients, as Petitioner claimed, but instead found that Petitioner and her employee made unsupported diagnoses for the seven patients involved with this case, which resulted in unnecessary tests and treatments. Based on the pattern of unsupported diagnoses and inappropriate testing found in the record, and the OPMC's expert testimony that the performance of an EMG was not clinically supported based on the subject patients' conditions, the court ruled that the ARB rationally concluded that Petitioner engaged in the fraudulent practice of medicine.

Next, the court rejected Petitioner's challenge to the charge that she failed to maintain accurate medical records. The court noted that whether a physician is guilty of this charge is not limited only to instances when the records fail to convey objectively meaningful medical information, and thereby compromises continuity of care, but also includes compliance with Education Law § 6530(32), which mandates, among other things, that physicians maintain records that "accurately reflect the evaluation and treatment of a patient" and are retained for at least six years. Petitioners expert's testimony that she could reconstruct a patient's history based upon the records provided was insufficient to show compliance with Education Law § 6530(32).

The court also rejected Petitioner's assertion that she was entitled to open the Administrative Record based on newly discovered evidence, because the statutory scheme did not allow it. Petitioner was restricted to the only two remedies available in an Article 78 proceeding, "vacatur or modification of the determination and order," pursuant to Public Health Law § 230(10)(q). However, Petitioner had not shown she was entitled to either relief.

# Legislative Update: A Preview of 2019

By James W. Lytle

For those of us focused on New York State policy and politics please don't refer to last November's elections as "the midterms." While the term may accurately describe the federal side of the ballot, there was nothing "midterm" about last fall's state campaigns, which resulted in the election of all four of New York's statewide officials and every one of the 213 members of its state legislature—and the consequences of the election will be significant on health-related legal and legislative matters for years to come.

As this is being written, the 2018 elections have just taken place and a few of the more hotly contested contests have just been called. Nevertheless, it is not too soon to begin assessing the impact of the 2018 election on New York State health policy in 2019 and beyond.

Even before the last votes are counted, the rumored "blue wave" of Democratic resurgence was evident in New York, even if the results were somewhat more mixed nationally. Democrats easily won each of the statewide races, maintained overwhelming control of the State Assembly and captured the State Senate majority, which had been the last bastion of Republican power in state government.

Governor Andrew Cuomo won a very convincing victory and commences his third term with a strong mandate for his version of what his father, Governor Mario Cuomo, called "progressive pragmatism." While he has denied national ambitions, his political resume will attract support as the Democrats prepare to select a nominee in 2020—and his proposals and policies governing health care, in particular, will inevitably be viewed through that lens. It might also be expected that the other statewide officials, State Comptroller Thomas DiNapoli, Lieutenant Governor Kathy Hochul and Attorney General-elect Letitia James will be increasingly scrutinized by observers who may wonder if the Governorship may be in their futures. For health care attorneys, Attorney General James' approach to her new responsibilities will bear especially close watching, given the important role her office plays in regulating health care practices, overseeing not-for-profit organizations and prosecuting Medicaid fraud.

Albany-watchers were most focused on the battle for control of the State Senate, which the Republicans controlled before the election by a single vote. Democrats captured several seats, including several held by Republicans on Long Island and in the lower Hudson Valley, and will begin the 2019 legislative session with an anticipated majority of either 39 or 40 members in the 63-member Senate, depending on whether independent-minded Senator Simcha Felder joins the Republican or Democratic caucus. Perhaps as consequence, six of the eight members of the more moderate Independent Democratic Conference were defeated in the primary by more progressive challengers, who may tilt the ideological balance in the Senate further to the left.

The new Senate Majority Leader, Andrea Stewart-Cousins, will be given the opportunity to appoint new Chairs to the subject-matter Committees in the Senate—a task that may not be undertaken until the session commences in January. It is assumed that the current ranking member of the Senate Health Committee, Senator Gustavo Rivera, may be appointed to Chair the Health Committee, a role that Senator Kemp Hannon has played (with one brief interruption) for over two decades with extraordinary leadership, insight and skill. Senator Hannon would have surrendered the role in any event, given the Democratic majority, but he was actually among the incumbent Republicans who were not returned to Albany.

Assembly Speaker Carl Heastie will continue to lead an overwhelmingly Democratic majority (107-43), despite the fact that the Republicans had a net gain of two seats in that lower house. As Senator Hannon displayed, the Health Committees play an instrumental role in shaping health policy, as evidenced by Assembly Health Committee Chair, Richard Gottfried, who has served even longer in that role and is expected to continue to do so.

While the change in Senate control may be the most dramatic result, the unusually large number of "freshmen" in both houses may be almost as noteworthy: there will be 17 *new* Senators, 15 Democrats and 2 Republicans, in the 63-seat Senate, meaning that more than one in four of the members have never served in the Senate before—many of whom have never held public office previously. Twenty-one *new* Assemblymembers were elected, including 12 Democrats and nine Republicans.

With Democrats in control of the Governor's Office and both chambers of the state legislature, it is likely that legislative initiatives that were stalled in the Republican Senate will receive new momentum. Among the healthcare issues likely to be debated this year are the following five:

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*Reproductive Health:* For several years, legislation that would codify *Roe v. Wade* and update other elements of New York law governing abortion has stalled in the State Senate. Prompt passage of the legislation is expected in early 2019, thanks to the new Democratic Senate majority and spurred by the prospect that *Roe* may be endangered by the re-aligned Supreme Court. Likewise, legislation that would strengthen provisions in the Affordable Care Act (ACA) and the New York Insurance Law requiring insurance coverage of contraception, known as the Comprehensive Contraception Coverage Act, is also expected to be enacted in the new session.

*Single Payor:* Assemblyman Gottfried's New York Health Act, which would establish a single payor health care system for New York State, has passed the Assembly routinely in recent years but has stalled in the Senate—where it was sponsored by virtually every member of the then-Senate minority Democratic caucus. Health care stakeholders, including the health insurance industry (which would be eliminated by the legislation), have mobilized in the last several months to try to block the bill and Governor Cuomo has expressed skepticism over whether a state-based single payor proposal is fiscally viable.

*Coverage Expansion and Insurance Market Stabilization:* In order to extend coverage to the 5 percent of New Yorkers who lack health insurance and to forestall the more radical single payor proposal, consideration is likely to be given to steps New York might take to expand coverage and enhance the affordability of individual coverage on the state's ACA exchange. Proposals may be advanced to stabilize the New York State of Health exchange coverage, to enact a state-only individual health insurance mandate (replacing the now repealed ACA mandate), to extend and expand Essential Plan and Medicaid coverage and to design some approach to providing coverage to undocumented immigrants, who make up about one-third of New York's uninsured.

*Marijuana:* Strong support for legalizing adult-use marijuana in the Democratic caucuses, together with the more recent endorsement by Governor Cuomo, puts that issue front and center in 2019, with the debate largely focused on the extent of state regulation, the inclusion of minority- and women-owned businesses among the authorized dispensaries and the potential impact of legalization on the existing medical marijuana facilities.

*Nurse Staffing Ratios:* For several years, the Legislature has considered proposals to enact mandatory nurse staffing levels in hospitals and other healthcare facilities, a proposal that Governor Cuomo endorsed last year. Despite sustained efforts by the New York State Nurses Association, the legislation has stalled due to vigorous opposition from the hospital and nursing home industry. The issue was defeated in a referendum last November by over 70 percent of Massachusetts voters—a factor that may be considered by the legislature when the issue re-emerges in 2019.

# In the New York State Agencies

By Francis J. Serbaroli

**Establishment and Operation of Market Stabilization Mechanisms for Certain Health Insurance Markets**

Notice of Adoption. The Department of Financial Services amended Part 361 (Regulation 146) of Title 11 NYCRR to allow for the implementation of a market stabilization pool for the individual and small group health insurance markets. *See* N.Y. Register August 15, 2018.

**Food and Beverages in Funeral Establishments**

Notice of Adoption. The Department of Health amended sections 77.5, 78.1 and 79.4 of Title 10 NYCRR to lift the ban of the consumption of food and beverages in funeral establishments. *See* N.Y. Register August 15, 2018.

**Patients' Bill of Rights**

Notice of Proposed Rulemaking. The Department of Health proposes to amend sections 405.7 and 751.9 of Title 10 NYCRR to require general hospitals and diagnostic and treatment centers to update their statements of patient rights. *See* N.Y. Register August 15, 2018.

**Certificate of Incorporation**

Notice of Adoption. The Office for People with Developmental Disabilities amended Part 681 of Title 14 NYCRR to remove a requirement for certificate holders that is no longer required under Mental Hygiene Law section 16.07. *See* N.Y. Register August 15, 2018.

**Statewide Planning and Research Cooperative System**

Notice of Proposed Rulemaking. The Department of Health proposes to amend section 400.18 of Title 10 NYCRR to revise the SPARCS regulation related to data intake. *See* N.Y. Register August 22, 2018.

**New York State Medicaid Infertility Treatment**

Notice of Proposed Rulemaking. The Department of Health proposes to amend sections 505.1 and 505.3 of Title 18 NYCRR to authorize Medicaid coverage of infertility benefits. *See* N.Y. Register August 22, 2018.

**Care Coordination Organizations**

Notice of Adoption. The Office for People with Developmental Disabilities amended Subpart 635-11 of Title 4 NYCRR to allow individuals to be enrolled in a CCO when individuals are unable to enroll themselves. *See* N.Y. Register August 22, 2018.

**Site-Based and Community-Based Prevocational Services**

Notice of Emergency Rulemaking. The Office for People with Developmental Disabilities amended Subpart 635-10 of Title 14 NYCRR to clarify site-based and community-based services and clarify reimbursement requirements. *See* N.Y. Register September 5, 2018.

**Enrollment in Medicare Prescription Drug Plans and Fully Integrated Duals Advantage Plans for IDO**

Notice of Emergency Rulemaking. The Office for People with Developmental Disabilities amended Subpart 635-11 of Title 14 NYCRR to allow individuals to be enrolled in a FIDA-IDD plan when individuals are unable to enroll themselves. *See* N.Y. Register September 5, 2018.

**The Rule Pertains to HIV/AIDS Prevention, Treatment and Confidentiality**

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposes to amend repeal of Parts 309, 1070, 1072; and addition of Part 807 of Title 14 NYCRR to clarify the statutory and regulatory obligations of OASAS programs relating to HIV/AIDS. *See* N.Y. Register September 12, 2018.

**Update Standards for Adult Homes and Standards for Enriched Housing Programs**

Notice of Emergency and Proposed Rulemaking. The Department of Health amended sections 486.7, 487.4, 488.4, 490.4 and 494.4 of Title 18 NYCRR to prohibit residential providers from excluding an applicant based solely on the individual's status as a wheelchair user. *See* N.Y. Register September 12, 2018.

**Minimum Standards for Form, Content and Sale of Health Insurance, Including Standards for Full and Fair Disclosure**

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 NYCRR to establish minimum requirements for policies of volunteer firefighter enhanced cancer insurance. *See* N.Y. Register September 19, 2018.

**Eligibility of Services**

Notice of Emergency Rulemaking. The Office for People with Developmental Disabilities added Part 629 to Title 14 NYCRR to create the eligibility for individuals applying

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**Compiled by Francis J. Serbaroli.** Mr. Serbaroli is a shareholder in the Health & FDA Business Group of Greenberg Traurig's New York office. He is the former Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the New York Law Journal, and is the former Chair of the Health Law Section. The assistance of Caroline B. Brancatella and Katharine J. Neer, respectively of counsel and associate of Greenberg Traurig's Health and FDA Business Group, in compiling this summary is gratefully acknowledged.

for OPWDD-authorized services. *See* N.Y. Register September 19, 2018.

**Site-Based and Community-Based Prevocational Services**

Notice of Adoption. The Office of People with Developmental Disabilities amended Subpart 635-10 of Title 14 NYCRR to clarify site-based and community-based services and clarify reimbursement requirements. *See* N.Y. Register September 19, 2018.

**Respite Services**

Notice of Adoption. The Office of People with Developmental Disabilities amended Subpart 635-10 of Title 14 NYCRR to remove language that conflicts with respite services related to the new 1115 waiver. *See* N.Y. Register September 19, 2018.

**Minimum Standards for Form, Content and Sale of Health Insurance, Including Standards of Full and Fair Disclosure**

Notice of Adoption. The Department of Financial Services added section 52.73 (Regulation 62) to Title 11 NYCRR to provide a formulary exception process for medication for detoxification or maintenance treatment of a substance use disorder. *See* N.Y. Register September 26, 2018.

**Minimum Standards for Form, Content and Sale of Health Insurance, Including Standards of Full and Fair Disclosure**

Notice of Adoption. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 NYCRR to ensure essential health benefits coverage in all individual, small and large group, and student accident and health policies. *See* N.Y. Register October 3, 2018.

**Transportation Network Companies: Minimum Provisions for Policies and Other Requirements**

Notice of Proposed Rulemaking. The Department of Financial Services proposes to amend section 60-3.7(b) of Title 11 NYCRR to extend the date in section 60-3.7(b) from January 1, 2019 to July 1, 2019 and to fix an incorrect citation. *See* N.Y. Register October 3, 2018.

**Minimum Standards for Form, Content and Sale of Health Insurance, Including Standards of Full and Fair Disclosure**

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 NYCRR to ensure essential health benefits coverage in all individual, small and large group, and student accident and health policies. *See* N.Y. Register October 10, 2018.

**Problem Gambling Treatment and Recovery Services**

Notice of Revised Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposes a repeal of Part 857; and addition of new Part 857 to Title 14 NYCRR to repeal existing gambling regulation and replace it with substantially updated provisions. *See* N.Y. Register October 17, 2018.

**Credentialing of Addictions Professionals**

Notice of Revised Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposes to repeal Part 853; addition of new Part 853 to Title 14 NYCRR to repeal obsolete rules and update process of credentialing addictions professionals. *See* N.Y. Register October 17, 2018.

**Durable Medical Equipment; Medical/Surgical Supplies; Orthotic and Prosthetic Appliances; Orthopedic Footwear**

Notice of Proposed Rulemaking. The Department of Health proposes to amend section 505.5 of Title 18 NYCRR to amend the Department's regulation governing Medicaid coverage of orthopedic footwear and compression and support stockings. *See* N.Y. Register October 17, 2018.

**Stroke Services**

Notice of Proposed Rulemaking. The Department of Health proposes the addition of section 405.34 to Title 10 NYCRR to establish the NYS criteria for stroke center designation as part of an accrediting process for certification by nationally recognized accrediting agencies. *See* N.Y. Register October 17, 2018.

**Office-Based Surgery Practice Reports**

Notice of Proposed Rulemaking. The Department of Health proposes to amend Part 1000 of Title 10 NYCRR to requires accredited Office-Based Surgery practices to submit adverse event and practice information which includes procedural data. *See* N.Y. Register October 17, 2018.

**Emergency Medical Services (EMS) Initial Certification Eligibility Requirements**

Notice of Revised Proposed Rulemaking. The Department of Health proposes the amendment of sections 800.6 and 800.12 of Title 10 NYCRR to reduce the EMS certification eligibility minimum age from 18 to 17 years of age. *See* N.Y. Register October 17, 2018.

**Operation of Crisis Residences in New York State**

Notice of Proposed Rulemaking. The Office of Mental Health proposes to amend Part 589 of Title 14 NYCRR to revise and update the categories of Crisis Residences to match what is currently operation in New York. *See* N.Y. Register October 24, 2018.

**Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards for Full and Fair Disclosure**

Notice of Adoption. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 NYCRR to establish minimum requirements for policies of volunteer firefighter enhanced cancer insurance. *See* N.Y. Register October 31, 2018.

**Medical Use of Marihuana**

Notice of Emergency Rulemaking. The Department of Health

amended section 1004.2 of Title 10 NYCRR to add additional serious conditions for which patients may be certified to use medical marihuana. *See* N.Y. Register October 31, 2018.

**Rates of Reimbursement—Alcoholism Facilities**

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 840 of Title 14 NYCRR to repeal obsolete regulations. *See* N.Y. Register November 7, 2018.

**Standards for Alcoholism Facilities to Participate in the Medicaid Program**

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 839 of Title 14 NYCRR to repeal obsolete regulations. *See* N.Y. Register November 7, 2018.

**Sale of Electronic Cigarette Flavored Liquids**

Notice of Proposed Rulemaking. The Department of Health proposes to amend Part 9 of Title 10 NYCRR to prohibit the sale of electronic cigarette flavored liquids. *See* N.Y. Register November 7, 2018.

**Telehealth**

Notice of Emergency and Proposed Rulemaking. The Office for People with Developmental Disabilities amended Subpart 635-13 and Part 679 of Title 14 NYCRR to authorize telehealth as a new modality for the delivery of clinical services. *See* N.Y. Register November 7, 2018.

# New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

## New York State Department of Health Medicaid Decisions

Compiled by Margaret Surowka Rossi

None reported.

## New York State Attorney General Press Releases

Compiled by Bridget Steele, Dena DeFazio and Eric Dyer

**New York Agreed to a Settlement With Pfizer for Its Deceptive Advertising in Its Copayment Card Program**—October 11, 2018—The settlement between New York and Pfizer led to Pfizer paying over $200,000 in restitution to consumers and $500,000 in penalties, fees and costs for its "Pay No More Than" drug copayment card program. Pfizer also agreed to change the text on its coupons to "pay as little as." In some cases, when consumers presented the "Pay No More Than" coupon at pharmacies, they were required to pay more than the stated out-of-pocket amount. https://ag.ny.gov/press-release/ag-underwood-announces-settlement-pfizer-deceptive-advertising-pay-no-more-drug.

**Unlicensed Nurse Arrested for Accepting Over $20,000 in Salary for Unauthorized Practice**—October 10, 2018—A Rochester nurse was arrested for Grand Larceny and the Unauthorized Practice of a Profession for allegedly accepting more than $20,000 in salary from a nurse staffing agency while practicing without a license. The nurse's license was suspended on October 4, 2017, but she continued providing nursing services until January 7, 2018. The charge for Grand Larceny in the Third Degree is a class D felony, and the Unauthorized Practice of a Profession is a class E felony. If convicted, the nurse faces a maximum sentence of seven years. https://ag.ny.gov/press-release/ag-underwood-announces-arrest-rochester-nurse-charged-grand-larceny-and-working.

**AmerisourceBergen Settles With States and Federal Government for $625 Million—October 1, 2018**—New York, 43 other states and the federal government reached a settlement with drug distributor AmerisourceBergen Corporation (ABC) for illegally distributing adulterated and misbranded drugs. The allegations stem from a pharmacy opened by an ABC subsidiary in Alabama that caused false claims to be submitted to Medicaid for unapproved, defective, contaminated and compromised drugs and for double billing for the same vial of drug product. The pharmacy allegedly broke the seal of FDA-approved drugs in an unsterile environment, and then combined and repackaged the drug vials in order to create excess drug product. The ABC subsidiary also pled guilty to illegally distributing misbranded drugs in September 2017, and agreed to pay $260 million in criminal fines and forfeitures. In total, the New York Medicaid program will receive over $7 million from the civil settlement. https://ag.ny.gov/press-release/ag-underwood-announces-625-million-national-agreement-amerisourcebergen-corporation.

**Orange County Taxi Cab Owner Arrested For Allegedly Stealing From Medicaid**—September 26, 2018—A cab owner and operator was arrested for submission of false claims concerning medical transportation services and improper receipt of over $200,000 from Medicaid between August 30, 2013 and October 1, 2017. The owner allegedly submitted individual mileage claims for each Medicaid recipient, even though the recipients travelled as a group. The owner also claimed the maximum amount of $50 in toll expenses, rather than the amount incurred. The charges include Grand Larceny in the Second Degree, a class C felony, and multiple counts of Offering a False Instrument for Filing in the First Degree, a class E felony. The charges could result in a sentence of five to 15 years. https://ag.ny.gov/press-release/ag-underwood-announces-arrest-orange-county-taxi-cab-company-owner-stealing-over-200k.

**A.G. Underwood Files Brief for Women's Birth Control Access**—September 25, 2018—Along with 17 other Attorneys General, the New York Attorney General filed an amicus brief in support of a Massachusetts lawsuit that challenges the Federal Government's attempt to change rules related to contraception coverage. The Federal Government has appealed an injunction that prevents its proposed rules from taking effect. The proposed rules permit employers with a religious or moral objection to be released from having to provide contraceptive coverage. The amicus brief argues that this rule change would violate the Affordable Care Act's requirement that insurance companies pay for preventive health care services without co-pays. https://ag.ny.gov/press-release/attorney-general-underwood-files-brief-protect-womens-birth-control-access.

**A.G. Underwood Announces Guilty Plea of Former Medical University President for Abusing His Position to Illegally Boost His Pay**—September 24, 2018—The former President of SUNY Upstate Medical University pleaded guilty to three counts of official misconduct, must pay more than $250,000 in restitution and fines, and is expected to receive three years' probation. An investigation found that while serving as president from September 2006 to November 2013, the former president abused

his authority and increased his pay without authorization by directing a subordinate to approve an unauthorized raise, receiving unauthorized housing expenses, and directing and overseeing the creation of a deferred compensation plan to benefit himself and others, without the SUNY Chancellor's authorization or knowledge. https://ag.ny.gov/press-release/ag-underwood-announces-guilty-plea-former-suny-upstate-medical-university-president.

**A.G. Underwood Announces Guilty Pleas of Former Nursing Home Operators for Endangering Resident**—September 12, 2018—A former corporate owner/operator and a high managerial agent pleaded guilty to Endangering the Welfare of an Incompetent or Physically Disabled Person in the Second Degree, a class A misdemeanor. The charges arose after an elderly resident was left in a recliner for approximately 41 hours without medication, food, water, services, treatment, or care. Four staff members were also convicted of neglect for making false entries in the resident's medical records. An investigation found that the owner/operator and managerial agent controlled the nursing home from October 2014 to December 31, 2017. During that time, staff payroll, staffing levels, and other necessary services and supplies were cut, resulting in inadequate staffing and insufficient supervision of staff members. The owner/operator and managerial agent received benefits from Medicaid funds for resident care through ownership or control of other companies. In addition to the guilty pleas, the owner/operator, managerial agent and corporation entered into an assurance of discontinuance and agreed to pay $1 million to the Medicaid program for restitution, damages and equitable relief to resolve civil claims. The owner/operator and managerial agent also agreed to divest themselves of all interests in health care providers operating in New York State; to not operate or administer any health care providers; nor have oversight or involvement in financial operations or decisions involving the delivery of health care services to nursing home residents for a period of five years. https://ag.ny.gov/press-release/ag-underwood-announces-guilty-pleas-former-focus-otsego-nursing-home-operators.

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**Ms. DeFazio** is a law clerk, awaiting admission to the New York State Bar, in the Firm's Albany office, focusing her practice in the health care controversies and health care and human services areas.

**A.G. Underwood Announces $1.65 Million Joint State-Federal Settlement With Centers Plan for Healthy Living Over False Medicaid Billing**—September 12, 2018—A settlement was reached resolving allegations that a long-term care plan violated both the state and federal False Claims Acts by submitting fraudulent requests to Medicaid for monthly premiums. Centers Plan contracted with licensed home care services agencies to provide skilled nursing and home health aide services to its managed long-term care plan members. An investigation stemming from a whistleblower lawsuit found that between April 1, 2013 and December 31, 2015, members did not receive services during at least a portion of the period for which they were enrolled. However, Centers Plan failed to disenroll these members in a timely manner, and continued to collect monthly Medicaid premiums of $2,500 to $4,300 per member, per month. The New York State Medicaid program will receive $1.65 million in restitution and penalties as a result of the settlement. https://ag.ny.gov/press-release/ag-underwood-announces-165-million-joint-state-federal-settlement-centers-plan-healthy.

**A.G. Underwood Leads New Amicus Brief Opposing Efforts to Defund Planned Parenthood**—September 4, 2018—A coalition of 18 Attorneys General, including New York, filed an amicus brief in the U.S. Court of Appeals, Sixth Circuit case *Planned Parenthood of Greater Ohio v. Himes*. The brief challenged an Ohio state law that would defund Planned Parenthood and other health services providers by prohibiting the award of public health grants to providers performing or promoting safe and legal abortions, despite the fact that the grants are unrelated to such services. Instead, the grants provide funds for health care services including breast and cervical cancer screenings, HIV and AIDS prevention, and infant mortality prevention, among others. The Attorneys General alleged violations of the First Amendment and Due Process Clauses, and that the law imposed an unconstitutional condition on state grants infringing on plaintiffs' right to free speech and to provide access to abortion services, as well as clients' rights to receive these services. https://ag.ny.gov/

press-release/ag-underwood-leads-new-amicus-brief-opposing-efforts-defund-planned-parenthood.

**A.G. Underwood Announces Prison Sentence of Patient Recruiter Who Bribed Medicaid Recipients to Undergo Unnecessary Medical Tests**—August 29, 2018—A Manhattan man was sentenced in Queens County Criminal Court to 1½ to 3 years in state prison for defrauding Medicaid, resulting in more than $10,000 in fraudulent claims. He previously pleaded guilty to Health Care Fraud in the Fourth Degree, Grand Larceny in the Fourth Degree, and Prohibited Practices for Persons Acting in Concert with a Medical Assistance Provider, all class E felonies. Undercover agents observed the man offering individuals with Medicaid coverage cash to undergo physicals and testing. The investigation showed that individuals were told to report certain specified health conditions to clinic staff, without regard for truthfulness, and that each patient received identical testing, regardless of medical history or need. Upon completion of the tests, the patients were paid cash. Patients did not receive their test results and no follow up appointments were scheduled. https://ag.ny.gov/press-release/ag-underwood-announces-prison-sentence-patient-recruiter-who-bribed-medicaid.

**A.G. Underwood Announces Restoration of $574 Million to NY's Essential Plan, Following AG Lawsuit**—August 29, 2018—Earlier in the year, the Attorney General filed a lawsuit to block the Trump Administration from cutting funding for New York's Essential Plan. A.G. Underwood announced that following the lawsuit, the Trump Administration ordered the restoration of $574 million for three-quarters of the year for New York's Essential Plan. https://ag.ny.gov/press-release/ag-underwood-announces-restoration-574-million-nys-essential-plan-following-ag-lawsuit.

**A.G. Underwood Announces $200,000 Settlement With Non-Profit for Exposing Clients' Sensitive Personal Information on Internet for Years**—August 29, 2018—The Attorney General announced a settlement with a nonprofit serving people with developmental disabilities for exposing its clients' personal information online. The organization notified affected clients, provided clients with a free one-year subscription to LifeLock to protect themselves from identity theft, and posted a link to information regarding the breach on its website. As part of the settlement, the nonprofit will pay $200,000, conduct a risk analysis, and review and revise its policies and procedures. https://ag.ny.gov/press-release/ag-underwood-announces-200000-settlement-buffalo-non-profit-exposing-clients-sensitive.

**A.G. Underwood and Governor Cuomo Announce Suit Against Purdue Pharma for Widespread Fraud and Deception in Marketing of Opioid Products**—August 14, 2018—A.G. Underwood and Governor Cuomo filed a lawsuit against Purdue Pharma L.P., Purdue Pharma Inc., and Purdue Frederick Company, Inc. ("Purdue") alleging that Purdue persistently made misrepresentations about its opioid products as less subject to addiction than other opioid products in order to increase opioid product sales. The lawsuit seeks disgorgement of profits, civil penalties, restitution, and costs to abate the harms caused. https://ag.ny.gov/press-release/attorney-general-underwood-and-governor-cuomo-announce-suit-against-purdue-pharma.

**A.G. Underwood Announces Arrest of Nurse Aide for Alleged Patient Abuse**—August 1, 2018—A Certified Nurse Aide working at a nursing home was arrested for allegedly wrestling a 64-year-old patient to the ground, punching him, yelling a racial epithet, smelling of alcohol and appearing high. The 57-year-old nurse aide was charged with Endangering the Welfare of an Incompetent or Physically Disabled Person in the First Degree and Willful Violation of Health Laws. https://ag.ny.gov/press-release/ag-underwood-announces-arrest-monroe-county-nurse-aide-alleged-patient-abuse.

**A.G. Underwood Takes Action Against "Gag Rule" That Jeopardizes Critical Family Planning Funding**—July 31, 2018—A.G. Underwood filed comments opposing the United States Department of Health and Human Services' (HHS) proposed rule that makes regulatory changes to the Title X program. The services provided through Title X include screenings for depression, sexually transmitted diseases, and breast and cervical cancers; counseling on family planning methods; and access to contraception. A.G. Underwood claims the proposed rule will reduce and delay patient access to care and decrease the quality of care provided through Title X, as certain requirements may make it difficult for many providers to continue participating in Title X. A.G. Underwood is seeking withdrawal of the proposed rule and plans to sue if it becomes law. https://ag.ny.gov/press-release/attorney-general-underwood-takes-action-against-gag-rule-jeopardizes-critical-family.

## New York State Office of the Medicaid Inspector General Update

Compiled by Eric Dyer

**OMIG Pharmacy Inspections, Referral Leads to Arrest of Brooklyn Pharmacist Who Illegally Diverted Oxycodone**—November 1, 2018—https://omig.ny.gov/latest-news/1115-omig-pharmacy-inspections-referral-leads-to-arrest-of-brooklyn-pharmacist-who-illegally-diverted-oxycodone.

**OMIG Issues 2017 Annual Report**—October 4, 2018—https://omig.ny.gov/latest-news/1108-omig-releases-2017-annual-report.

**UPDATE: Second Doctor Who Participated in $30 Million Health Care Fraud Scheme Sentenced in Federal Court**—August 22, 2018—https://omig.ny.gov/latest-news/1105-update-second-doctor-who-participated-in-30-million-health-care-fraud-scheme-sentenced-in-federal-court.

# In the Law Journals

Edited by Cassandra Rivais

*A Bottom-Up Approach to Understanding Low-Income Patients: Implications for Health-Related Policy*, Madu Viswanathan et al., 46 J. of Law, Med. & Ethics 658 (2018).

*A Hiatus in Soft-Power Administrative Law: The Case of Medicaid Eligibility Waivers*, David A. Super, 65 UCLA L. Rev. 1590 (2018).

*Able Accounts: A New Means to Preserve Benefits for Disabled Clients*, Jack T. Carney, 79 Ala. Law. 327 (2018).

*Administering Health Innovation*, Rachel E. Sachs, 39 Cardozo L. Rev. 1992 (2018).

*Advance Directives and Alzheimer's Disease*, Deena S. Davis, 46 J. of Law, Med. & Ethics 744 (2018).

*Alzheimer's Disease — Perspective from Political Science: Public Policy Issues*, Robert H. Blank, 46 J. of Law, Med. & Ethics 724 (2018).

*Civil Litigation Reform in the Trump Era: Threats and Opportunities: The Looming Battle for Control of Multidistrict Litigation in Historical Perspective*, Andrew D. Bradt, 87 Fordham L. Rev. 87 (2018).

*Clearly Unconvincing: How Heightened Evidentiary Standards in Judicial Bypass Hearings Create an Undue Burden under Whole Woman's Health*, Haley Hawkins, 67 Am. U.L. Rev. 1911 (2018).

*Common Sense: Rethinking the New Common Rule's Weak Protections for Human Subjects*, Ahsin Azim, 71 Vand. L. Rev. 1704 (2018).

*CRISPR Future for Gene-Editing Regulation: A Proposal for an Updated Biotechnology Regulatory System in an Era of Human Genomic Editing*, Tracey Tomlinson, 87 Fordham L. Rev. 437 (2018).

*Cyber Babel: Finding the Lingua Franca in Cybersecurity Regulation*, William

Pierotti, 87 Fordham L. Rev. 405 (2018).

*Data Collection, EHRs, and Poverty Determinations*, Craig Konnoth, 46 J. of Law, Med. & Ethics 622 (2018).

*Doctors on the Take: Aligning Tort Law to Address Drug Company Payments to Prescribers*, Lars Noah, 66 Buffalo L. Rev. 855 (2018).

*Failed Charity: Taking State Tax Benefits into Account for Purposes of the Charitable Deduction*, Roger Colinvaux, 66 Buffalo L. Rev. 780 (2018).

*Health Care Law: New Model Health Care Power of Attorney Form Addresses Alzheimer's Patients' Needs*, Marsha A. Goetting and Kathy Kenyon, 43 Montana Lawyer 22 (2018).

*Incentivizing Pharmaceutical Testing in an Age of Off-Label Promotion*, Ryan Sila, 93 N.Y.U.L. Rev. 942 (2018).

*Influenza Mandates and Religious Accommodation: Avoiding Legal Pitfalls*, Dorit Rubinstein Reiss and V.B. Dubal, 46 J. of Law, Med. & Ethics 756 (2018).

*Is There an Employer in the House?: Evaluating the National Labor Relations Board's Joint-Employer Standard in the Fissured Health Care Workplace*, James van Wagtendonk, 98 B.U.L. Rev. 1105 (2018).

*Market Power and Antitrust Enforcement*, John B. Kirkwood, 98 B. U. L. Rev. 1170 (2018).

*Michelle Carter and the Curious Case of Causation: How to Respond to a Newly Emerging Class of Suicide-Related Proceedings*, Nicholas LaPalme, 98 B.U.L. Rev. 1444 (2018).

*Motherhood, Abortion, and the Medicalization of Poverty*, Michelle Oberman, 46 J. of Law, Med. & Ethics 665 (2018).

*Not So Different after All: The Status of Interpretive Rules in the Medicare Act*, Graham Haviland, 85 U. Chi. L. Rev. 1511 (2018).

*Renovations Needed: The FDA's Floor/Ceiling Framework, Preemption, and the Opioid Epidemic*, Michael R. Abrams, 117 Mich. L. Rev. 144 (2018).

*Reorienting the Rules of Evidence*, Gillian R. Chadwick, 39 Cardozo L. Rev. 2116 (2018).

*Sexual Harassment and Corporate Law*, Daniel Hernel and Dorothy S. Lund, 118 Colum. L. Rev. 1583 (2018).

*State Action and the Constitution's Middle Band*, Louis Michael Seidman, 117 Mich. L. Rev. 2 (2018).

*Supported Decision-Making in the Lone-Star State*, Eliana J. Theodorou, 93 N.Y.U.L. Rev. 974 (2018).

*The Implications of Medical Malpractice Tort Reform in Missouri on Physician Supply*, Charles L. Baum II, 74 J. Mo. B. 246 (2018).

*The Futility of Futility: An Analysis of the Charlie Gard Case Within the Framework of U.S. Law*, Elana Bengualid, 40 Cardozo L. Rev. 464 (2018).

*The Limits of Professional Speech*, Claudia E. Haupt, 128 Yale L. J. F. 185 (2018).

*The Restoration Remedy in Private Law, Omri Ben-Shahar and Ariel Porat*, 118 Colum. L. Rev. 1901 (2018).

*The Role of Community Health Needs Assessments in Medicalizing Poverty*, Arden Caffrey, Carolyn Pointer, Da-

**Cassandra Rivais** is an Associate Attorney at Rivkin Radler, LLP in the Health Services Group.

vid Steward and Sameer Vohra, 46 J. of Law, Med. & Ethics 615 (2018).

*The Tethered President: Consistency and Contingency in Administrative Law*, William W. Buzbee, 98 B.U.L. Rev. 1358 (2018).

*The Trouble with Corporate Conscience*, James D. Nelson, 71 Vand. L. Rev. 1656 (2018).

*Unmothering Black Women: Formula Feeding as an Incident of Slavery*, Andrea Freeman, 69 Hastings L. J. 1546 (2018).

*When Artificial Intelligence Systems Produce Inventions: An Alternative Model for Patent Law at the 3A Era*, Shlomit Yanisky Ravid and Xiaoqiong (Jackie) Liu, 39 Cardozo L. Rev. 2217 (2018).

*Where Breaking Glass Ceilings Leads to Glass Walls: Gender-Disparate Managerial Decision-Making Power and Authority*, Bina Nayee, 87 Fordham L. Rev. 371 (2018).



# For Your Information

By Claudia O. Torrey

The following information is a brief overview and reminder of some delayed implementation changes to the Federal Policy for the Protection of Human Subjects (the Common Rule, or "CR); the new date is January 19, 2019 (Revised CR, 82 Fed. Reg. No.12, January 19, 2017). Effective January 19, 2019, some of the clarion CR changes will affect continuing review, exemptions, and informed consent.

Continuing review will no longer be needed for ongoing research that can undergo an expedited review, or for research studies wherein the only remaining activity is the analysis of identifiable data/biospecimens or activity to obtain observational follow-up clinical data. Expounding upon an expedited review, such requires research review by the Institutional Review Board (IRB) chair or by one or more experienced reviewers designated by the chairperson (45 C.F.R. Part 46.110).

There will be some new categories and clarifications for exempt research (45 C.F.R. Part 46.110 and 21 C.F.R. Part 56.110) yielding "Limited IRB Review and/or Self-Determination Review." While a limited review may be self-explanatory, self-determination review permits the principal investigator to issue an exemption determination based on responses to key questions within the qualifying human subjects' exemption categories. Of course, one would expect that an entity involved in any research that accesses Protected Health Information would not permit a self-determination exemption.

Regarding informed consent there are some waiver changes, as well as the utilization of a "broad consent" alternative consent option allowed *only* for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens for future use. Research teams that utilize a broad consent will be required to (a) identify the types of research that may be conducted with the data/biospecimens; (b) record and track who has refused or agreed to consent; and track consent terms to determine whether proposed future secondary research use falls within the scope of identified research types.

It should also be noted that as of January 20, 2020, most federallyfunded domestic collaborative research will be required to utilize a *single* IRB (academic, hospital-based, or commercial)—this is seen as less burdensome (Single IRB-of-record/sIRB).


**Claudia O. Torrey** is a Charter Member of the Health Law Section.

# The Impact on NYS Research Institutions of the Amended Federal Common Rule on Human Subject Research

By the Health Law Section Committee on Medical Research and Biotechnology

*Note: This Report was issued on January 4, 2018 in anticipation of a change to the federal Common Rule that was then expected to go into effect January 19, 2018. The change was postponed one year—until January 19, 2019. Accordingly, the Report now has renewed relevance, and is being published in the* Journal.

*Shortly before this edition of the Journal went to print, the Department of Health indicated that it is exploring ways to deem PHL 24-A inapplicable to research at institutions that comply with federal policies and regulations for all of its human subjects research.*

*—Sam Servello and Alex Brownstein,*
*Committee Co-Chairs*

As a result of a change in federal rules relating to human subjects research, a large amount of human subjects research conducted in New York will potentially no longer be subject to such federal regulations, and instead will have to start to comply with New York law governing such research. Without steps by the New York State Department of Health (DOH), this change could simultaneously diminish protections for human subjects in New York while also imposing significant new burdens on researchers, research institutions, and DOH. As explained below, we propose that DOH remedy the problem by finding that research institutions that commit by policy to follow the federal human subjects research standards either (i) remain exempt from New York law, or (ii) are in compliance with such law.

## I. Background

On January 19, 2017, HHS and 15 other federal agencies issued a final rule amending the federal Policy for the Protection of Human Subjects, also known as the Common Rule.[1] The Common Rule is a set of federal regulations that governs human subjects research funded by one of the adopting federal agencies. Among other changes, the revised U.S. Department of Health and Human Services' Office of Human Research Protections (OHRP) policy will eliminate the ability of a research institution to agree, as part of the assurance process discussed below, to comply with the Common Rule for those human subjects research activities that would not otherwise be subject to the Common Rule (i.e., research that is not federally funded—referred to in this memo, together with other research that does not involve FDA-regulated drugs or articles, as "non-federal human research").[2]

A research institution that conducts human subjects research funded by an adopting agency must submit a Federal Wide Assurance (FWA) form, a written assurance of compliance with the Common Rule, to OHRP. Currently, the FWA allows a research institution to voluntarily comply with the Common Rule for all human subjects research conducted by the institution, bringing even non-federal human research under the oversight of the OHRP. This election is commonly referred to as "checking the box" on the FWA form. However, under the revised federal rules, that option to "check the box" will be removed on January 19, 2018, when the final rule is expected to take effect.[3] As a result, research institutions will in the future lose the opportunity to subject their non-federal research to OHRP oversight through this process. However, OHRP has informally indicated that it will continue exercise oversight over non-federal research at any facility that "checked the box" prior to January 19, 2018, for so long as its FWA remains valid.

This change has significant implications for human subjects research conducted in New York. In 1975, New York State enacted Public Health Law Article 24-A - Protection of Human Subjects.[4] The statute, enacted in response to research abuses in New York,[5] defines "human research,"[6] requires informed consent for human research,[7] prohibits any person other than a licensed professional to conduct human research,[8] requires prior review and approval of human research by a "human research review committee"[9] (hereinafter, HRRC), requires reporting of violations to the Commissioner of the Department of Health (hereinafter, the "Commissioner"),[10] and requires the prior consent of the Commissioner for research involving "minors, incompetent persons, mentally disabled persons and prisoners."[11]

Significantly, PHL Article 24-A exempts from its applicability research that is subject to federal regulations aimed at the protection of human subjects, principally the Common Rule:

> **§ 2445. Applicability**
>
> The provisions of this article shall not apply to the conduct of human research which is subject to, and which is in compliance with, policies and regulations pro-

Opinions expressed are those of the Section/Committee preparing this memorandum and do not represent those of the New York State Bar Association unless and until they have been adopted by its House of Delegates or Executive Committee.

> mulgated by any agency of the federal government for the protection of human subjects.

The reason for the exemption is stated in the legislative memorandum supporting the passage of PHL Article 24-A. After noting the abuses the bill would address, the sponsor wrote:

> Federal regulations, promulgated since the occurrence of these incidences, cover those situations where federal funds are involved. This bill covers those remaining situations where federal regulations do not apply.[12]

Research institutions that "check the box" on the FWA become "subject to" the federal human subjects research regulations for all of their human subjects research, including their non-federal human research. Accordingly, they become exempt from PHL Article 24-A for non-federal research performed in compliance with federal regulations.[13]

*"Research institutions that 'check the box' on the FWA become 'subject to' the federal human subjects research regulations for all of their human subjects research, including their non-federal human research."*

Once research institutions lose the opportunity to check the box on a FWA, there is a concern that all of their non-federal research will become subject to PHL Article 24-A. If so, research institutions will face the complexity and administrative burden of complying with different regulations for different research protocols. This will also interfere with New York research institution participation in multistate research. Most importantly, this will significantly diminish the protection of research subjects by encouraging research institutions to decline to follow the comprehensive, detailed and up- to-date Common Rule safeguards for non-federal research.

Fortunately, DOH can avert the consequences of this federal change by taking the steps described below.

First, DOH can simply publicly acknowledge that institutions that checked the box on their FWA are still subject to OHRP oversight for the duration of their FWA and therefore remain exempt from PHL Article 24-A for that period (unless and until ORHP indicates otherwise). This step will provide significant immediate, if temporary, relief.

But the bigger issue, of course, relates to non-federal research conducted by institutions with new FWAs that do not include the checked box.

## II. Alternative Suggestions on How the Department May Move Forward

As explained below, provided a research institution adopts the policies described below, DOH can conclude that the research conducted by the institution either (i) continues to be exempt from PHL Article 24-A (See Section II.A.) or (ii) complies with PHL Article 24-A (See Section II.B).

### A. Research Institutions Continue to Be Deemed Exempt from PHL 24-A

Under PHL §2445, the NYS human subject research law does not apply to research "which is subject to, and which is in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects." Currently institutions voluntarily make themselves subject to the federal regulations by "checking the box." While that mechanism will disappear on January 19, 2018, there are other ways for an institution to legally commit itself to comply with the federal Common Rule.

Specifically, a research institution can adopt a policy that sets forth its commitment to comply with the Common Rule. This commitment would be legally enforceable: in the event the institution fails to follow Common Rule requirements, DOH would terminate the institution's exemption from PHL § 2445, and could if warranted, impose sanctions for PHL Article 24-A violations.

To be sure, research institutions will no longer be able to strictly comply with two procedural aspects of the Common Rule: the obligation to submit reports to OHRP and to allow inspections by OHRP. However, the institution's policy could remedy this by committing to make such reports to, and allow such inspections by, DOH.[14]

In this manner, the institution would continue to be legally subject to the substantive and ethical requirements of the federal regulations for the protection of human subjects, and subject to equivalent procedural requirements. This is a sufficient basis for the DOH to find that institutions that adopt such policies continue to qualify for the PHL §2445 exemption.

### B. Research Institutions That Comply with The Common Rule Will be Deemed in Compliance with PHL Article 24-A.

Even if a research institution is not exempt under PHL § 2445, it would be able to fully comply with Article

24-A by complying with the Common Rule, provided it takes some additional steps described in Section II.B.2. below.

### 1. Common Rule and PHL Article 24-A Compared

The Common Rule is both a far more comprehensive and detailed regulatory regime than PHL Article 24-A. Even with the recent amendments, intended in part to "reduce administrative burdens,"[15] the Common Rule is notable for the breadth and specificity of its requirements. Notably, it defines "research" much more broadly than PHL Article 24-A, and thereby governs a more extensive range of activity. Its requirements relating to IRBs and informed consent are lengthy and specific.

In contrast, PHL Article 24-A is relatively brief and general and states key concepts, primarily the need for informed consent and review by an HRRC, without much detail. Moreover, while the Common Rule is up to date, having undergone extensive federal rulemaking processes with broad participation by many stakeholders, PHL Article 24-A has remained unchanged for over 40 years since its original enactment in 1975.

As a result, for the most part the Common Rule requirements encompass and go beyond the PHL Article 24-A requirements. Thus, for the most part, compliance with the Common Rule constitutes compliance with PHL Article 24-A. This is demonstrated by the attached chart, which sets forth every provision in PHL Article 24-A, and shows the parallel Common Rule requirement where there is one. (Attachment 1).

Yet the attached chart also reveals six places where PHL Article 24-A has a requirement that does not expressly appear in the Common Rule, or where the Common Rule has an exception to a requirement and PHL Article 24-A does not expressly have that exception.

**a.** *Waiver and alteration of informed consent.* PHL Article 24-A prohibits the conduct of human research without informed consent of the subject or other authorized person.[16] It does not set forth a process for waiver of the requirement, or alteration of the elements of the informed consent.

In contrast, the Common Rule allows IRBs to approve waiver or alteration of informed consent requirements in narrow circumstances. The only circumstance that is relevant here is a waiver/alternation of informed consent where:

i. The research involves no more than minimal risk to the subjects;

ii. The research could not practicably be carried out without the requested waiver or alteration;

iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

v. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

The Common Rule defines "minimal risk" as follows:

> *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[17]

Since the definition of "human subject research" in PHL § 2441 is narrow and requires a "physical or psychological intervention on the body of the subject ... not required ... for the diagnosis, prevention, or treatment of disease"[18] only a rare and unusual case of human subject research could involve "no more than minimal risk" and thus be eligible for the Common Rule waiver. As a result, the waiver provision in the Common Rule is not in any material conflict with the requirements of PHL Article 24-A.

**b.** *Commissioner approval of HRRC membership.* PHL § 2444.1 requires that HRRC members must be "approved by the commissioner." There is no parallel provision in the Common Rule. Given the detailed IRB eligibility criteria in the Common Rule, the Commissioner could exercise his or her approval authority by approving in advance any person who meets Common Rule IRB membership criteria. Indeed the imposition of requirements for deemed approval would be an advance over current practice, in which this approval provision has been largely or entirely disregarded.

**c.** *Commissioner approval of HRRC statement of principle and policy.* PHL §2444.2 requires that the institution or agency that sponsors an HRRC must promulgate a statement of "principle and policy," and "the Commissioner shall approve that statement prior to its taking effect." The Common Rule requires each IRB to establish written procedures,[19] but does not call it a "statement of principle or policy" or have it approved in advance by the Commissioner. Again, given the detailed Common Rule requirements regarding IRB functions and operations, including the requirement that it adopt procedures, the Commissioner could exercise his or her authority by approving in advance any IRB policy that meets Common Rule IRB policy requirements.

**d.** *Expedited review.* PHL Article 24-A does not authorize "expedited review" (e.g., approval by the Chair and one other member) of any categories of research. In

contrast, the Common Rule offers an expedited review process for research involving no more than minimal risk, and for minor changes in previously approved research. As discussed above in connection with waiver or alteration of informed consent, activities that involve no more than minimal risk are unlikely to fall within the PHL definition of "human subject research." And there is no PHL Article 24-A requirement for HRRC approval of minor modifications to previously approved research. As a result, the expedited review provision in the Common Rule is not in conflict with the requirements of PHL Article 24-A.

**e.** *Duty to report violations*. PHL § 2444.2 requires the HRRC to report violations of its policies to the Commissioner. The Common Rule has no such requirement. For compliance with the Common Rule to meet PHL Article 24-A standards, this omission will have to be addressed. See Section II.B.2.b. below.

**f.** *Vulnerable populations*.

PHL § 2444.2 requires the approval of the Commissioner for certain categories of vulnerable subjects. Specifically, it states:

> In addition to the voluntary informed consent of the proposed human subject as required by section twenty-four hundred forty-two of this chapter, the consent of the committee and the commissioner shall be required with relation to the conduct of human research involving minors, incompetent persons, mentally disabled persons and prisoners.

In contrast, the Common Rule does not require governmental approval of such research. Instead, the Common Rule requires the following:

> When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.[20]

Moreover, the Common Rule also includes various subparts that set forth detailed and specific safeguards related to review of research involving certain populations, such as pregnant women (Subpart B), prisoners (Subpart C), and children (Subpart D). This Common Rule framework has been broadly accepted on a national level as an effective framework for addressing the particular vulnerabilities of these populations, without requiring governmental agency approval of each study. The issue of additional safeguards for "incompetent persons" and "mentally disabled persons" is discussed in Section II.B.2.d. below.

### 2. Steps Institution Would Take to Be Deemed In Compliance with PHL Art 24-A:

In all but a few respects, the Common Rule standards meet or exceed the PHL Article 24-A standards, and compliance with the Common Rule meets or exceeds compliance with PHL Article 24-A. However, the analysis in this paper reveals a few gaps, and a few requirements that require adaptation. Accordingly we believe that the Commissioner can accept compliance by a research institution with the Common Rule as compliance with PHL Article 24-A, with the provisos described below.

Research institutions that want to be deemed compliant with PHL Article 24-A by complying with the Common Rule must adopt a policy as described below.

**Adoption of a policy**. The research institution must adopt a policy, or amend an existing policy (the "Policy"), relating to "Non-Federal Human Research," (i.e. human subjects research not legally subject to the Common Rule or FDA regulation) that includes the following:

a. **Commitment to comply with Common Rule for Non-Federal Human Research.** The Policy must state that the institution will follow the Common Rule for all of its Non- Federal Human Research, with the adaptations set forth below. This is substantially the same commitment the institution now makes by "checking the box" on the FWA.

b. **Reporting to the Commissioner**. The Policy must state that for Non-Federal Human Research, any reports that would have been made to OHRP under the Common Rule must be made to the Commissioner.

c. **Books and Records**. The Policy must provide that for Non-Federal Human Research, any inspection rights that would have been given to OHRP under the Common Rule must be given to the Commissioner.

d. **Research Involving Vulnerable Subjects.**

   **i. Pregnant Women, Prisoners and Children:** The Policy should provide that the institution will comply with Subparts B, C and D of the Common Rule implementing safeguards protecting pregnant women, prisoners and children, respectively, for all Non-Federal Human Research.

   *Rationale for this recommendation*: The PHL §2444.2 requirement of Commissioner approval for research involving subjects is the most significant difference between the Common

Rule and PHL Article 24-A. As noted previously, PHL §2444.2 requires the consent of the Commissioner for research involving minors, incompetent persons, mentally disabled persons and prisoners.

As also noted above, the Common Rule includes three Subparts that set forth requirements specifically tailored to afford safeguards for three of the categories of vulnerable subjects specified in PHL §*2444*.2: pregnant women (Subpart B), prisoners (Subpart C), and children (Subpart D). Given those detailed safeguards, the Commissioner could and should exercise her or her consent authority by approving in advance research that meets Subpart B, C and D requirements.

**ii. "Incompetent persons" and "mentally disabled":**

a. The Policy should state that the institution will apply the safeguards in the Common Rule for incapable subjects (including consent by a legally authorized representative) for: (1) Non-Federal Human Research studies not focusing on individuals who lack capacity (e.g., a cancer study) that may include individuals who meet the inclusion criteria for that study but may lack capacity, as well as (2) Non-Federal Human Research studies focusing on individuals who lack capacity (e.g., an Alzheimer study) that involve no more than minimal risk.

b. For Non-Federal Research focusing on individuals who lack capacity (e.g., an Alzheimer study) that involve more than minimal risk the Policy must require that the IRB expressly *consider* whether an "Independent Consent Monitor" and/or "Medically Responsible Clinician" (as those terms are described below) is needed to protect the interests of the subject, and document that consideration. This could be accomplished on either a protocol-by-protocol basis, or address the issue in the policies of the IRB.

*Rationale for this recommendation*: The issue of additional safeguards for "incompetent persons" and "mentally disabled persons" is more complex. In 2009, a subcommittee appointed by OHRP—The Subcommittee for the Inclusion of Individuals With Impaired Decision Making in Research (SIIIDR)—*recommended* various safeguards for research involving subjects with impaired decision making.[21] HHS has not adopted those recommendations, so there is no Subpart with safeguards specific to that population.

In 2014 the NYS Task Force on Life and the Law recommended safeguards for research involving subjects who lack capacity, drawing in many respects upon the SIIIDR's recommendations.[22] The Task Force did not call for statutory or regulatory change; it focused on providing guidance for IRBs and researchers.[23] In particular, after categorizing research based on degree of risk to the incapable subject versus prospect of benefit to the subject, for certain categories it recommended assigning an "Independent Consent Monitor" (ICM)[24] for each subject, and for other categories it recommended a "Medically Responsible Clinician" (MRC) as well.[25]

Notably, the Task Force took the position that the adoption of certain safeguards "would obviate the need for full case-by-case Commissioner/Department of Health review."[26] We agree with the Task Force that the Commissioner can fulfill the PHL § 2444.2 approval requirement by categorical rather than case-by-case approvals.

We recommend that the Commissioner can and should categorically approve Non-Federal research that principally involves subjects who lack capacity provided that, in those protocols involving more than minimal risk to the subject, the IRB must expressly consider whether an "Independent Consent Monitor" and/or "Medically Responsible Clinician" is needed to protect the interests of the subject, and document that consideration. It could accomplish this either on a protocol-by-protocol basis, or address the issue in its policies.

However, this is an obligation to *consider* the utility of an ICM and MRC; we would not recommend imposing an ICM or MRC requirement without further review of the implications of such requirement, including the concern about a disparity between state and federal requirements. Moreover we believe the argument for this mandated consideration of an ICM and MRC is warranted only when the research is focused on subjects who lack capacity; the safeguards in the Common Rule for incapable subjects (including consent by a legally authorized representative) are sufficient in research not focused on incapable patients (e.g., a cancer protocol) even if the protocol does not exclude subjects who lack capacity.

## III. Conclusion

Research institutions in New York State conducting human subjects research have operated under the Federal Common Rule framework, and not under PHL Article 24-A, for decades. The Common Rule regime is comprehensive, detailed and highly protective of subjects. There is a compelling interest in avoiding the unexpected and unintentional application of PHL Article 24-A to such research. With these adaptations identified in this memo, the Commissioner can accept a research institution's

commitment, by policy, to comply with the Common Rule as either a basis for continued exemption from PHL 24-A or as compliance with PHL Article 24-A.

We note that the Commissioner has authority to adopt regulations to implement PHL Article 24-A,[27] and could adopt these recommendations by regulation. However, the Commissioner may determine that he or she can take these steps through guidance in a form other than regulations.

## Endnotes

1. 82 Fed. Reg 7149. The "Common Rule" refers to uniform federal regulations governing human subjects research adopted by 16 separate federal agencies. As adopted the U.S. Department of Health and Human Services, the Common Rule is set forth at 45 CFR Part 46.
2. *Id*. at 7156, 7181.
3. HHS and the other agencies describe this change in the Notice of Final Rule at 7152 as follows:

   > An additional, a nonregulatory change that was described in the NPRM will be made to the assurance mechanism. The prior option that enabled institutions with an active FWA to "check the box" (described in section IV.A above) is being eliminated. Importantly, institutions could, if they so desire, continue for purposes of their own internal rules to voluntarily extend the regulations to all research conducted by the institution, but this voluntary extension will no longer be part of the assurance process and such research will not be subject to OHRP oversight. We expect this change to have the beneficial effect of encouraging some institutions to explore a variety of flexible approaches to overseeing low-risk research that is not funded by a Common Rule department or agency, without reducing protection of human subjects, thus furthering the goal to decrease inappropriate administrative burdens Common Rule department or agency, without reducing protection of human subjects, thus furthering the goal to decrease inappropriate administrative burdens.

4. NYS L. 1975, c.450.
5. *See T.D. v. NYS Office of Mental Health*, 228 A.D. 2d 95 (First Dep't 1996) (app. dsmd. 89 NY2d). See also NYS Task Force on Life and the Law, Report and Recommendations for Research with Human Subjects who Lack Capacity (January 2014) (hereinafter "NYS Task Force Report") at p.5.
6. NYS Public Health Law (PHL) § 2441.
7. *Id*., § 2442.
8. *Id*., § 2443.
9. *Id*., § 2444.
10. *Id*., § 2444.
11. *Id*., § 2444.
12. Memorandum of Member of Assembly Alan G. Hevesi, *supra*; 1975 N.Y. State Legislative Annual, p. 275. *See T.D. v. OMH*, *supra*, at 104.
13. In *T.D. v. OMH*, the court rejected the argument by NYS OMH that it was exempt from PHL Article 24-A because it has submitted an FWA. However, the court relied upon that the fact that in its FWA, OMH declined to subject itself to certain HHS reporting requirements. *T.D. v. OMH*, *supra* at 110.
14. This situation differs from the situation in *T.D. v. Surles*, where OMH research facilities could have but chose not to apply the federal research requirements completely, and instead chose to make reports to DOH instead of OHRP.
15. HHS Press Release, January 18, 2017, "Final rule enhances protections for research participants, modernizes oversight system." http://wayback.archive- it.org/3926/20170127095200/ https://www.hhs.gov/about/news/ 2017/01/18/final-rule-enhances- protections-research-participants-modernizes-oversight-system.html.
16. PHL § 2442.
17. 45 CFR 46.102(i).
18. PHL § 2441.
19. 45 CFR 45.108(a)(3).
20. Subsection (b) of 45 CFR 46.111 "Criteria for IRB approval of research."
21. *Recommendations from the Subcommittee for the Inclusion of Individuals With Impaired Decision Making in Research* (SIIIDR), http://www.hhs.gov/ohrp/sachrp/20090715letterattach.html.
22. Report and Recommendations for Research with Human Subjects who Lack Capacity (hereinafter "NYS Task Force Report." See https://www.health.ny.gov/regulations/task_force/docs/report_human_subjects_research.pdf. (Hereinafter, "Task Force Report.").
23. See Task Force Report at 57. It did, however, suggest that "At the discretion of the Department of Health, the Department may (1) reject the study, (2) approve the study, or (3) convene a special review panel of experts who will examine the study and issue recommendations to the IRB on whether the study should be approved. DOH has not acted on that suggestion.
24. "[A]n ICM is an individual not affiliated with the study or research institution, who is designated by an IRB to monitor the informed consent process." NYS Task Force Report at 52. Presumably a subject's health care agent or surrogate could agree to be the ICM.
25. "An MRC is a licensed medical doctor skilled and experienced in working with the research population and is independent from the study. Ideally, this person should be the physician already attending to the participant's health care needs—who is not involved in the research—but an MRC may also be any qualified physician not affiliated with the research study." NYS Task Force Report at 54.
26. Task Force Report, pp. 57 and 64. Specifically, it advised that research institutions could assure the Commissioner that they would follow the Common Rule for nonfederal research by submitting a "State Multiple Project Assurance." This memo suggests that the same end will be achieved with less burden on DOH if such institutions simply adopt policies that include that commitment.
27. PHL § 2446.

**Attachment comparing PHL Article 24-A and The Common Rule (as amended effective 1/19/2018) appears on pages 29–55**

## ATTACHMENT 1
## Comparison of PHL Article 24-A and The Common Rule (as amended effective 1/19/2018)

| PHL 24-A | Common Rule (with amendments effective 1/19/2018) | Will compliance with the Common Rule result in compliance with PHL 24-A ? |
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| § 2440. Policy and purpose<br><br>The use of human subjects in medical research projects has brought about many beneficial scientific advances resulting in the increased health and well-being of the human race. Safeguarding the rights and welfare of individual human subjects in the conduct of these human research projects is a matter of vital state concern. Every human being has the right to be protected against the possible conduct of medical or psychological research upon his body without his voluntary informed consent. Human research may effect dangerous and unanticipated results causing irreversible damage to the human subject. Accordingly, it shall be the policy of this state to protect its people against the unnecessary and improper risk of pain, suffering or injury resulting from human research conducted without their knowledge or consent. | Not relevant to this analysis | Not relevant to this analysis |
| § 2441. Definitions<br><br>For the purposes of this article:<br><br>1. "Human subject" shall mean any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs or which increases the ordinary risk of daily life including the recognized risks inherent in a | 46 CFR § 102<br>(e)(1) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:<br><br>(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or<br><br>(ii) Obtains, uses, studies, analyzes, or | **Yes -** The Common Rule definition includes and exceeds the NYS definition. |

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| chosen occupation or field of service. | generates identifiable private information or identifiable biospecimens. | |
| **2.** "Human research" means any medical experiments, research, or scientific or psychological investigation, which utilizes human subjects and which involves<br><br>■ physical or psychological intervention by the researcher upon the body of the subject and<br><br>■ which is not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject.<br><br>■ Human research shall not, however, be construed to mean the conduct of biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice, or to include epidemiological investigations. | 46 CFR § 102<br>(l) Research means a systematic investigation, including research development, testing, and evaluation,<br>designed to develop or contribute to<br>generalizable knowledge.<br>Activities that<br>meet this definition constitute research<br>for purposes of this policy, whether or<br>not they are conducted or<br>supported<br>under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the<br>following activities are deemed not to be<br>research:<br><br>(1) Scholarly and journalistic activities (e.g., oral history, journalism,<br>biography, literary criticism, legal research, and historical scholarship),<br>including the collection and use of information, that focus directly on the<br>specific individuals about whom the<br>information is collected.<br><br>(2) Public health surveillance activities, including the collection and<br>testing of information or biospecimens,<br>conducted, supported, requested, ordered, required, or authorized by a<br>public health authority. Such activities<br>are limited to those necessary to allow<br>a public health authority to identify, | **Yes -** The Common Rule definition includes and exceeds the NYS definition. |

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| | monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).<br><br>(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.<br>(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.<br>(m) Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format. | |
| **3.** "Fluid" means a normal body excretion or any fluid formed by normal or pathological body processes obtained during diagnostic or therapeutic procedures conducted for the benefit of the human subject. | Not relevant to this analysis | Not relevant to this analysis |
| **4.** "Tissue" means part or all of any organ of a human subject removed during a diagnostic or therapeutic procedure conducted for the benefit of the human subject. | Not relevant to this analysis | Not relevant to this analysis |
| 5. "Voluntary informed consent" | (b) Basic elements of informed | **Yes,** except as noted |

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| means the legally effective knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion.<br><br>With regard to the conduct of human research, the basic elements of information necessary to such consent include:<br><br>(a) a fair explanation to the individual of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;<br><br>(b) a description of any attendant discomforts and risks reasonably to be expected;<br><br>(c) a description of any benefits reasonably to be expected;<br><br>(d) a disclosure of any appropriate alternative procedures that might be advantageous for the individual;<br><br>(e) an offer to answer any inquiries by the individual concerning the procedures; and<br><br>(f) an instruction that the individual is free to withdraw his consent and to discontinue participation in the human research at any time without prejudice to him. | consent. Except as provided in paragraph (d), (e), or (f) of this section,<br>in seeking informed consent the following information shall be provided<br>to each subject or the legally authorized<br>representative:<br><br>(1) A statement that the study involves research, an explanation of the<br>purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are<br>experimental;<br><br>(2) A description of any reasonably foreseeable risks or discomforts to the<br>subject;<br><br>(3) A description of any benefits to the<br>subject or to others that may reasonably<br>be expected from the research;<br><br>(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;<br><br>(5) A statement describing the extent,<br>if any, to which confidentiality of records identifying the subject will be<br>maintained;<br><br>(6) For research involving more than<br>minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical<br>treatments are available if injury occurs<br>and, if so, what they consist of, or where<br>further information may be obtained; | further below in the analysis of PHL § 2442 Informed Consent.<br><br>Specifically, the Common Rule's basic requirement for informed consent includes and exceeds the NYS requirement, except as noted further below in the analysis of PHL § 2442 Informed Consent. |

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| | (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;<br><br>(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and<br><br>(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:<br><br>(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or<br><br>(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research | |

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| | studies.<br><br>(c) Additional elements of informed consent. Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:<br><br>(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;<br><br>(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;<br><br>(3) Any additional costs to the subject that may result from participation in the research;<br><br>(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;<br><br>(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to | |

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| | the subject;<br><br>(6) The approximate number of subjects involved in the study;<br><br>(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;<br><br>(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and<br><br>(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).<br><br>(d) Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in | |

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| | paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:<br><br>(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;<br><br>(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;<br><br>(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;<br><br>(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the | |

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| | identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);<br><br>(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;<br><br>(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and<br><br>(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm. | |
| **6.** "Researcher" means any person licensed under title VIII of the education law to perform diagnosis, treatment, medical services, prescription or therapeutic exercises with regard to or upon human beings, or any other person deemed | 46 CFR § 102<br><br>(e)(1) Human subject means a living individual about whom an investigator (whether professional or student) | **Yes** - While the Common Rule does not define "Researcher", it uses the term "investigator" for any person conducting human subject research. |

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| appropriately competent and qualified by a human research review committee as provided by section twenty-four hundred forty- four of this chapter. | conducting research:<br><br>(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or<br><br>(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. | See analysis of PHL § 2443 further below. |
| **§ 2442. Informed consent**<br><br>No human research may be conducted in this state in the absence of the voluntary informed consent subscribed to in writing by the human subject.<br><br>If the human subject be a minor, such consent shall be subscribed to in writing by the minor's parent or legal guardian.<br><br>If the human subject be otherwise legally unable to render consent, such consent shall be subscribed to in writing by such other person as may be legally empowered to act on behalf of the human subject.<br><br>No such voluntary informed consent shall include any language through which the human subject waives, or appears to waive, any of his legal rights, including any release of any individual, institution or agency, or any agents thereof, from liability for negligence. | **§ ll.116 General Requirements for Informed Consent**<br><br>(a) General. General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere | **Yes,** except as noted below:<br><br>Overall, the Common Rule's basic requirements for informed consent include and exceed the NYS requirements.<br><br>However, the Common Rule allows an IRB to waive or alter informed consent under narrow circumstances described in § 45.116(e) and (f). There is no such waiver/alteration mechanism under PHL 24-A.<br><br>But to qualify for the waiver, the activity must involve "no more than minimal risk. " Such activity (e.g., a questionnaire, survey or medical record review) is unlikely to meet the PHL Article 24-A definition of human subject research. |

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| | in this policy:<br><br>(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.<br><br>(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.<br><br>(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.<br><br>(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.<br><br>(5) Except for broad consent obtained in accordance with paragraph (d) of this section:<br><br>(i) Informed consent must begin with a concise and focused presentation of the key information that is most | |

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| | likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.<br><br>(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.<br><br>(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.<br><br>[Paragraphs (b) - (d) are addressed alongside PHL § 2441(5) above.<br><br>(e) Waiver or alteration of consent in research involving public benefit and service programs conducted by or | |

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| | subject to the approval of state or local officials—<br>(1) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.<br><br>(2) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section. | |

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| | (3) Requirements for waiver and alteration. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:<br><br>(i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:<br>(A) Public benefit or service programs;<br>(B) Procedures for obtaining benefits or services under those programs;<br>(C) Possible changes in or alternatives to those programs or procedures; or<br>(D) Possible changes in methods or levels of payment for benefits or services under those programs; and<br><br>(ii) The research could not practicably be carried out without the waiver or alteration.<br><br>(f) General waiver or alteration of consent—<br>(1) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) | |

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| | of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.<br><br>(2) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.<br><br>(3) Requirements for waiver and alteration. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:<br><br>(i) The research involves no more than minimal risk to the subjects;<br>(ii) The research could not practicably be carried out without the requested waiver or alteration;<br>(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;<br>(iv) The waiver or alteration will | |

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| | not adversely affect the rights and welfare of the subjects; and<br>(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.<br><br>(g) Screening, recruiting, or determining eligibility. An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:<br><br>(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or<br><br>(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.<br><br>(h) Posting of clinical trial consent form. (1) For each clinical trial conducted or supported by a Federal department or agency, one IRB approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or | |

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| | agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.<br>(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.<br><br>(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.<br><br>(i) Preemption. The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.<br><br>(j) Emergency medical care. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or | |

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| | local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe). | |
| **§ 2443. Conduct of human research** No one except a researcher shall conduct human research in this state. | No parallel provision | **Yes.** The Common Rule is broad enough to encompass PHL 24-A.<br><br>Specifically, the Common Rule uses the term "investigator," without an express definition, for the person who conducts the research. It then imposes requirements (e.g., informed consent, IRB approval, etc.) on the investigator. |
| **§ 2444. Human research review committees**<br><br>1. Each public or private institution or agency which conducts, or which proposes to conduct or authorize, human research, shall establish a human research review committee.<br><br>Such committee shall be composed of not less than five persons, approved by the commissioner, who have such varied backgrounds as to assure the competent, complete and professional review of human research activities conducted or proposed to be conducted or authorized by the institution or agency.<br><br>No member of a committee shall be involved in either the initial or continuing review of an activity in which he has a conflicting interest, except to provide information required by the committee.<br><br>No committee shall consist entirely of persons who are officers, employees, or agents of, or who are otherwise associated with the institution or agency, apart from their membership on the committee, and | **§ 46.107 IRB membership.**<br><br>(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore | **Yes.** The Common Rule is broad enough to encompass PHL 24-A.<br><br>Specifically, the Common Rule meets these PHL § 2444 requirements:<br><br>at least 5 members<br><br>diverse membership<br><br>safeguards against conflicts of interest<br><br>cannot be composes entirely of institution employees<br><br>cannot be composed entirely of one profession |

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| no committee shall consist entirely of members of a single professional group. | include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.<br><br>(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.<br><br>(c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.<br><br>(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.<br><br>(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond | |

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| | or<br>in addition to that available on the IRB.<br>These individuals may not vote with the<br>IRB. | |
| **2.** The human research review committee in each institution or agency shall require that institution or agency to promulgate a statement of principle and policy in regard to the rights and welfare of human subjects in the conduct of human research, and the committee and the commissioner shall approve that statement prior to its taking effect.<br><br>The committee shall review each proposed human research project to determine<br><br>(1) its necessity;<br><br>(2) that the rights and welfare of the human subjects involved are adequately protected,<br><br>(3) that the risks to the human subjects are outweighed by the potential benefits to them or by the importance of the knowledge to be gained;<br><br>(4) that the voluntary informed consent is to be obtained by methods that are adequate and appropriate, and<br><br>(5) that the persons proposed to conduct the particular medical research are appropriately competent and qualified.<br><br>The committee shall periodically examine each existing human research project with regard to the proper application of the approved principles and policies which the institution or agency has promulgated. The committee shall report any violation to the commissioner.<br><br>In addition to the voluntary informed | **§ 46.108 IRB functions and operations.**<br><br>(a) In order to fulfill the requirements<br>of this policy each IRB shall:<br>. . .<br>(3) Establish and follow written procedures for:<br><br>(i) Conducting its initial and continuing review of research and for reporting its findings and actions to the<br>investigator and the institution;<br><br>(ii) Determining which projects require review more often than annually<br>and which projects need verification<br>from sources other than the investigators that no material changes<br>have occurred since previous IRB review; and<br><br>(iii) Ensuring prompt reporting to the<br>IRB of proposed changes in a research<br>activity, and for ensuring that investigators will conduct the research<br>activity in accordance with the terms of<br>the IRB approval until any proposed<br>changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.<br><br>(4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or | Yes, except as noted further below.<br><br>Specifically, the Common Rule sections 46.108 and 46.111 prompt the IRB to determine, in substance if not always terminology:<br><br>■ that the proposed project is necessary, that the rights and welfare of the human subjects involved are adequately protected, that the risks to the human subjects are outweighed by the potential benefits to them or by the importance of the knowledge to be gained, that the voluntary informed consent is to be obtained by methods that are adequate and appropriate, and that the persons proposed to conduct the particular medical research are appropriately competent and qualified.<br><br>■ that the IRB must periodically examine each project;<br><br>However, the Common Rule does not meet PHL § 2444 standard in three respects:<br><br>**1. Statement of principle and policy.** The Common Rule does not require Commissioner approval of a statement of principle and policy; Section § 2444 does, in its opening sentence. |

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| consent of the proposed human subject as required by section twenty-four hundred forty-two of this chapter, the consent of the committee and the commissioner shall be required with relation to the conduct of human research involving minors, incompetent persons, mentally disabled persons and prisoners. | agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of<br><br>(i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and<br><br>(ii) Any suspension or termination of IRB approval.<br><br>(b) Except when an expedited review procedure is used (as described in § ll.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.<br>(Approved by the Office of Management and Budget under Control Number 0990–0260)<br>**§ ll.109 IRB review of research.**<br>(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under § ll.104 for which limited IRB review is a condition of exemption (under | **2. Expedited review.** The Common Rule offers an expedited review process, in which the IRB chair and another experienced member may approve limited categories of research and minor modifications to approved research. Section 2444 offers no such process.<br><br>**3. Vulnerable populations**. The Common Rule does not require Commissioner approval of research involving vulnerable populations. It requires instead the following<br><br>(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. It specifies those safeguards for children, prisoner and pregnant women in Subparts B, C and D. |

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| | § ll.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).<br><br>(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with § ll.116. The IRB may require that information, in addition to that specifically mentioned in § ll.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.<br><br>(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § ll.117.<br><br>(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.<br><br>(e) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, | |

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| | not<br>less than once per year, except as described in § ll.109(f).<br><br>(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following<br>circumstances:<br><br>(i) Research eligible for expedited review in accordance with § ll.110;<br><br>(ii) Research reviewed by the IRB in<br>accordance with the limited IRB review<br>described in § ll.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);<br><br>(iii) Research that has progressed to<br>the point that it involves only one or<br>both of the following, which are part of<br>the IRB-approved study:<br>(A) Data analysis, including analysis<br>of identifiable private information or<br>identifiable biospecimens, or<br>(B) Accessing follow-up clinical data<br>from procedures that subjects would<br>undergo as part of clinical care.<br><br>(2) [Reserved.]<br><br>(g) An IRB shall have authority to observe or have a third party observe the<br>consent process and the research.<br>(Approved by the Office of Management and<br>Budget under Control Number 0990–0260)<br><br>**§ ll.111 Criteria for IRB approval of<br>research.**<br>(a) In order to approve research covered by this policy the IRB shall<br>determine that all of the following | |

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| | requirements are satisfied:<br><br>(1) Risks to subjects are minimized:<br><br>(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and<br>(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.<br><br>(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.<br><br>(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in | |

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| | which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decisionmaking capacity, or economically or educationally disadvantaged persons.<br><br>(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § ll.116.<br><br>(5) Informed consent will be appropriately documented or appropriately waived in accordance with § ll.117.<br><br>(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.<br><br>(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.<br><br>(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of | |

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| | data.<br><br>(ii) [Reserved.]<br><br>(8) For purposes of conducting the limited IRB review required by § ll.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:<br><br>(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § ll.116(a)(1)–(4), (a)(6), and (d);<br><br>(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § ll.117; and<br><br>(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.<br><br>(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. | |

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| **3.** Each person engaged in the conduct of human research or proposing to conduct human research shall affiliate himself with an institution or agency having a human research review committee, and such human research as he conducts or proposes to conduct shall be subject to review by such committee in the manner set forth in this section. | **§ 46.109 IRB review of research.**<br><br>(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or<br>disapprove all research activities covered by this policy, including exempt research activities under<br>§ ll.104 for which limited IRB review<br>is a condition of exemption (under § ll.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)). | **Yes -** The Common Rule includes and exceeds the NYS standard with respect to requiring IRB approval of human subjects research. |
| **§ 2445. Applicability** The provisions of this article shall not apply to the conduct of human research which is subject to, and which is in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects. | Not relevant to this analysis | Not relevant to this analysis |
| **§ 2446. Rules and regulations** The commissioner shall have the power to promulgate such rules and regulations as shall be necessary and proper to effectuate the purposes of this article. | Not relevant to this analysis | Not relevant to this analysis |

# Emerging Issues in Using Mobile Apps for Clinical Research

By Nathan Prystowsky and Jonathan Walland

Since the advent of smart phones, lawmakers and regulators have been slow to react to the exponential development of mobile health apps. Health lawyers faced with advising clients on the first generation of mobile health apps faced the daunting task of trying to situate novel technologies onto laws that were promulgated in a pre-digital age: Could a given app be deemed a medical device subject to FDA regulation? When are use and disclosure of medical information in an app subject to the provisions of HIPAA? Are direct-to-consumer health apps created by non-medical entities subject to any kind of regulation?

Recent settlements, FDA guidance, and safe harbors for limited functionality health apps have provided some emerging frameworks and regulatory assurances. However, a key area of regulatory uncertainty remains in the use of mobile health apps for clinical research. Depending on the research aims and the nature of the parties conducting and sponsoring a given research study, it may be subject to an overlapping web of laws, regulations, and standards including the Federal Policy for the Protection of Human Subjects (also known as the "Common Rule"), FDA drug or device testing regulations, and G.C.P. (Good Clinical Practice). A recurring theme they all share, is the paramount importance of data reliability and accuracy.

Historically, clinical research data has been generated and collected by trained healthcare workers using standard collection methods and verifiable source documents. But smart phone-enabled mobile health apps offer the tantalizing prospect of real-world, continuous, and real-time interaction with research subjects. A number of use cases exist for mobile health apps in a research context:

- A mobile app might be used to collect self-reported data from research subjects;
- A mobile app might be used as a health intervention;
- A mobile app might be used to collect and measure quantitative biometric values from a research subject using a smart phone's built-in functionality or peripherals including wearables.

We hypothesize that both regulators and study sponsors will increasingly be interested in using mobile apps for the third purpose, in order to provide more reliable real-time data that is potentially superior to the "snapshot" approach provided by weekly or monthly research subject visits to an investigator's laboratory or clinic. Yet two intertwined challenges remain to the widespread implementation of mobile apps in clinical research: (i) the need to validate the technology behind mobile health apps, and (ii) the need to develop regulatory frameworks that support the use of mobile health app technology in research.

This article will begin with an overview of the challenges raised by using mobile health apps and devices in a research context. We will summarize the regulatory landscape for mobile health apps and offer suggestions for lawyers advising clients who want to conduct research involving mobile apps in the life sciences sector.

## FDA Regulation of Mobile Apps

The FDA's 2015 Guidance on Mobile Medical Applications, defined mobile application or "mobile app" 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."[1] An enhanced category of mobile medical app was designated for mobile apps that also satisfied the Food Drug and Cosmetic Act's criteria for a medical device *and* were intended "to be used as an accessory to a regulated medical device; or to transform a mobile platform into a regulated medical device."[2] Initially, the underlying criteria for whether a mobile app should be deemed a medical device drew on the familiar FDA analysis of whether it was meant 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 human body. These criteria were further modified by the medical device definition in the 21st Century Cures Act and subsequent guidance, which moved some examples of mobile apps for which FDA intends to exercise enforcement discretion to the class of mobile apps that FDA categorically deems not medical devices.[3]

FDA guidance has identified three broad categories of mobile app technology that would be deemed "regulated medical devices," subject to one of the existing medical device approval pathways (e.g., premarket review, 510(k) exemption etc.): (i) mobile apps that connect to a medical device for purposes of active patient monitoring,

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or analyzing medical device data; (ii) mobile apps that transform a mobile platform into a medical device by using attachments, display screens, sensors or by including functionalities similar to those of currently regulated medical devices; and (iii) mobile apps that function as regulated software by performing patient-specific analysis, diagnosis, or treatment recommendations.

The FDA guidance provides instructive examples of technology across disparate medical disciplines that would likely fit the foregoing criteria: (i) apps that provide the ability to control inflation and deflation of a blood pressure cuff through a mobile platform; (ii) mobile apps that control the delivery of insulin on an insulin pump by transmitting control signals to the pumps from the mobile platform; (iii) mobile apps that use peripheral attachments to perform medical device functions, such as attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter; (iv) attachment of electrocardiograph (ECG) electrodes to a mobile platform to measure, store, and display ECG signals; (v) a mobile app that uses the built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea; (vi) a mobile app that uses sensors (internal or external) on a mobile platform for creating an electronic stethoscope function, thus transforming the mobile platform into an electronic stethoscope; (vii) patient monitoring mobile apps that monitor a patient for heart rate variability from a signal produced by an electrocardiograph, vectorcardiograph, blood pressure monitor and would be classified as cardiac monitoring software; and (viii) treatment planning software apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy.

On the other end of the spectrum, are "low risk" technologies and functionalities which FDA has repeatedly identified in its guidance for enforcement discretion, or more recently under the 21st Century Cures Act, as irrefutably "not regulated devices."[4] These include many consumer and health care provider (HCP) health apps intended to: (i) help coach patients to make diet, exercise, and lifestyle improvements, (ii) help patients track and organize their health information; (iii) serve as EMR portals that enable patient access to medical records and related instructional health articles to manage symptoms; (iv) serve as telemedicine portals that enable patients to communicate with HCPs via a device's sound and video functionality; and (v) function as HCP clinical tools that perform very basic calculations such as Body Mass Index.

## Use of Mobile Apps and Wearables in Traditional IRB-Approved Research

Initial deployment of mobile apps in clinical research was often focused on collection of patient self-reported data, including electronic pill diaries to monitor investigational drug adherence, symptom diaries, adverse event recording, and patient reported outcomes. One of the earliest sources of recommendations was the FDA's December 2009 guidance document, "Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims."[5] This guidance defined patient reported outcomes (PROs) as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[6] FDA included suggestions on the type of information suitable for PRO data, generally measurement of patient symptoms, disease severity, and other concepts best known by the patient or best measured from the patient perspective.[7] Of particular interest for this article, was the guidance included in Section IV. Clinical Trial Design, Subsection F. Specific Concerns When Using Electronic PRO Instruments.

In a research context, mobile health app data, including PRO data, would be considered a source document. Accordingly, Subsection F raised several notable concerns about the need for data reliability, including compliance with FDA's electronic data integrity standards set forth in 21 C.F.R. § 11, and the need for investigators to ensure accurate record keeping, maintenance, and access.[8] Another key takeaway, was FDA's emphasis on the proper allocation of responsibilities between sponsors and investigators. Because investigators are expected to control source documents, FDA identified potential pitfalls when research sponsors control electronic PRO tools. FDA recommended that to satisfy the regulations, sponsors should not have exclusive control over electronic tools that will be relied upon as source documents, and that adequate audit trails exist to ensure data are not modified.[9]

For clinical researchers interested in measuring bodily function by collecting biometric device data from a mobile app or wearable, the regulatory analysis should include consideration of validation and testing to confirm the accuracy and reliability of data generated. This is especially true if the mobile app or wearable functionality crosses the line into the realm of "regulated medical device." One could imagine a drug study conducted under an Investigational New Drug (IND) application that uses an unapproved medical device requiring its own regulatory pathway for an Investigational Device Exemption (IDE). Validation of such mobile app or wearable for clinical research uses might require pilot testing or head-to-head comparisons with traditional data generated from clinic visits, laboratory analysis, and physician-validated assessment tools. Research sponsors will invariably face the question of how much validation is needed before a mobile app or wearable can be deemed sufficiently robust to be deployed in a research study to gather submission-quality data.

Although concerns about data privacy and confidentiality have practically monopolized recent technology discussions, we argue that traditional issues of quality and data integrity should be the starting point when developing mobile apps and wearables for clinical re-

search. Data integrity is defined as the extent to which data are complete, consistent, accurate, trustworthy and reliable.[10] Clinical research auditors have historically used the acronym ALCOA as a pneumonic descriptor of the relationship between source documents and the data captured onto case report forms or electronic data capture systems—data should be attributable, legible, contemporaneous, original, and accurate.[11] For FDA-regulated clinical research that will be used as part of a submission for a new drug or device application, the standards set forth in 21 C.F.R. § 11 establish minimum criteria for data integrity and reliability. These regulations distinguish between "open" versus "closed" systems. An open system is one in which control of the system is not in the hands of the individual responsible for generating the content of the electronic record. Relying on data from mobile apps and wearables can pose challenges for authenticating the identity of users and the veracity of information collected. Outside of the controlled clinic environment, a research subject might allow another household member to use a mobile device or wearable. To what extent must research sponsors and investigators authenticate the identity of the mobile app users? Should such authentication be a one-time event when logging in or setting up the device? Should there be periodic checks? How might the reliability of data gathered from a mobile app or wearable differ from data collected by an investigator or research coordinator in a clinic setting?

The Food Drug and Cosmetic Act as well as regulations under 21 C.F.R. §§ 50 and 56 protect human subjects participating in research for clinical trials. Generally, consumer mobile health apps are not marketed as clinical support medical devices that fall under 21 U.S.C. § 321 (h). When a mobile health application counts as "software as a medical device" (SaMD under 21 U.S.C. § 321(h)), it then requires an Investigational Device Exemption (IDE) under 21 C.F.R. § 812. This in turn further requires an analysis of device in the trial for significant risk (SR), non-significant risk (NSR), or exempt status.

While consideration of SaMD devices goes beyond the scope of this article, it is worth noting that using mobile health applications that fall outside of the SaMD regulatory framework can lead to clinical validation issues. Devices outside of the SaMD framework presumably have not gone through the FDA recommended principles of software validation. The FDA has required software validation as part of its design control provisions under 21 C.F.R. § 820.30(g) in addition to other validation requirements under 21 C.F.R. § 11.10(a).

Industry guidance has been developing along with technology to account for the appropriate compliance considerations for software generally in the clinical research setting. New guidance for collecting data from electronic health record (EHR) systems that are interoperable with Electronic Data Capture Systems (EDC) for clinical trials touches on many of the of the same interoperability points of consideration for using a mobile health application.

The Office for Human Research Protection in the Department of Health and Human Services (OHRP) recommends that institutions have policies in place that designate an individual or entity authorized to determine whether research involving coded private information constitutes human subject research. In the event the authorized individual or entity determines the investigator will know or may be able to readily ascertain the identity of the individuals to whom the obtained private information pertains, it would be considered human subject research.

A human subject is defined by Federal Regulations as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (45 C.F.R. § 46.102(e)(1)). Identifiable private information "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place" (such as a public restroom) "and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record)." (45 C.F.R. § 46.102(e)(4)).

IRB review of a proposed research study is required unless the research project is determined to be exempt under HHS regulations at 45 C.F.R. 46.104. Otherwise, informed consent of the subjects would be required unless the IRB approved a waiver of informed consent under 45 C.F.R. §§ 46.116(c) or (d). In the health care setting informed consent can be particularly problematic because HIPAA restricts the ability to obtain a compound individual privacy authorization, except in limited circumstance. For example it may be possible incorporate a HIPAA Privacy authorization into a research consent in accordance with 45 C.F.R. § 164.508(b)(3) and (4).

As with IRB studies outside of FDA approved clinical trials, there are issues with respect to obtaining the consent of subjects. When informed consent is required, the consent must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained according to 21 C.F.R. § 50.25(a)(5). Since the FDA may inspect and copy records relating to clinical investigations under 21 U.S.C. § 374 (a)(1) and 21 C.F.R. §§ 312.58(a), 312.68, and 812.145(b) the consent process should describe the possibility that FDA inspectors and FDA submission reviewers may need to review source material and electronic logs for mobile app data, which in some cases may include communication between the research subject and HCPs. While some EHR systems include audit mode capabilities that permit regulatory inspection of medical records in a secure environment with direct patient identifiers removed, this functionality might not exist in novel health and medical apps.

It is also worth noting that mobile health applications are not always capable of transmitting data in a format that will be interoperable with the intended data depository. The software being used to house, access, and analyze the data in the research data repository often has a different format that creates an obstacle hindering the transmission and storage of data from a mobile health application. This has implications for data integrity in long-term storage situations where research may extend beyond the lifecycle of the software. Consequently, data management centers also need to be aware of data retention requirements.

Under 21 C.F.R. §§ 312.62, 511.1(b)(7)(ii) and 812.140, the clinical investigator must retain records required to be maintained under §§ 312, 511.1(b), and 812, for a period of time specified in these regulations. The retention period should not be ignored. "White listing" software upgrades throughout the software lifecycle (i.e., the process of validating interoperability of new versions with other interfaced software applications) is necessary to preserve data integrity while also meeting the need to update software that addresses current vulnerability threats in the cyber security framework of the institution housing the research data repository. These issues become especially relevant and challenging if expired "legacy systems" that preserve data become inaccessible. For example, the early generation iPhones have been sun-setted by Apple, making them nearly unusable with current operating systems and network environments.

Finally, in November of 2018, the FDA launched the MyStudies app website, which includes open source code to enable researchers and app developers to link real world data and electronic health records in order to support high-quality collection and use in regulatory submissions.[12] These tools are intended to comply with the requirements of 21 C.F.R. § 11 and enable efficiencies in the drug development and safety monitoring process.[13] In the long term, the ability to harness real world evidence through so-called "pragmatic clinical trials" might improve patient experience and accelerate the drug development process. On the other hand, this may lead to a diminished role for experienced clinical investigators and researchers, as the clinical research and standard care world will increasingly converge. Questions remain on how IRBs, sponsors, and investigators will ensure adequate protections for human research subjects if everyone's smart phone becomes a medical data collection tool. These concerns have already started to surface in the field of consumer health apps.

## Clash of the Civilizations: Disruptive Technology and Consumer Health Apps Meets Research Regulators

Before the growing prevalence of mobile health applications, the Institute of Medicine charged a Committee on Health Research and the Privacy of Health Information to assess the HIPAA Privacy Rule and make recommendations on facilitating health research while maintaining protections for individual privacy. In its 2009 report, the committee noted "public opinion polls suggest that a significant portion of the American public would like to control all access to their medical records for research via an individual consent mechanism."[14] Mobile health apps have broad applications in these various types of regulated research because of their ability to generate large quantities of scalable data.

Consumer health apps that collect health data are already being used to support human subject research covering a broad spectrum from recording vitals during FDA-approved clinical trials and minimal risk IRB-approved behavioral research. For this reason, researchers need to take into account important considerations with respect to the types of data being generated in the research setting and whether that data is protected data under a regulatory scheme limiting its use in a research setting.

The modern era of technology innovation has been marked by a distinct obliviousness to legal and regulatory requirements in the interest of speeding products and services to market. In diverse areas such as online gambling, taxi car service, and employee benefits, enthusiastic tech entrepreneurs have launched start-up companies despite in many cases being unfamiliar and non-compliant with existing legal frameworks, or in other cases, choosing to deliberately ignore them.

Health apps are no exception to this trend. Many early health apps were developed by non-health care entities, unfamiliar with potential privacy concerns or perhaps emboldened by their status as non-HIPAA covered entities and their direct-to-consumer business model. In many cases, user health data was collected and analyzed for commercial data aggregation/monetization purposes, or as part of research studies intended to validate a mobile health app's purported benefits. For example, the 2014 launch of Apple's HealthKit created a common framework for developers to share patient-generated health data (PGHD) among apps, services, and providers, which at one point had over 1,500 apps developed that could make use of a variety of PGHD including: data collected, captured step counts, body measurements, vital signs, exercise patterns, nutrition, reproductive health, and sleep.[15] These adjuvant research uses of both fitness and health-related mobile apps, initially caught lawmakers and stakeholders off guard, and triggered a slow but growing wave of regulation. Among the key concerns: data privacy, data governance, and data permissioning.

Consequently, consumers have a growing concern over what happens to their data, and data collected by consumer wearables often does not have any relationship to a covered entity and as such does not get protected by HIPAA. With the growth of health information data collected outside of the protected regulatory framework

of HIPAA, or the IRB and FDA approval processes for research, other agencies have taken action to use broad consumer protection laws to create privacy protections for mobile health applications.

The Federal Trade Commission (FTC) has designed a consumer protection framework that requires certain disclosures in the End User License Agreement (EULA). Section 5 of the FTC Act authorizes the Commission to challenge "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a). In April 2016, the FTC launched a Mobile Health App web portal intended to help guide developers towards regulatory compliance, by highlighting some of the applicable laws in the field.[16] The site includes a HIPAA privacy decision tree tool, to help determine which regulations might apply to mobile health app developers.

Of particular interest for New York health lawyers, the Attorney General's Office (OAG) has relied on the same consumer protection framework to aggressively prosecute direct-to-consumer health app companies for perceived shortcomings in device efficacy, privacy disclosures, and research practices.[17] In a trilogy of settlements announced in 2017, three mobile health app manufactures paid fines and agreed to cease making unsupported functionality claims and bolster privacy risk disclosures to consumers. The settlements involved the My Baby's Beat–Baby Heart Monitor App, the Heart Rate Monitor, Heartbeat & Pulse Tracker, and the Cardiio-Heart [*sic*] Rate Monitor.[18] The OAG faulted the companies for launching the products without adequate device validation and for gathering and sharing user data, including in some cases health information, without informing users that such data might not be protected by the HIPAA Privacy Rule.[19] It is unclear to the authors if a court would necessarily agree and impose an affirmative duty on a non-HIPAA covered entity to inform users that they are not subject to the HIPAA Privacy Rule, Security Rule, and Breach Notification Rule, but there are several noteworthy clinical research concerns raised by the OAG in these cases.

From a consumer protection perspective OAG was displeased that all three app developers had launched their products without sufficient testing. This was reflected in the settlement language emphasizing OAG's belief on validation testing: "The testing must be performed by researchers qualified by training and experience to conduct such testing."[20] It seems clear that mere reliance on software developers and product engineers may not be enough. The regulators seem to be demanding that mobile health apps be validated by researchers with clinical research training and experience, especially mobile health apps that might satisfy the earlier referenced FDA criteria for regulated medical devices—i.e., those that measure or monitor critical patient health conditions or seek to replace existing regulated medical devices. Requiring mobile health app developers to conduct validation studies may hamper innovation by adding to production costs and product development timelines.

From a privacy protection perspective, OAG faulted all three app developers for inadequate disclosures on how they might aggregate, analyze, and disclose user information to third parties. Although the settlements do not make clear the extent to which the companies might have intended to aggregate and monetize user health information for subsequent research, OAG asserted that collecting health data without clear warnings and user consent would be seen as violations under NY General Business Law §§ 349 and 350, and under NY Executive Law § 63(12) deceptive business practices. This is especially noteworthy because many consumer health apps have built their business model with an eye to non–IRB-approved research consisting of user data aggregation and data mining analytics.

## The Next Frontier: Mobile Health Apps Data Aggregation and Data Mining

The Office of the National Coordinator for Health Information Technology (ONC) has recognized that PGHD from consumer devices has the ability to enhance future health care and research.[21]

As an example, the ONC has recognized that research-oriented platforms, such as Apple ResearchKit, offers new recruitment methods that may speed up research studies by increasing the rate of enrolment and making it easier to build a dataset sufficient for analysis.[22] The exploration of using PGHD from consumer devices has led to initiatives, such as the Precision Medicine Initiative, which are being supported by the National Institute of Health (NIH) and ONC by a Sync for Science pilot program, which is "developing and testing the technology to enable patients to share data from their clinicians' EHRs with researchers."[23]

Data generated by a mobile health application generally is classified in two ways. In its broadest sense, individual health information generated, collected, and then aggregated by a consumer health application is classified as Individually Identifiable Health Information (IIHI). More narrowly, IIHI that is created, received, maintained, or transmitted by a HIPAA covered entity (e.g., health plan, health care provider, or business associate) would be considered Protected Health Information under HIPAA.[24] Conversely, health information shared by a consumer or between two consumers, independent of a covered entity or business associate is not PHI under HIPAA.

However, as noted above, even if IIHI does not become PHI under HIPAA it does not mean that the data can be freely used. In the research setting there are three broad sets of regulations that protect individuals who volunteer their data to entities that seek to collect and make use of that data for study. The Food Drug and Cosmetic Act as well as regulations under 21 C.F.R. §§ 50 and

56 protect human subjects participating in research for clinical trials. Human subject research for generalizable knowledge requires compliance with 45 C.F.R. § 46 (the "Common Rule") for the protection of human subjects. Even if a given mobile health app research project would be exempt from FDA regulation or the Common Rule, in New York it might be subject to the New York State clinical research laws under § 24-A of the Public Health Law.[25] Although § 24-A contains exceptions for epidemiological research and is focused on interventional research, it does notably include psychological interventions where there is no underlying therapeutic intent.

We believe that regulatory pressure, media scrutiny, and growing public awareness might push mobile health app developers to limit mobile health app data aggregation and data mining activities, or pursue a formal IRB review and approval before embarking on big data analyses of health data generated by consumer health apps.

## Technical Regulatory Considerations for Aggregating Mobile Health Data and Developing Mobile Health Apps

Research sponsors and companies thinking of developing mobile health apps might consider engaging a vendor to develop the software or technology that will be used for research purposes. Such vendors might be unfamiliar with privacy requirements and FDA data validation requirements. Accordingly, contracts with such vendors should carefully address questions of intellectual property ownership, allocation of risk for liability, and indemnification. In addition, attention should be paid to permitted uses of data, privacy considerations, breach notification, data integrity, and data transfer.

In the electronic environment most data will exist in one or more Structured Query Language (SQL) databases, which are known by the technical term "instances," that are run by a larger software program functioning for a particular industry purpose. One industry purpose would be an ONC-certified EHR system. Whether the information collected from a mobile health application goes directly into an EHR, an academic research database, or an FDA-regulated EDC System often changes the analysis of how the data gets protected under the different regulations governing human subject research.

Once the data migration path from the mobile health application to the larger database is determined, further analysis is needed to ascertain how to create a data repository for mining purposes. To begin, a person charged with identifying the applicable regulatory framework should ask whether the mobile health app creates, receives, maintains, or transmits identifiable information. If "yes," the legal analysis might then turn to consideration of the connection between the mobile health app and any applicable covered entity under HIPAA.[26] If the consumer downloads a mobile health application and directs it to transmit health data to an EHR that interoperability arrangement alone does not create a business associate relationship with the developer.[27] On the other hand, if the provider has a contract with the developer to perform a covered function (e.g., for remote patient monitoring), such developer may very well be creating and maintaining that data on behalf of a covered entity.[28]

If a proposed study makes use of a mobile health app with a relationship to a covered entity that cannot be avoided, it is worth considering whether the data can be de-identified using an approved method, as described below. The advantage of de-identification is that the HIPAA Privacy Rule permits disclosure of de-identified information, since it would no longer be considered PHI. However, without de-identification the recipient of data may have to enter into a data use agreement spelling out certain safeguards required under the Privacy Rule.

The other advantage of using de-identified information is that whether a given study is human research depends upon the definition of human subject under 45 C.F.R. § 46.102(e)(4). Obtaining identifiable private information becomes individually identifiable according to the OHRP when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.[29]

There are two ways of de-identifying data under HIPAA: (1) the expert determination method under § 164.514 (b)(1) or (2) the safe harbor method under § 164.514 (b)(2). The expert method requires a person with "appropriate knowledge of an experience with generally accepted statistical and scientific principles" to evaluate the data set. Alternatively, the safe harbor method requires the removal of eighteen (18) specific identifiers.

If the research can be performed with de-identified data, then best practices would be to go through one of the de-identifying processes to assemble the data repository for research. However, the Institute of Medicine has noted that many researchers find using de-identified data sets problematic because the lack of essential identifiers causes a form of self-selection that can bias results and moreover limits the ability to use available metrics that genuinely impact the outcome of a given study.[30] Another emerging concern is the risk of re-identification, as computing power increasingly allows for the re-identification of individual subjects using minimal amounts of information from de-identified datasets with available information from social media networks, public records, and other sources.

## Conclusion

Mobile health app technology continues to evolve and will increasingly play a role in clinical research, as a data gathering tool where an investigational product is being tested, where the health app itself is being validated, and for collection of real world evidence. Companies and researchers interested in using mobile health apps

and wearables for research still face uncertainty and conflict between a myriad of state and federal rules designed for a pre-digital era.

Familiarity with relevant laws and guidance can help lawyers skillfully navigate and advise clients on this rapidly evolving space, with an eye to generating reliable, high-quality research data and ensuring human subject protection.

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# Claim of Genetically Modified Babies: If True, a Grave Abuse of Human Rights

By Center for Genetics and Society

Chinese scientist Jiankui He has announced the birth of twin girls whose DNA he claims to have altered using the gene-editing technique CRISPR.

"If true, this amounts to unethical and reckless experimentation on human beings, and a grave abuse of human rights," said Marcy Darnovsky, Executive Director of the Center for Genetics and Society, a public interest organization that brings social justice and human rights perspectives to human biotechnologies.

"We wish the best for the health of these babies, but strongly condemn the stunt that threatens their safety, and puts the rest of us at risk," Darnovsky said. "Throwing open the door to a society of genetic haves and have-nots undermines our chances for a fair and just future."

"Policy makers, scientists, and public interest groups around the world have called for a moratorium or ban on altering the genes of future children and generations," Darnovsky continued. "He's experiment violates the closest thing to a policy consensus we have. It would be illegal in dozens of countries."

Though there has been no independent confirmation of the claim, He launched what amounts to a public relations campaign to publicize it, complete with promotional YouTube videos in English. The timing of his announcement, on the eve of the Second International Summit on Human Genome Editing in Hong Kong, seems deliberately calculated to preempt that high-profile scientific meeting.

China is effectively a co-sponsor of the Hong Kong Summit, through the Academy of Sciences of Hong Kong. But it is unclear whether the Chinese government authorized He's experiment. The procedures were apparently conducted in secret, and He has reportedly applied for a patent on them. He is chairman and co-founder of Direct Genomics, a DNA sequencing company in Shenzhen.

"This unscrupulous experiment overrides both the summit and the public deliberations on human germline modification that have been widely called for," said Katie Hasson, CGS's Program Director on Genetic Justice. "It is imperative that the scientists gathered in Hong Kong, and the Chinese authorities, clearly denounce this act of scientific grandstanding. The actions of a few rogue scientists should not derail the urgently necessary process of democratic deliberation. We need to put in place enforceable regulations now to stop reproductive gene editing while this public conversation takes place."

*"It's hard to imagine a graver abuse of a child. If this goes unchallenged, other rogue actors will soon offer wealthy parents purported genetic enhancements for their children."*

**—Marcy Darnovsky**

Jiankui He's recklessness is underscored by his own self-justification. As He acknowledged, though the babies' biological father is infected with HIV, this would not prevent him from having healthy children. The embryos created with his sperm, and subjected to the dangers of gene editing, were not affected by HIV or AIDS. The attempt to disable a gene in order to produce future resistance to HIV was apparently done to provide a proof of principle. But some reports suggest that the experiment actually did not work as well as He claims: in one twin, only one copy of the gene was changed and there were signs of mosaicism.

"It's hard to imagine a graver abuse of a child," Darnovsky said. "If this goes unchallenged, other rogue actors will soon offer wealthy parents purported genetic enhancements for their children. In a time of resurgent racism and socio-economic disparity, the last thing we need is for some people and groups to consider themselves biologically superior to others."

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# Reproductive Gene Editing Imperils Universal Human Rights

The prohibition on reproductive gene editing to enhance human capabilities is weakening in the face of scientific breakthroughs—leaving universal human rights at risk without immediate intervention.

By Marcy Darnovsky, Leah Lowthorp and Katie Hasson

What do recent advances in molecular genetics have to do with human rights? Quite a lot, it turns out. And key human rights documents have recognized this for some time.

Over the past few years, new "gene editing" tools that are cheaper, easier to use, and more accurate than previous ways to change living organisms' DNA have rapidly spread to labs around the world. Scenarios that previously seemed far-fetched or far off now confront us, including the prospect of directly controlling the genes and traits that are passed down to future children and generations. Since 2015, a half dozen research teams, in China, the UK, and the United States, have separately reported efforts to modify specific genes in human embryos. These developments have brought us to a critical juncture: human reproductive gene editing now poses a threat to the human rights of future generations.

Gene editing for human reproduction carries huge social risks. It has the potential to threaten the health and autonomy of future generations, to exacerbate existing social disparities, and to lay the basis for a new market-based eugenics that would fuel discrimination and conflict. A debate about whether to risk these outcomes is now raging, though mostly in the publications and meetings of scientific and professional organizations, far away from public view and civil society attention. It is essential that human rights advocates make their voices heard in this debate.

Imagine a world where wealthy parents could purchase genetic enhancements to give their children real or alleged advantages, where children's futures were thought to be determined by their genes, and where babies were labeled at birth as "good" or "bad" based on their DNA. What would be the implications for human rights, and for the right of children to decide their own futures?

Gene editing for human reproduction, also known as human inheritable or germline modification, involves making changes to the DNA of human sperm, eggs, or embryos. It is distinct from efforts to use gene editing as a medical treatment , which target the somatic or non-reproductive cells of existing patients. While somatic gene editing, or "gene therapy," aims to treat or cure disease in living people, reproductive gene editing is not a medical treatment. It would create a new person with a pre-determined genetic make-up that would be inherited by all of their descendants.

Gene therapy, if it can be made safe, effective, and broadly affordable, will be a welcome addition to modern medicine. Germline gene editing, by contrast, doesn't treat anyone. It creates future children, and deprives them and future generations of the choice to consent to modifications made to their DNA. And if the goal is to avoid the transmission of inheritable disease, it is unnecessary. Where there is risk of passing on a serious genetic mutation, an existing embryo screening technique (pre-implantation genetic diagnosis or PGD) can in almost all cases eliminate the unwanted gene variant from the family's lineage. To be sure, embryo screening for PGD raises challenging ethical questions about what conditions are considered "unworthy of life." But it is far safer and less socially and ethically fraught than manipulating the human germline.

Around 20 years ago, an earlier wave of concern about human germline modification swept through scientific and policy circles, and popular culture. The 1997 dystopian film GATTACA depicted a brutal society that privileged the genetically enhanced over the unenhanced. Similarly, Princeton University molecular biologist Lee Silver made news with his vision of a genetically stratified society, predicting that "the already wide gap between wealthy and poor nations could widen further and further with each generation until all common heritage is gone."

During the same period, concerns about safety, human rights, and the potential for a high-tech, market-

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based eugenics prompted more than 40 countries—including nearly every nation with a significant biotech sector—to prohibit the modification of genes passed down to subsequent generations. Several important international human rights instruments also concluded that human germline modification would violate human dignity, a concept at the core of human rights.

One of these, the Council of Europe's 1997 European Convention on Human Rights and Biomedicine (also known as the Oviedo Convention), is a binding international treaty. Its Article 13 explicitly prohibits interventions "seeking to introduce any modification in the genome of any descendants."

Another, UNESCO's 1997 Universal Declaration on the Human Genome and Human Rights, asserts that "the human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity," concluding in Article 24 that "germ-line interventions" could be "contrary to human dignity."

In fact, an important motivation for the Universal Declaration of Human Rights was an abhorrence of the eugenic abuses perpetrated by Nazis during World War II. The same logic provides the foundation for the consumer-based eugenics that would result if germline modification were allowed, where people's life chances would be limited if their unmodified genes were considered from birth to be inferior.

This prospect should make recent attempts to backpedal on the widespread and longstanding international opposition to human germline modification particularly worrying to human rights advocates. For example, a 2017 report by a committee of the US National Academies of Sciences and Medicine recommended that gene editing for human reproduction be permitted in certain circumstances, leaving open the possibility of expanding those circumstances in the future. But in the real world of commercial pressures and regulatory inadequacy, such limits would simply not hold. If the door to the use of human germline modification is cracked open, it will be impossible to limit its spread and applications.

### If the Door to the Use of Human Germline Modification Is Cracked Open, It Will Be Impossible to Limit Its Spread and Applications

At this critical juncture, it's important to remind ourselves why key human rights documents specifically prohibited these practices, long before they were technically feasible. The medical justifications for human germline modification fall short, and the temptation to "enhance" future generations is profoundly dangerous. Down that road, our scientific achievements would all too likely become not instruments of enlightenment and emancipation, but mechanisms for exacerbating inequality. And our desire to improve the human condition would lead us away from the realization of the human rights that we know are needed for individuals, societies, and humanity to thrive.

The rapid pace of these developments creates an urgent need for the global community—perhaps gathering under UN auspices—to reaffirm existing agreements and clearly prohibit the dangerous and unethical use of reproductive gene-editing.

# Gene Editing in Context

By Karen L. Illuzzi Gallinari

In 1969, Hans Jonas, a German-born American Jewish philosopher and the Alvin Johnson Professor of Philosophy at the New School for Social Research in New York City from 1955 to 1976, commented on scientific advances. He warned "that a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having."[1]

Over 40 years later, such warnings remain front and center. The recent controversy regarding a Chinese biophysics researcher who claimed to have genetically altered twin girls has caused renewed concern about dangers from poorly controlled genetic research and genetic manipulation.[2]

> *"Medical practice, informed consent, consumer protection, institutional policy requirements and institutional review boards provide some protection from irresponsible development and use of privately funded genetic technologies."*

The CRISPR[3] gene editing technology reported to be used is the latest advance in the arsenal of gene therapies which present tremendous potential to treat challenging diseases. It was the subject of intense patent litigation[4] and is especially concerning to some due to its ease of use and efficiency.[5] While concern is warranted, the technology is not yet widely available.

> Gene therapy is currently available primarily in a research setting. The U.S. Food and Drug Administration (FDA) has approved only a limited number of gene therapy products for sale in the United States. Hundreds of *research* studies (clinical trials) are under way to test gene therapy as a treatment for genetic conditions, cancer, and HIV/AIDS.[6]

Numerous media outlets have researched the issue and several try to balance the information and put the controversy in context. An example is a recent *New York Times* article, noting:

> Some worry that this is the first step toward using gene editing to create people with extreme intelligence, beauty or athletic ability. But that, for now, is not possible. Such traits are thought to be affected by possibly hundreds of genes acting in concert, and affected in turn by the environment. The biggest ethical concerns for now are with rogue scientists enticing couples who do not realize the risks to babies that might result from the experiments. And when those children grow up, the altered genes will be passed on to their children, and to their children's children, for generations to come.[7]

The legitimate concerns being articulated anew have been under deliberation for some time and remain under serious consideration by multiple scientific and medical bodies throughout the world. These include the National Academies of Science, Engineering, and Medicine,[8] The National Human Genome Research Institute,[9] The National Institute of Health's (NIH) Recombinant DNA Research Advisory Committee (RAC),[10] the Food and Drug Administration (FDA),[11] the British Royal Society, the Chinese Academy of Sciences, the Korean Society of Developmental Biology,[12] the New York State Bar Association Health Law Section's Ethics and Biotechnology and Medical Research Committees, and the New York City Bar Association's Science, Law, Health and Bioethical Issues Committees.[13]

In addition to the host of governmental and voluntary scientific, medical and legal organizations trying to ensure progress does not race ahead of our moral values, we have research, treatment, and product safety regulations. The relevant regulations[14] in the United States include the Dickey-Wicker Amendment, which limits the use of federal funds for research involving human em-

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bryos.[15] In addition, the NIH will not currently consider research which involves genetic changes that would be passed onto an individual's offspring.[16] The FDA is similarly prohibited from approving such genetic research or related treatment products.[17] These limitations on federally funded genetic technology have not prevented the private market from emerging.[18] Medical practice,[19] informed consent,[20] consumer protection,[21] institutional policy requirements and institutional review boards[22] provide some protection from irresponsible development and use of privately funded genetic technologies. Despite all these existing regulations, and the best efforts of those at the forefront of the challenging debate between progress and caution, the ability to sufficiently control the pace of scientific progress is limited. All the more reason to raise concerns, listen, deliberate and pause, to the extent possible. This includes a need to pay increased attention to analyses of why and how a revised regulatory framework would provide more effective assurance of safety and ethical behavior.[23]

The pros and cons of alternative methods to address genetic disease will also continue to be evaluated. Prenatal genetic diagnosis and invitro fertilization are already used safely and effectively, without altering the genes of future offspring. These therapies, however, may lead to the destruction of embryos which carry disease and are not options for all couples.[24]

In addition to listening carefully to our medical, scientific, legal and ethical experts, agencies responsible for enforcement of existing regulations and any future regulations must be sufficiently funded and supported. The stakes are high. The potential for human rights abuses presented by genetic research and treatment are discussed in this issue of the New York State Bar Association's Health Law Section *Journal* by Marcy Darnovsky and Katie Hasson of the Center for Genetics and Society.[25]

As continued deliberations will evidence, Professor Jonas' efforts to sound the alarm years ago were not premature. Those in similar positions today voice practical, reasoned caution. Art Caplan, Ph. D, the Drs. William F. and Virginia Connolly Mitty Professor of Bioethics at New York University recently commented: "I don't worry about the slippery slope. I think eliminating and preventing diseases makes a lot of sense. I think it would be almost impossible to argue against it." Professor Caplan cautions, however, that "Speed is important. But speed kills."[26] Professor Caplan further acknowledges the economic challenges presented by our advancing technologies. "Do not tell me about helping humanity until you tell me how you are going to make it affordable."[27]

The bottom line is, we have little choice but to move ahead, with reasonable speed. All these issues need attention, as do related equitable access[28] and public health implications.[29] These are challenges we will continue to face and manage as long as science progresses. Hopefully, forever.

## Endnotes

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# New York State Assembly Bill to Prohibit Human Cloning

**BILL NUMBER**: A6632

**SPONSOR**: Fitzpatrick

**TITLE OF BILL**: An act to amend the public health law, in relation to creating the human cloning prohibition act

**PURPOSE**: To prohibit the use of cloning technology to initiate the development of new human beings at the embryonic stage of life for any purpose, therapeutic or reproductive.

**SUMMARY OF PROVISIONS**: Amends the public health law by adding a new article 32-B to ensure the foregoing.

**JUSTIFICATION**: On November 25, 2001, a biotechnology firm in Worcester, Massachusetts known as Advanced Cell Technology announced that it had cloned human embryos. The company's CEO, Mr. Michael West, insisted that the company did not intend to implant cloned embryos and grow them into babies; they sought only to create a new source for stem cells for research which can potentially aid in the cure of disease. Other scientists and groups however, have announced that they will try to produce live-born children by human cloning. These developments have renewed the government's interest in the issue.

Human cloning creates a new living organism that is genetically identical to a previously existing human organism. It violates human dignity and medical ethics to either allow experimentation on these human organisms or to implant these human organisms for pregnancy and subsequent live birth. This legislation would prohibit human cloning for both scientific research purposes and for reproductive purposes.

Human cloning technology represents an alarming assault on the dignity and value of human life. Human cloning reduces human life to a manufactured product that can be created and discarded at will. Cloning is the ultimate dehumanizing of human reproduction. New human lives are made in the laboratory, tailored to preset specifications to be mere carriers of genetic traits that others find useful.

This bill in no way stifles legitimate scientific research that could lead to the diagnosis, treatment and prevention of human disease and disorders. It does not alter the legal status of gene therapy, the cloning of plants and animals, the cloning of human organs for transplantation, or adult stem cell research. Such morally appropriate technology can be developed to generate human cells that may be needed to treat certain illnesses (Alzheimer's Disease, Multiple Sclerosis, Cancer, Parkinson's Disease, etc.) - Without creating and killing human embryos.

**PRIOR LEGISLATIVE HISTORY**:

2016—A. 6566—Held in Health Committee

2014—A.3198—Held in Health Committee

2012—A.2612—Held in Health Committee

2010—A.4311—Held in Health Committee

2008—A.5393—Died in the Health Committee

2006—A.4855—Died in the Health Committee

**FISCAL IMPLICATIONS**:

None to State

**EFFECTIVE DATE**:

This act shall take effect on the sixtieth day after it shall have become a law.

**EXPLANATION**: Matter in italics (underscored) is new; matter in brackets [ ] is old law to be omitted.

2017-2018 Regular Sessions

**IN ASSEMBLY**

March 10, 2017

Introduced by M. of A. FITZPATRICK, FINCH—read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to creating the human cloning prohibition act

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Short title. This act shall be known and may be cited as the "human cloning prohibition act".

§ 2. Legislative findings. The legislature finds that: At least one company has announced that it has successfully cloned a human being at the early embryonic stage of life, and others have announced that they will attempt to clone a human being using the technique known as somatic cell nuclear transfer. Efforts to create human beings by cloning mark a new and decisive step toward turning human reproduction into a manufacturing process in which human beings are made in laboratories to preordained specifications and, potentially, in multiple copies. Creating cloned live-born human children, so-called "reproductive cloning," begins by creating cloned human beings at the embryonic stage of life, a process which some also propose as a way of creating human embryos for destructive research as sources of stem cells and tissues for possible treatment of other humans, so-called "therapeutic cloning". Many scientists agree that attempts at "reproductive cloning" pose a massive risk of either producing children who are stillborn, unhealthy, or severely disabled, and that attempting "therapeutic cloning" always results in the destruction of human beings at the embryonic stage of life when their stem cells are harvested. Creating new human life solely to be exploited via "reproductive cloning" or destroyed via "therapeutic cloning" in these ways has been condemned on moral grounds by many as displaying a profound dis-

respect for life. The distinction between "therapeutic" and "reproductive" cloning is a false distinction scientifically because both begin with the creation of a human being at the embryonic stage of life, one destined for implantation in a womb, one destined for destructive farming of its stem cells; regardless of its ultimate destiny, all human embryos are simultaneously human beings. It will be nearly impossible to ban only attempts at "reproductive cloning" if "therapeutic cloning" is allowed because:

(i) cloning would take place within the privacy of a doctor-patient relationship;

(ii) the transfer of embryos to begin a pregnancy is a simple procedure; and

(iii) any government effort to prevent the transfer of an existing cloned embryo, or to prevent birth once transfer has occurred, would raise substantial moral, legal, and practical issues.

Based on the above findings, it is the purpose of this act to prohibit the use of cloning technology to initiate the development of new human beings at the embryonic stage of life for any purpose, therapeutic or reproductive.

§ 3. The public health law is amended by adding a new article 32-B to read as follows:

ARTICLE 32-B

HUMAN CLONING PROHIBITION ACT

Section 3230. Definitions.

3231. Human cloning prohibitions.

3232. Exceptions.

3233. Penalties for violations.

3234. Severability.

§ 3230. Definitions. As used in this article, the following terms shall have the following meanings:

1. "Human cloning" means human asexual reproduction, accomplished by introducing the genetic material of a human somatic cell into an oocyte whose nucleus has been removed or inactivated, to produce a living organism with a human or predominantly human genetic constitution.

2. "Somatic cell" means a cell having a complete set of chromosomes obtained from a living or deceased human body at any stage of development.

3. "Oocyte" means the human female egg.

4. "Embryo" means an organism of the species homo sapiens from the single cell stage to eight weeks development.

5. "Fetus" means an organism of the species homo sapiens from eight weeks development until complete expulsion or extraction from a woman's body, or removal from an artificial womb or other similar environment designed to nurture the development of such organism.

§ 3231. Human cloning prohibitions. It shall be unlawful for any person or entity, public or private, to intentionally or knowingly:

1. perform or attempt to perform human cloning;

2. participate in an attempt to perform human cloning;

3. transfer or receive the product of human cloning for any purpose; or

4. transfer or receive, in whole or in part, any oocyte, embryo, fetus, or human somatic cell, for the purpose of human cloning.

§ 3232. Exceptions. Nothing in this article shall restrict areas of scientific research not specifically prohibited by this article, including in vitro fertilization, the administration of fertility-enhancing drugs, research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, tissues, organs, plants, or animals other than humans, or cells other than human embryos.

§ 3233. Penalties for violations. 1. (a) Any person or entity that violates subdivisions one and two of section thirty-two hundred thirty-one of this article shall be guilty of a class D felony.

(b) Any person or entity that violates subdivisions three and four of section thirty-two hundred thirty-one of this article shall be guilty of a class A misdemeanor.

2. Any person or entity that violates any provision of this article and derives a pecuniary gain from such violation shall be fined up to one million dollars pursuant to the prevailing federal penalty guidelines or twice the amount of gross gain, or any amount intermediate between the foregoing, at the discretion of the court.

3. Any violation of this article shall constitute unprofessional conduct and shall result in permanent revocation of the violator's license to practice medicine.

4. Any violation of this article shall be the basis:

(a) for denying an application for,

(b) for denying an application for the renewal of, or

(c) for revoking any license, permit, certificate, or any other form of permission required to practice or engage in a trade, occupation or profession.

§ 3234. Severability. If any clause, sentence, paragraph, section or part of this article shall be adjudged by any court of competent jurisdiction to be invalid and after exhaustion of all further judicial review, the judgment shall not affect, impair or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, section or part of this article directly involved in the controversy in which the judgment shall have been rendered.

§ 4. This act shall take effect on the sixtieth day after it shall have become a law.

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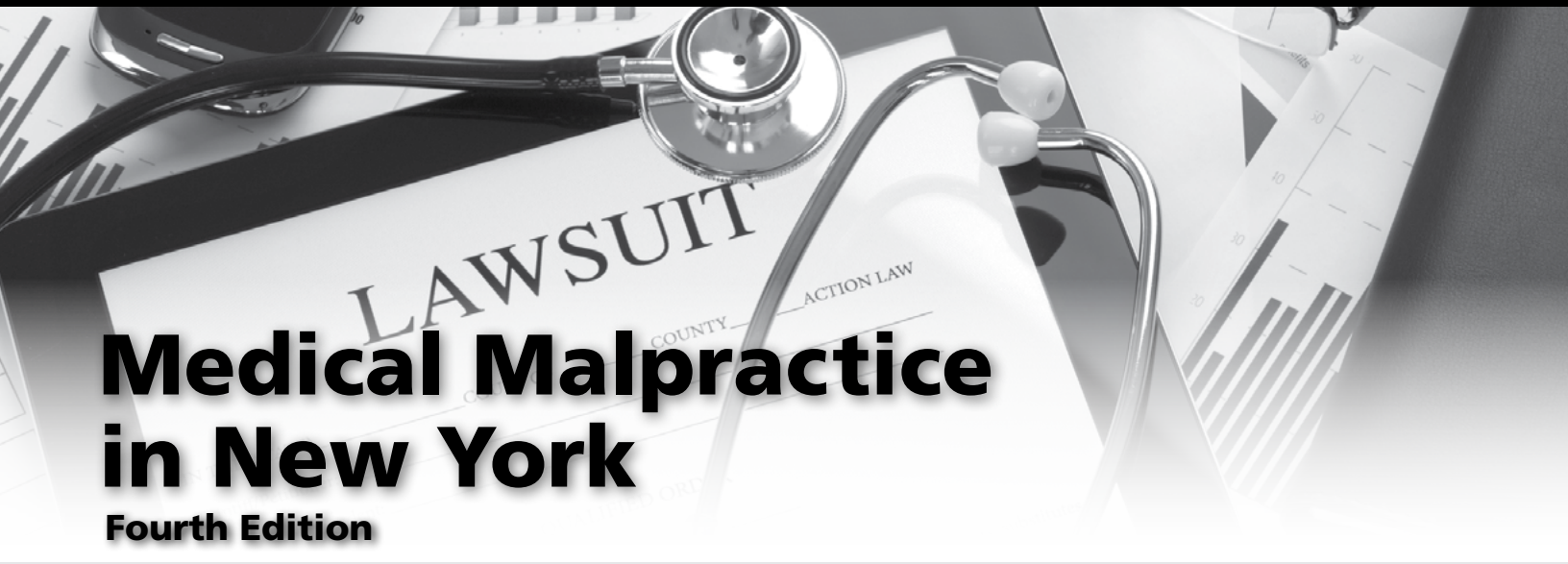


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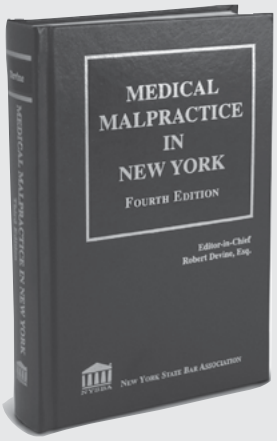


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# Informed Consent in Medical Decision Making: A Historical Examination and Future Development

By Adam S. Herbst

The modern informed consent doctrine reflects the contemporary sensitivity to patient rights and the development of patient-centered care. It values active collaboration, autonomy and dignity, and has taken a place at the heart of medical decision-making. It emphasizes the examination and comparison of treatment benefits, while incorporating consideration of patient values, fears and preferred outcomes.[1] It also encourages patient engagement, improves quality of care and enables the patient to set boundaries in the doctor-patient relationship. Many believe it is also changing the attitudes of a new generation of doctors toward their patients. But the doctrine of informed consent, which has benefited both sides of the doctor-patient relationship, is a relatively modern one, following a slow development, adoption and pitfalls.[2] It is a dynamic story of reform and legal progress, combining developments in bioethical philosophies with innovations in judicial thought that continue today.

Informed consent in the medical context involves two different duties: a duty of disclosure of information to patients and a duty to seek the consent of the patient prior to treatment. Although outside the scope of this article, informed consent is also a foundation for federal regulations on human experimentation and the touchstone for end-of-life decision-making.[3] The consent forms that a health care institution requires all patients to sign upon admission and before various procedures are the most concrete manifestations of the doctrine.[4] Accordingly, jurisdictions across the United States subscribe to three basic elements of a valid informed consent: (i) *disclosure*—fully revealing the reasonably appropriate amount of information that is necessary for a patient to make an informed decision; (ii) *capacity*—the ability for a patient to both understand the information provided and form a reasonable judgment based on the potential consequences of their decision; and (iii) *voluntariness*—the patient's right to freely exercise their decision without being subjected to external pressure (such as coercion, manipulation, or undue influence). These foundational elements, well established for over 40 years, safeguard the patient's individual autonomy, avoid fraud or duress and foster rational decision-making by the patient.[5] Strikingly, each of these elements developed independently and for different reasons, leading to the question of whether further elements will be added as technology and informational resources continue to revolutionize our culture.

To consider this question, it's helpful to trace why, and how, this doctrine developed from an isolated, inequitable thought to an interdependent, pragmatic medical principle and then consider what future changes may be necessary to guarantee the patient/consumer is still sitting at the table.

## Early American Philosophies

At a minimum, patients desire respect, dignity and a degree of independence when receiving medical care; however, by tradition and under the common law, which reflected it, physicians subordinated these desires in favor of a paternalistic relationship marked by nondisclosure, one first authored by the esteemed Hippocrates.[6] The doctor, as the expert, agreed to treat the patient, who would acquiesce to whatever care was advised. Obtaining patient consent was gratuitous. Benjamin Rush, a contributor to the Continental Congress and a leading mind in colonial American medicine, promoted the idea of medical paternalism as an obvious function of practice.[7] Dr. Rush wrote on the necessity of physician authority while revealing little knowledge to the patient, including on treatment or condition.[8] Inauspiciously for the patient, the paternalistic attitude was not unique to early American medicine. After its founding in 1847, the American Medical Association published an instructive guide on medical ethics, outlining the patient right to reliability and faithfulness, but counseling the physician on the need, in certain cases, to prevaricate so as to ensure appropriate treatment.[9] Common law reinforced the viewpoint that a doctor must deliver all of the needed care but eschewed patient consent and participation.[10] In *M'Clallen v. Adams*, an 1837 Massachusetts Supreme Court decision, the court ruled that once the patient was placed in the doctor's care, an implied consent was given to the physician to provide the required care.[11] Although inconceivable today, the decision at no time explored the patient's right to decision-making or preferences.

Patient rights gradually developed under common law with the extension of tort theories involving trespass to the body and negligence.[12] The trespass theory was

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The author would like to thank Evelina Khorenko and Vincent Rotondo for their research contributions to this article.

straightforward: an intentional, unconsented touching of the patient constituted a battery.[13] The Supreme Court of Minnesota in *Mohr v. Williams* supported the tort theory of battery when it decided that it was necessary and proper for a patient to grant permission prior to physical contact by the physician.[14] If, for example, a surgeon operated on the wrong (non-consented) body part, courts noted that both intentional (battery) and unintentional (negligence) torts were acceptable theories of liability.[15] In battery, the tort is completed at the moment of the unconsented-to touching, whereas in negligence there must be actual injury in order for a plaintiff to make a prima facie case.[16] Common law now established that the moment a physician touched the patient's body to perform a treatment without proper patient consent, a battery had been committed.[17] If the patient suffered an actual injury from the operation, the physician could be liable for both battery and negligence.[18] Paternalism was mutable; the green light for a doctor to do as he pleased was changing.

## Cardozo Period and the Post WWII Period

As medicine and its practice advanced, the re-examination of battery and negligence as appropriate theories for actions involving patient harm resulting from nondisclosure began in 1914 with Justice Benjamin Cardozo's landmark decision in *Schloendorff v. Society of N.Y. Hospital*. This case involved a patient who successfully sued the physician and hospital for being subjected to surgery against her expressed wishes. The case further eroded the physician's paternalistic attitude as Justice Cardozo wrote, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."[19] Subsequent to *Schloendorff*, in *Salgo v. Leland Stanford Jr. University Board of Trustees*, the court first authored the term "informed consent" as it considered the case of a patient who suffered paralysis as a surgical complication without first being informed of the risk. The court wrote that a "physician violates his duty…and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."[20] *Schloendorff* and *Salgo* thus broadened the physician's fiduciary obligation within medical practice, creating a new responsibility to fully disclose essential decision-making information to the patient. This analysis was applied for approximately the next 40 years, and the disclosure duty extended to possible benefits, risks and alternatives of proposed medical treatments.[21] The advancement was episodic however, and was not without limitations as courts still struggled with the notion of informed consent.[22] In *Natanson v. Kline*, where the patient was injured despite being told there were no risks associated with her treatment, the court attempted to establish the proper standard of care.[23] *Natanson* determined that informed consent cases were like any other malpractice actions and the standard should be that of what the reasonable medical practitioner would have done in the same or similar circumstances: "The primary basis of liability in a malpractice action is the deviation from the standard of conduct of a reasonable and prudent medical doctor of the same school of practice as the defendant under similar circumstances."[24]

Notwithstanding the legal innovations, some courts were still suspicious of offering the patient too much autonomy and were prone to extend exceptions to the physician, recognizing, for example, the "extension" doctrine, which freed the physician from disclosing inherent dangers if they were deemed so obvious that the patient should have reasonably been aware of them or if the patient should have had knowledge from past experience or learning.[25] Revealing collateral risks that were not material to the patient's decision in accepting or rejecting an offered treatment was also exempted.[26] The notion of a "therapeutic" privilege was also extended to physicians, limiting the scope of disclosure under the pretense of medical necessity. The therapeutic privilege accepted that a doctor may choose which risks and information to disclose (to avoid frightening the patient out of treatment) to obtain valid informed consent.[27] The "emergency" doctrine allowed the physician to choose immediate care despite lacking authority from the patient.[28] Some courts struggled with these exceptions, as they often contradicted the notion of informed consent, leaving the mandate of disclosure both subjective and undefined. The scope of exceptions generated two different standards of practice: (1) what the medical profession believed a patient needed to know to give a knowledgeable consent to a proposed treatment or procedure; and (2) what the patient needed to know to maintain his right of self-determination.[29]

## Canterbury and Present Day

The reasonable medical practitioner standard would be rejected in *Canterbury v. Spence*, which adopted a patient-oriented perspective in creating the informed consent doctrine we know today.[30] *Canterbury* involved a young man who underwent thoracic spine surgery but was never told about possible risks.[31] Upon suffering paralysis due to the surgery, he argued that the doctor failed to inform him of the risks that existed. The court analyzed the physician's obligation to disclose, outlining a new standard that would define the duty to that owed a reasonable patient.[32] Judge Spotswood Robinson opened his elaborate opinion with a strong statement calling for a patient-oriented test. He noted that "it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests lie."[33] The disparity in power and access to information is extreme in the medical setting; the patient is dependent on the doctor for information, in fact "well-nigh abject." The case first rejects the professional standard as the measure of disclosure, since the "reality of any discernible custom reflecting a professional consensus on communication of option and risk information to patients is open to serious doubt. . . . what in fact is no custom at all may be taken as an affirmative

custom to maintain silence. . . ."[34] Judge Robinson notes that these cases are not complicated and there is little need to defer to medical judgment; the standard of ordinary care applies, "conduct which is reasonable under the circumstances."[35] The scope of disclosure is set by the patient: his or her "right of self-decision shapes the boundaries of the duty to reveal."[36] The patient's need governs, and "[t]hus, the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked."[37] Judge Robinson notes that often the decision has nontechnical elements, and prevailing medical practice may have some evidentiary significance but nothing more, since "...surely in nondisclosure cases the fact finder is not invariably functioning in an area of such technical complexity that it must be bound to medical custom as an inexorable application of the community standard of reasonable care."[38] The patient's "...right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is the information material to the decision…All risks potentially affecting the decision must be unmasked."[39]

The historic *Canterbury* decision rejected any use of subjective criteria in determining proximate cause. Adopting an objective test instead, the court asked "what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance."[40] If a reasonable patient in the plaintiff's position would have foregone the treatment knowing the risks involved, causation was established. If, however, a reasonable patient would have consented to treatment nonetheless, there is no causation.[41] Prior to *Canterbury*, courts almost unanimously held that a doctor had a duty to disclose only those risks which a reasonable medical practitioner of the same school of medicine would have disclosed to the patient in order to obtain an informed consent.[42] *Canterbury* modified the informed consent doctrine, introducing a widely accepted standard that was applied in the majority of American jurisdictions.[43]

Notwithstanding the *Canterbury* decision, a slight majority of jurisdictions presently have adopted the professional disclosure standard, determining the duty to disclose by the standard of the reasonable medical practitioner similarly situated and requiring expert testimony to establish the content of a reasonable disclosure.[44] The *Canterbury* rule, using the "reasonable patient" as the measure of the scope of disclosure, has been adopted by several states in the last few years. However some states have adopted tort reform legislation that imposes the professional disclosure standard.[45] New York, for example, has codified the concept that a reasonably prudent patient lacks informed consent if there was a "failure of the person providing the professional treatment…to disclose to the patient such alternatives…in a manner permitting the patient to make a knowledgeable evaluation.[46] *Davis v. South Nassau Communities Hosp.*, a New York Court of Appeals decision, slightly limited the state statute by noting that it is "a function of…physician to advise the patient of … risks and side effects…the medical professional need do no more than simply warn the patient of dangers."[47] What does this say about the patient-centered model in New York? What justifies the professional standard in light of the *Canterbury* decision? Are we to question the amount of disclosure that follows? Jurisdictions that abide by the professional standard ordinarily require the plaintiff to offer medical testimony to establish (1) that a reasonable medical practitioner in the same or similar community would make this disclosure, and (2) that the defendant did not comply with this community standard.[48] Judge Robinson suggested that the *Canterbury* standard is nothing more than the uniform application of the negligence principle to medical practice. However, the negligence principle normally evaluates the conduct of a reasonable actor—not the expectations of a reasonable victim.[49] The values served by the doctrine—patient autonomy and dignity—are unrelated to the values served by the doctrine of negligence. Informed consent really serves the values we otherwise identify with the doctrine of battery. It is ironic that a doctrine developed to foster and recognize individual choice should be measured by an objective standard.[50]

## Future Development

Today, a patient treated without her consent still may bring a battery action against the treating physician in most jurisdictions, though claims involving treatment in the complete absence of patient consent are rare.[51] More commonly, a claim for a breach of the duty to obtain informed consent to treatment is a claim of negligence, alleging that a physician failed to disclose important information to the patient prior to obtaining the patient's consent.[52] While most jurisdictions presently require that a proper informed consent involve disclosure of significant treatment options and risks, this does not mean the physician is obligated to discuss every conceivable option and risk. Courts have debated how far a doctor must go, but the answer continues to be far from settled. What if a patient says she does not want to hear any more? Can a patient remain ignorant? Some bioethicists have argued that there are situations where one has a right to remain uninformed about the risks of a particular medical treatment.[53] The most rational decision in some cases may be to risk the consequences of not knowing.[54] Is that argument applicable to "informed refusal" and shared decision-making? More than half of the states have enacted legislation dealing with informed consent, largely in response to various malpractice crises in their states.[55] The statutes take a variety of forms, from specific to general, but all share the common thread of moving the informed consent standard toward greater deference to medical judgment.[56] Given the current state and national trend of

legislative limitations on common law tort remedies, it may be expected that the common law of informed consent will continue to be affected by legislative action.[57]

Most patients have a limited understanding of medicine, so it is difficult, if not impossible, for a physician to confirm that a patient has given adequate informed consent. An informed consent form, or other written documentation of the patient's verbal consent, is treated in many states as presumptively valid agreement to the treatment at issue, with the burden on the patient to rebut the presumption.[58] The issue for many physicians (and patients), however, is that informed consent forms have become highly technical, complex and lengthy documents, which are difficult to understand.[59] This may be where new forms of technology can promote shared decision-making and help improve the way physicians speak with patients. Newer electronic decision aids can better protect individual autonomy while also encouraging physicians to carefully consider their decisions. The quality and growth of decision-making aids, such as web-based sites and DVD'developers have compiled clearinghouses of decision aids that meet acceptable standards of informed consent for specific patient choices. These tools can provide patients with another source of detailed and specific information on treatment options, helping the physician clarify and guide the patient through the decision-making process.[60] Decision aids are being incorporated with electronic medical record (EMR) systems and introduced into national legislation. With the exception of a handful of politically charged issues, policies that focus on patient choice have become a national focus in public health. The Affordable Care Act adopted the use of decision aids for preference-sensitive care in section 3506 defining it as:[61]

> medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option

and mandating that "the use of such care should depend on the informed patient choice among clinically appropriate treatment options." Section 3501 of the ACA adopts the patient decision aid concept, and develops a regulatory approach for implementing shared decision aids with the stated purpose of facilitating collaboration and providing information on treatment options that incorporate patient preferences and values into the medical plan.[62] Improved use of electronic decision aids will better help protect patients and minimize the possibility of coercion in the 21st century.

The continuous advancements in other technology introduce new resources and new obstacles for the informed consent doctrine. The *New England Journal of Medicine* recently released an article titled "Informed Consent," discussing how technology may impact informed consent.[63] This article notes that digital technology has transformed the way we communicate and that "[t] echnological and societal changes in information practices present fresh opportunities for innovative implementation of informed consent . . . Technologies allow for methods of informed consent that are modern, green, interactive, and dynamic." It discusses new challenges that may arise with the use of electronic forms in informed consent. The article suggests that "promoting informed consent will require the creative use of electronic technologies that are simple, easy to use, and in widespread and common use."[64] It asks whether there should be one standard for situations when the risk to a patient is low and another for when the risk is high, and suggests that further dialogue is needed to guide both physician and patient on establishing a "standard" informed consent.

Moving legally protected patient expectations from being the passive recipient of medical care to a fully informed patient/consumer is a welcome innovation. Although informed consent has been an extraordinary graft onto medical practice, research suggests that transparency and health outcomes improve if the paternalistic physician-mindset is jettisoned for more shared decision-making.[65] The Affordable Care Act has taken patient engagement one step further and promoted public engagement as a central component of health care delivery and payment.[66] As such, technology and public policy are ushering in a fourth new and dynamic element to the informed consent doctrine, one with ethical advantages that includes society's help in safeguarding against deception or omissions in medical decision-making.[67] As technology progresses, doctors should expect their patients, and the public in general, to ask even more questions about their medical care. The definition of informed consent will likely continue to evolve, mirroring societal expectations of what a reasonable person would require. It reflects a process of change that will hopefully benefit us all.

## Endnotes


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3. *Id.*
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8. *Id*.
9. *Id*
10. Kumar, *supra* note 6.
11. *McClallen v. Adams*, 36 Mass. 333 (1837). (A doctor treated a patient for an extended period of time, culminating in the amputation of that patient's breast and the patient's unfortunate demise.).
12. Kumar, *supra* note 6.
13. Michael W. Rosen, *Informed Consent in New York under the Medical Malpractice Insurance Act*, 4 Hofstra L.Rev. 3 (1976).
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15. Rosen, *supra* note 13.
16. *Id*.
17. *Id*.
18. *Id*.
19. *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92 (N.Y. 1914).
20. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 154 Cal. App. 2d 560 (1957). (The patient sued after becoming paralyzed following a translumbar aortography. The patient asserted that the surgeon committed a tort in res ipsa loquitur and the spinal injury occurred while the patient was receiving the treatment following surgery.).
21. *Id*.
22. Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 Yale L.J. 2 (1985).
23. Linda Babbitt Jaeckel, *New Trends in Informed Consent*, 54 Nebraska L.Rev. 1 (1975).
24. *Spencer v. Martin K. Eby Constr. Co.*, 186 Kan. 345, 411 (1960); *Natanson v. Kline*, 350 P.2d 1093, 1107 (1960).
25. Jaeckel, *supra* note 23.
26. *Id*.
27. Shultz, *supra* note 22.
28. *Id.*
29. *Id*.
30. *Id*.
31. *Canterbury v. Spence*, 150 U.S. App. D.C. 263, 464 F.2d 772 (1972). (A young man who underwent a surgery was not told about the risk of paralysis as a potential outcome of the surgery. Unfortunately, he became paralyzed and sued, alleging that the doctor negligently failed to disclose the risk of paralysis before the operation.)
32. Jaeckel, *supra* note 23.
33. *Canterbury*, 464 F.2d 772.
34. *Id*.
35. *Id*.
36. *Id*.
37. *Id*.
38. *Id*.
39. *Id*.
40. Jaeckel, *supra* note 23.
41. *Id*.
42. *Id*.
43. *Id*.
44. Barry R. Furrow, Health Law, *supra* note 4.
45. *Eady v. Landford*, 351 Ark. 249, 92 S.W.3d 57 (2002).
46. N.Y. Pub. Health Law § 2805-d (McKinney).
47. *Davis v. S. Nassau Cmtys. Hosp.*, 26 N.Y.3d 563 (2015) (A patient, soon after being discharged from the hospital, drove her car into a bus operated by Davis, who sued the hospital because the hospital allegedly had a duty to the plaintiff to warn the patient that medication the hospital gave the patient could impact driving skills and that the hospital was the only party that could provide a proper warning of the side effects of the medication.).
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49. *Id*.
50. *Id*. King and Moulton conclude that 25 states have the physician-based standard, two a hybrid standard, and the rest a patient-based standard (Jaime Staples King & Benjamin Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decisionmaking*, 32 Am. J. Law & Med. 429, 493-501 (2006)).
51. *Id*.
52. *Id*.
53. Mark Strasser, *Mill and the Right to Remain Uninformed*, 11 J. Medicine & Philosophy 265 (1986), contra, David E. Ost, *The "Right" Not To Know,* 9 J.Med. & Philosophy 301 (1984).
54. *Id*.
55. Barry R. Furrow, Health Law, *supra* note 4.
56. *Id*.
57. *Id*.
58. *Id*.
59. *The Future of Informed Consent*: *Part 3 Of MESM's Series on Proposed Federal Research Regulation Amendments and The Impacts on Commercial Sponsors and Research Organisations* (Aug. 2016), https://www.mesm.com/media/1320/mesm120-federal-research-regulations-informed-consent-pt-3.pdf.
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62. *Id*.
63. Christine Grady, Steven R. Cummings, M.D., Michael C. Rowbotham, et al., *Informed Consent*, New Eng. J.Med. (Mar. 2, 2017), https://www.nejm.org/doi/full/10.1056/NEJMra1603773.
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# H.R. 5062—Advancing Access to Precision Medicine Act

To provide for a study by the National Academy of Medicine on the use of genetic and genomic testing to improve health care, and for other purposes.

**IN THE HOUSE OF REPRESENTATIVES**

**February 15, 2018**

Mr. Swalwell of California (for himself, Mr. Shimkus, Mr. Peters, Mr. Paulsen, and Mr. Vargas) introduced the following bill; which was referred to the Committee on Energy and Commerce

**A BILL**

To provide for a study by the National Academy of Medicine on the use of genetic and genomic testing to improve health care, and for other purposes.

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

## SECTION 1. SHORT TITLE.

This Act may be cited as the "Advancing Access to Precision Medicine Act."

## SEC. 2. NATIONAL ACADEMY OF MEDICINE STUDY.

(a) In General.— Not later than 60 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall enter into an arrangement with the National Academy of Medicine under which the Academy agrees to study—

(1) how genetic and genomic testing may improve preventative care and precision medicine;

(2) how genetic and genomic testing may reduce health disparities;

(3) how the Federal Government may help to reduce barriers to genetic and genomic testing, including—

(A) encouraging the expansion of health insurance coverage of genetic and genomic testing, including diagnostic, predictive, and presymptomatic testing, and whole genome sequencing;

(B) supporting the collection of evidence for the clinical utility and appropriate use of genetic and genomic tests; and

(C) improving access to genetic counselors, pathologists, and other relevant professions, including strengthening related workforce education and training efforts;

(4) (A) the extent to which coverage provisions in the Medicare and Medicaid programs under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq., 1396 et seq.) may restrain the use of genetic and genomic testing that may improve clinical outcomes for beneficiaries; and

(B) how the Centers for Medicare & Medicaid Services may make coverage determinations that better suit a precision medicine approach to treatment; and

(5) how genetic and genomic testing may improve health outcomes for all populations in the United States, including

(A) individuals with a rare disease, including—

(i) a metabolic disease;

(ii) a hereditary cancer syndrome; and

(iii) a neurologic disease with known treatments; and

(B) special populations, including—

(i) infants and children;

(ii) critically ill (non-infectious and non-trauma) patients;

(iii) transplant patients;

(iv) individuals with cardiac disease; and

(v) individuals with, or who have a family history of, a birth defect or developmental disability.

(b) REPORT.—

(1) IN GENERAL.—The arrangement under subsection (a) shall provide for the National Academy of Medicine to submit, not later than 3 years after the date of enactment of this Act, a report on the results of the study under subsection (a) to—

(A) the Secretary of Health and Human Services;

(B) the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives; and

(C) the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate.

(2) CONSULTATION.—The arrangement under subsection (a) shall provide for the National Academy of Medicine, in developing the report required by paragraph (1), to consult with physicians, other health professionals, health educators, health professional organizations, relevant companies, patients, patient organizations, the Health Resources and Services Administration, the National Cancer Institute, the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services.

## SEC. 3. STATE OPTION TO PROVIDE WHOLE GENOME SEQUENCING CLINICAL SERVICES FOR CERTAIN CHILDREN.

Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1943 the following new section:

### "SEC. 1944. STATE OPTION TO PROVIDE WHOLE GENOME SEQUENCING CLINICAL SERVICES FOR CERTAIN CHILDREN.

"(a) IN GENERAL.—Notwithstanding section 1902(a)(1) (relating to statewideness), section 1902(a)(10)(B) (relating to comparability), and any other provision of this title for which the Secretary determines it is necessary to waive in order to implement this section, beginning January 1, 2019, a State, at its option as a State plan amendment, may provide for medical assistance under this title to an eligible individual for purposes of providing the individual with whole genome sequencing clinical services.

"(b) PAYMENTS.—

"(1) IN GENERAL.—A State shall provide a health care provider (as defined by the State) with payments for the provision of whole genome sequencing clinical services to any eligible individual. Payments made to a health care provider for such services shall be treated as medical assistance for purposes of section 1903(a), except that, during the first 8 fiscal year quarters that the State plan amendment is in effect, the Federal medical assistance percentage applicable to such payments shall be equal to 75 percent.

"(2) METHODOLOGY.—The State shall specify in the State plan amendment the methodology the State will use for determining payment for the provision of whole genome sequencing clinical services. Such methodology for determining payment shall be established consistent with section 1902(a)(30)(A).

"(3) PLANNING GRANTS.—

"(A) IN GENERAL.—Beginning January 1, 2019, the Secretary may award planning grants to States for purposes of developing a State plan amendment under this section. A planning grant awarded to a State under this paragraph shall remain available until expended.

"(B) STATE CONTRIBUTION.—A State awarded a planning grant shall contribute an amount equal to the State percentage determined under section 1905(b) for each fiscal year for which the grant is awarded.

"(c) HOSPITAL REFERRALS.—A State shall include in the State plan amendment a requirement for any hospital that is a participating provider under the State plan (or a waiver of such plan) to establish procedures for referring any eligible individual who seeks or needs treatment in a hospital emergency department to a health care provider who is qualified (as determined by the State) to provide whole genome sequencing clinical services.

"(d) REPORTS BY STATES.— Not later than three years after the date on which the State plan amendment under this section is approved, a State shall submit a report to the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Health Resources and Services Administration on —

"(1) the extent to which whole genomic sequencing clinical services reduce health disparities; and

"(2) the extent to which coverage under the State plan (or a waiver of such plan) impedes the use of genetic and genomic testing that may improve clinical outcomes for eligible individuals enrolled in the State plan (or under a waiver of such plan).

"(e) REPORTS BY HEALTH CARE PROVIDERS.— As a condition for receiving payment for whole genome sequencing clinical services provided to an eligible individual, a health care provider shall report to the State, in accordance with such requirements as the Secretary shall specify, on all applicable measures for determining the quality of such services.

"(f) DEFINITIONS.— In this section:

"(1) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who—

"(A) is eligible for medical assistance under the State plan (or a waiver of such plan);

"(B) is under the age of 21 (or, at the option of the State, under the age of 20, 19, or 18 as the State may choose), or in the case of an individual described in section 1902(a)(10)(A)(i)(IX), under the age of 26;

"(C) has been referred or admitted to a pediatric intensive care unit for a chronic or undiagnosed disease; and

"(D) has been seen by at least one medical specialist for such chronic or undiagnosed disease; and

"(E) is suspected by at least one medical specialist to have a pediatric-onset genetic disease.

"(2) WHOLE GENOME SEQUENCING CLINICAL SERVICES.—The term 'whole genome sequencing clinical services', with respect to an eligible individual—

"(A) means the unbiased sequencing of all deoxyribonucleic acid bases in the genome of such individual and, if for the sole benefit of the individual, a biological parent of such individual for the purpose of determining whether one or more potentially disease-causing genetic variants are present in the genome of such individual or such biological parent; and

"(B) includes any analysis, interpretation, and data report derived from such sequencing."

# NEWS flash

## What's Happening in the Section

### New Litigation Committee—A Message from the Chair

**Dear Members:**

I am very excited to announce the creation and formal kickoff of the NYSBA Health Law Section Health Care Litigation Committee. Many attorneys in our Section are active in litigating health law-related matters in the various civil, criminal, and administrative venues that exist for resolving healthcare related matters, and each of you are invited and encouraged to join!

The Health Care Litigation Committee will explore the unique and challenging issues related to litigating disputed matters within our rapidly changing health care industry.

The Committee hopes to provide our health law litigators with an opportunity for in-depth exploration of a variety of issues, including venue, remedies, and procedures that are relevant to handling litigation and other controverted health care disputes common to our Section.

Our kickoff meeting was on Wednesday, January 16, 2019, 7:45 a.m. - 8:45 a.m., at the New York Hilton Midtown, 1335 Avenue of the Americas, NYC, during the NYSBA Annual Meeting. This was immediately prior to the Health Law Section's Annual Meeting CLE program. The meeting included a planning discussion for the coming year.

We hope you will consider joining the Committee.

**Linda Jane Clark, Esq.**
**Barclay Damon LLP, Albany**
**Chair, Health Care Litigation Committee**

### Committee's Mission Statement

The Committee's Mission Statement is below. Joining the Committee is complimentary for NYSBA Health Law Section members.

To join the Committee, email Amy Jasiewicz at: ajasiewicz@nysba.org.

**Mission Statement:**

In recognition of the quickly growing and ever-evolving field of health care litigation, the Health Law Litigation Committee will focus on areas of health law involving the adversarial litigation process, both civil and criminal, that are relevant to health care disputes.

This Committee seeks to study and review challenges unique or relevant to participants in the health care industry, including patients, providers, and payors, as well as promote collegial sharing among NYSBA lawyers, and the dissemination of information and expertise in both litigation and other resolutions of health care-related disputes.

# Section Committees and Chairs*

The Health Law Section encourages members to participate in its programs and to volunteer to serve on the Committees listed below. Please contact the Section Officers or Committee Chairs for further information about these Committees.

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