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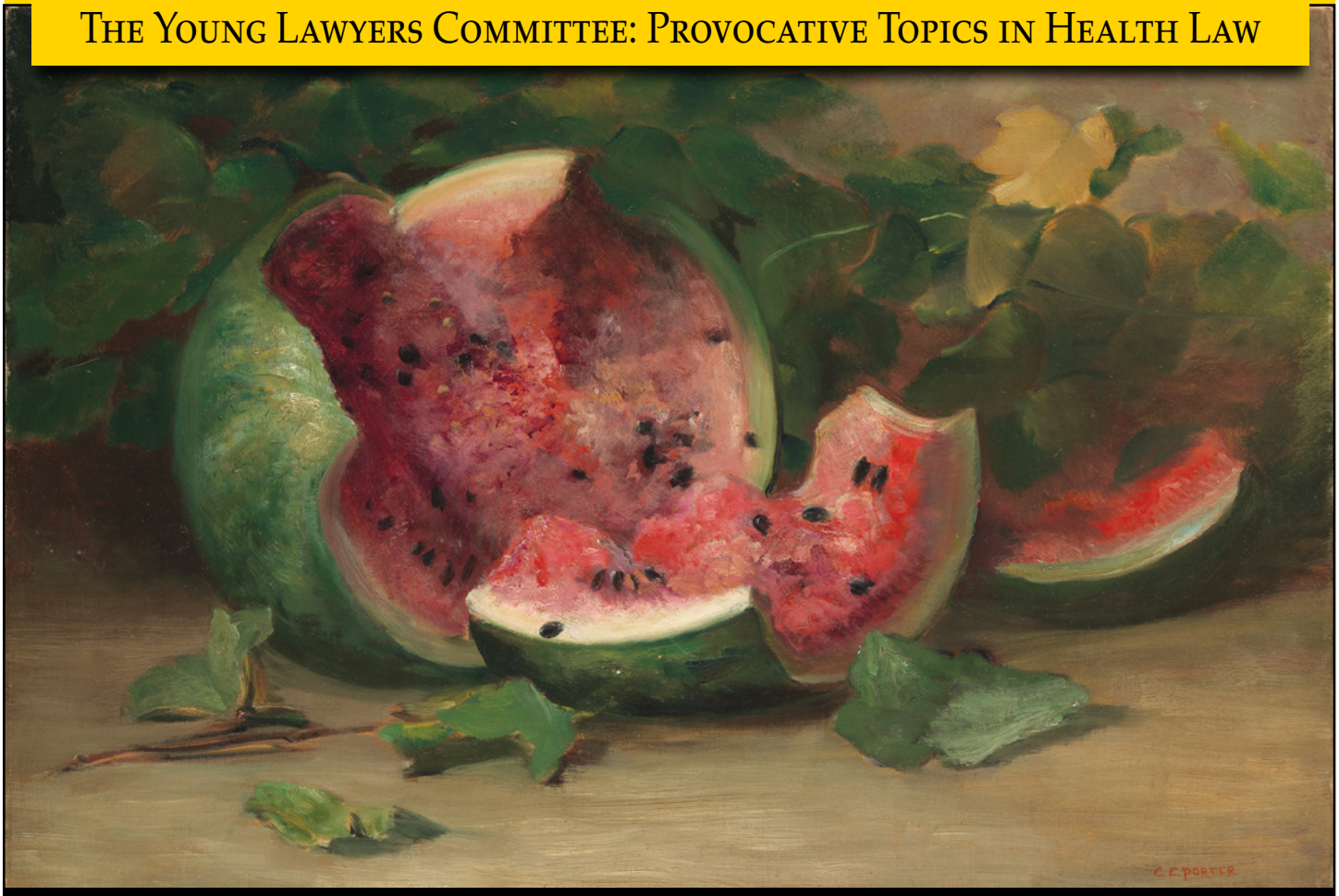
Health Law Journal

A publication of the Health Law Section
of the New York State Bar Association

THE YOUNG LAWYERS COMMITTEE: PROVOCATIVE TOPICS IN HEALTH LAW



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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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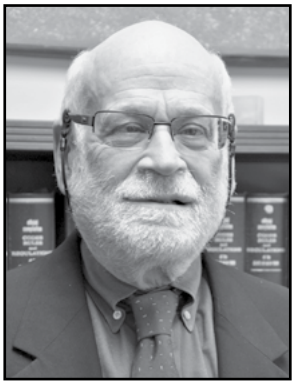
Cover artwork: Untitled (Cracked Watermelon) by Charles Ethan Porter (1847-1923). Credit: Purchase, Nancy Dunn Revocable Trust Gift, 2015. On View at The Met Fifth Avenue in Gallery 762.

Message from the Section Chair



The 2017-2018 year for the Health Law Section (Section) is shaping up to be one of a great deal of activity, including organizational work and committee projects, as well policy input on the national and state level. Much of this activity will be driven by efforts to "repeal and replace" the Affordable Care Act and the responses of New York State to those "reforms." The Section will also be addressing its committee structure and continue to strengthen its outreach to young lawyers and law students interested in health law. Since its founding in 1996, under the leadership of Barry Gold, the Section has had a significant impact on my legal career and professional growth. During the course of my involvement the information and knowledge received from its educational programs, dialogue with colleagues and exposure to the various approaches taken to health law issues, has been invaluable. I hope that my contributions as Section Chair will add to the strength of the Section and its programs in the tradition of the 20 past chairs.

The success of the Section's activities rests on the strength of its committees. A list of those committees appears elsewhere in this publication. Whether your interest and professional commitment is in the area of mental health or developmental disabilities law, continuing legal education, medical research and biotechnology, the ethics of health care, health care professionals, technology and e-health, enhancing the number and diversity of Section membership, professional discipline, public health law, reimbursement, working with other young attorneys in the field or other a eas related to health law, you will find that your thoughts, ideas, expertise an participation will be a welcome addition on a committee. During this past year we have sponsored a variety of CLE programs, including the Section's fall meeting and program at the NYSBA Annual Meeting, senior housing, health care program integrity and enforcement, organ and tissue donation, disciplinary proceedings, and the False Claims Act. The Section has launched an outreach program to law schools and attorneys throughout the state and reviewed, researched and taken positions on legislative issues. Just recently, the Health Law Section Committee on Ethical Issues in the Provision of Health Care worked with the Disability Rights Committee, an independent committee of the Bar Association, in organizing and hosting a day-long session on proposed reforms to guardianship under Article 17-A of the Surrogate's Court Procedure Act. The morning part of that meeting reviewed proposed changes to guardianship proceedings in response to the perceived absence of due process, equal protection and ADA rights under statutory procedures that have existed since the late 1960s and are currently the subject of federal litigation. In the afternoon the discussion centered on the proposed changes offered by the Governor's Task Force on Life and the Law to healthcare decision making under the guardianship statute. Representatives from the Health Law Section, Disability Rights Committee, Civil Rights Committee, Elder Law and Special Needs Section, and the Trusts and Estates Section were present for the meeting. A short time after that meeting, prior to the issuance of the notes from the meeting and follow-up, two pieces legislation were introduced in the New York State Assembly and Senate to reform the Surrogate's Court Procedures Act Article 17-A Guardianship. Within a short time thereafter the Health Law Section issued a statement in support of those reforms, as did the Elder Law and Special Needs Section. The Section Committee on Medical Research and Biotechnology drafted positions on legislation and federal policy that were adopted by Section as a whole and distributed.

In addition, the Section initiated a series of evening receptions, with short CLEs attached, scattered throughout the state in an effort to reach out geographically to attorneys. Several of these, as well as additional programs, were held at law schools. They were held in New York City, Albany, Rochester and Buffalo.

The challenges facing this Section in the coming year will include efforts to significantly inc ease our reach out to law students and young attorneys (it should be noted that the Young Lawyers Committee of the Section is the sponsor of this edition of the *Health Law Journal)*, strengthening the committee structure of the Section, and responding to changes both in the delivery of health care and the legislation affecting that delivery. In particular, the Section will need to be on top of proposed changes to the Affordable Care Act and, in particular, New York State's reaction thereto. The governor has already called for a series of forums around the state, which will have been completed before this edition appears, to open discussion of proposed state responses to federal law. The Section will need to respond quickly to any changes both from an advocacy perspective and to assist our members in understanding and meeting the challenges faced by our clients.

The Section will also be increasing its membership activities in an effort to attract and retain additional members. This will be done through receptions and outreach as well as designing programs to attract law students

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and attorneys. CLE programs already being planned for the coming year include one on the basics of health law, the October Annual Meeting in Albany and the January health law update at the NYSBA Annual Meeting. Additional items being discussed include a CLE on proposed reforms in health care delivery, possibly including a "respectful" debate on the issue of "is health care a right" in an effort to see if there are areas we can identify of mutual agreement. Finally, but certainly not least, the continued publication of this *Journal*, under the able and long term editorship of Robert Swidler, serves both the Section membership and potential Section membership as an invaluable source of information and education. Regular features such as the health care legislative review, the review of actions by New York State agencies, recent New York State fraud abuse and compliance developments, and a review of articles in law journals relative to health law should not be overlooked.

I welcome the opportunity to work with others during this next year toward the growth and development of this Section and urge and encourage you to work with us on these endeavors.

Lawrence Faulkner

In the New York State Courts

By Leonard M. Rosenberg

Appellate Division Upholds Decision Barring Medical Provider From Recovering First-Party No-Fault Benefits Based on Insurers' Fraudulent Incorporation Defense

Andrew Carothers, M.D., P.C. v. Progressive Ins. Co., 150 A.D.2d 192, 51 N.Y.S.3d 551 (2d Dep't 2017).

Appellant, a professional corporation that performed MRIs for patients injured in motor vehicle accidents, appealed the decision of the Appellate Term that affirmed a jud - ment, upon a jury verdict, dismissing Appellant's action against the defendant insurer to recover assigned first-party no-fault benefits. Affirming the judgment of the Appellate Term, the Appellate Division, Second Department held that because Appellant was co-owned and controlled by two non-parties who were not physicians, Appellant was "fraudulently incorporated" under the New York Business Corporation Law, and ineligible to recover the assigned benefits

New York State law requires all professional corporations to be owned and controlled by licensed professionals. In furtherance of that law, the Court of Appeals held in *State Farm Mut. Auto Ins. Co. v. Mallela*, 4 N.Y.3d 313 (2005) that an insurance carrier may withhold payment for medical services provided by a professional corporation that has been "fraudulently incorporated" to allow non-physicians to share in its ownership and control. The issue presented on appeal is what elements are necessary to establish the defense of fraudulent incorporation under *Mallela*, and whether the jury in this action was properly instructed on the elements of a fraudulent incorporation defense.

Andrew Carothers, a radiologist, formed a professional service corporation (Appellant Andrew Carothers, M.D., P.C.) to perform MRI scans at

three locations in New York City. Appellant leased the three facilities and all the medical and office equipment used at the facilities from companies owned and controlled by non-party Hillel Sher. The majority of the MRI scans were performed for patients allegedly injured in motor vehicle accidents. These patients assigned their right to receive first party no-fault insurance benefits to Appellant, who in turn billed the patients' insurance companies to recover payment on the assigned claims. When payment was not made in many instances, Appellant commenced thousands of actions against the insurers, including the appellee, Progressive Insurance Company ("Progressive"), to recover the unpaid claims. The actions were combined in a joint trial.

As a defense to nonpayment, the insurers contended that Appellant was not entitled to payment for the unpaid claims because, pursuant to *Mallela*, Appellant was fraudulently incorporated. Specificall , the insurers alleged that Appellant was not solely owned and controlled by Dr. Carothers, who was listed on corporate filings as Appellant's sole owner, shareholder, director, and office . Rather, the insurers contended that Dr. Carothers was merely a nominal owner, and that Appellant was actually owned and controlled by Sher, Appellant's landlord, and Irina Vayman, Appellant's executive secretary, both non-physicians. Although Sher and Vayman were deposed prior to trial, both invoked their Fifth Amendment privilege against self-incrimination in response to virtually all questions posed to them.

During the course of the trial, the insurers presented evidence that: (i) Appellant's profits we e funneled to Sher and Vayman through money transfers and grossly inflated equi - ment and lease payments; (ii) Dr. Carothers had no real involvement with the management and control of Appellant; (iii) no tax returns were filed on behalf of Appellant and no books or records were maintained; and (iv) Sher and Vayman received a majority of Appellant's profits. When Dr. Carothers was called to testify, Dr. Carothers was unable to present any proof to refute such evidence.

Although the parties agreed that neither Sher nor Vayman were available to testify at trial within the meaning of CPLR 3117(a)(3), the court permitted defense counsel to read portions of their deposition transcripts to the jury over Appellant's objection. The court also charged the jury that an adverse inference could be drawn against Appellant based upon Sher and Vayman's invocation of the Fifth Amendment.

Before the civil court delivered its jury charge, Appellant requested that the jury be instructed that: (i) in order to prove fraudulent incorporation, the insurers were required to prove the traditional elements of common law fraud, including the

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element of fraudulent intent; (ii) the insurers were required to prove such intent was present at the time Appellant was incorporated; and (iii) the jury must consider the business judgment rule in evaluating whether Dr. Carothers' decisions were reasonable and whether he engaged in sham transactions as defined under the fe - eral tax law.

The civil court denied these requests, and instructed the jury that the insurers had to establish that Sher and/or Vayman were de facto owners of Appellant or that they exercised substantial control over Appellant. In making that determination, the civil court instructed the jury to consider the totality of the circumstances, and provided the jury with a list of 13 factors that it might want to consider. Based on these instructions, the jury returned a verdict, finding that the insurers proved that Appellant was fraudulently incorporated by clear and convincing evidence. Denying Appellant's motion to set aside the verdict, the civil court entered a judgment in favor of the insurers. On appeal, the Appellate Term upheld that portion of the verdict that found Appellant was fraudulently incorporated and affirmed the judgment on that basis.

The Second Department affirmed on appeal. The court held that the jury's charge on fraudulent incorporation, read as a whole, adequately conveyed the correct legal principles articulated by the Court of Appeals in *Mallela*. Specificall , the court held that the charge properly focused the jury on whether Dr. Carothers was a mere nominal owner of Appellant, and if, in actuality, it was Sher and/or Vayman who owned or controlled Appellant such that the profits we e funneled to them. The court noted that although Appellant is correct that certain factors enumerated in the non-exhaustive list of factors with which the jury was charged could not, standing alone, support a finding of fraudulent incorporation, the jury was properly instructed to consider the totality of the circumstances, rather than any one particular factor.

The court also held that the civil court did not err in declining to instruct the jury as to common-law fraud, the business judgment rule, and whether Dr. Carothers' had the requisite fraudulent intent at the time of incorporation. As the court held, *Mallela* involved fraud "in the corporate form," rather than the more traditional form of common law fraud. As for fraudulent intent, the court held that good faith compliance with the requirements of a professional corporation does not end when the certificate of incorporation is filed and does not defeat a claim of fraudulent incorporation if the evidence shows that at some point after the initial incorporation, the physician owner turned over control of the business to non-physicians. The court also held that the civil court correctly determined that the evidence presented at trial did not support a business judgment charge given: (i) Dr. Carothers' inability to refute the evidence demonstrating that the vast majority of Appellant's funds were transferred to Sher and Vayman; and (ii) the fact that Dr. Carothers' testimony displayed an almost complete lack of knowledge about the operations and finances of the Appellant. Finally, the court held that the civil court properly denied Appellant's request to charge the jury, in accordance with federal tax law, that a "sham transaction" is "one that has no business purpose or economic substance" given that the jury was instructed that salary and lease payments should not be considered profits if it found they were negotiated in good faith and were not a means to funnel profits to non-physicians

Lastly, with regard to the civil court's adverse inference charge, the court held that the Appellate Term properly determined that the civil court erred in permitting defense counsel to read portions of Sher and Vayman's deposition transcripts into evidence and in instructing the jury that it could draw an adverse inference against Appellant based on the Fifth Amendment. Nevertheless, the court held that because the evidence clearly favored a verdict in the insurers' favor, and the outcome of the trial would have been the same absent the error, the civil court's error was harmless, and the judgment was properly affirmed

In Split with Second Department, Third Department Finds "Soft Cap" on Executive Compensation for Covered Health Care Providers Unconstitutional

LeadingAge New York, Inc. v. Shah, 2017 WL 2674258 (3d Dep't, June 22, 2017).

Petitioners brought combined proceedings pursuant to CPLR Article 78 and actions for declaratory judgment, seeking to invalidate portions of 10 N.Y.C.R.R. Part 1002. Such regulations, which the New York State Department of Health (DOH) promulgated in May 2013, impose limits on the executive compensation and administrative costs of certain health care providers.

In January 2012, following a task force investigation revealing that taxpayer funds were being used to cover excessive overhead costs and executive compensation of service providers, Governor Andrew Cuomo issued Executive Order No. 38 (EO38), which directed multiple State agencies, including the DOH, to curtail abuse and ensure that State funds allocated for needy New Yorkers are spent primarily on direct care or services. Among other things, EO38 instructed State agencies, to the extent practicable, not to provide funding for executive compensation in excess of $199,000 per year.

In accordance with EO38's mandates, the DOH implemented 10 N.Y.C.R.R. §§ 1002.2(a) and 1002.3(a), which place restrictions on administrative expenses and executive compensation for certain health care providers who receive State funding (the "Hard Cap"). Under 10 N.Y.C.R.R. § 1002.3(a), "covered providers" are generally prohibited from using State funds or State-authorized pay-

ments for executive compensation to any "covered executive" in excess of $199,000 per year. The DOH also implemented 10 N.Y.C.R.R. § 1002.3(b), which places further restrictions on executive compensation, regardless of whether such compensation is provided by taxpayer funds (the "Soft Cap"). Specificall , the Soft Cap subjects covered providers to penalties if they provide compensation to covered executives in excess of $199,000 from any source and (1) such compensation exceeds the 75th percentile for comparable executives, as identified in 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 DOH regulations also permit covered entities to apply for a waiver of the limits on executive compensation or administrative costs on a showing a good cause.

Petitioners separately brought hybrid Article 78 proceedings and declaratory judgment actions in the Supreme Court, Albany County, contending that both the Hard Cap and Soft Cap provisions violate the separation of powers doctrine and are otherwise arbitrary and capricious. After consolidating the proceedings, the Supreme Court ruled that the Hard Cap provisions are a constitutional exercise of the DOH's rulemaking authority and not arbitrary or capricious, but granted the petitions insofar as it found that the Soft Cap provision is unconstitutional. All parties appealed.

The Appellate Division, Third Department began its analysis with the constitutional principle that it is the role of the Legislature to make policy determinations and the executive branch to implement those policies. The court asserted that the Legislature may grant rulemaking authority to an administrative agency, and the agency's regulations may go beyond the text of the enabling legislation, but such regulations cannot be inconsistent with the statutory text or its underlying intent. The court then stated that the four-factor test set forth by the Court of Appeals in *Boreali v. Axelrod*, 71 N.Y.2d 1 (1987) serves as the touchstone for determining whether an agency has exceeded its statutory rulemaking authority. Such factors, which are not mandatory and need not be weighed evenly, include: (1) whether the agency simply balanced costs and benefits acco ding to preexisting guidelines or made value judgments as to broad policy goals; (2) whether the agency merely filled i 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 o der to develop the challenged regulation.

The court then assessed Public Health Law §§ 201 and 206 and Social Services Law § 363-a, which the DOH cited as the statutory authority for its promulgation of 10 N.Y.C.R.R. Part 1002. The court found that the Legislature granted the DOH broad latitude to regulate the use of State funds appropriated for health care services, including the administration of Medicaid, for which it possesses "inherent authority to protect the quality and value of services rendered by providers."

Applying the *Boreali* factors, the Third Department found that the Hard Cap provisions did not violate the separation of powers doctrine. As to the first facto , it held that the DOH has a statutory obligation to ensure that taxpayer dollars are used efficiently and for the benefit of recipients of health care services, and thus the agency did not attempt to resolve a complex policy issue beyond its purview. As to the second factor, the court determined that the Hard Cap provisions merely filled in the details of th Legislature's broad policy objectives. As to the third factor, the court recognized that similar provisions were proposed but not enacted by the Legislature, but it nonetheless found that the Hard Cap provisions did not intrude on an area of continued legislative deadlock. As to the fourth factor, the court stated that the DOH relied upon its special expertise in regulating public health care spending.

Turning to the Soft Cap provision, the court weighed the *Boreali* factors and concluded that the DOH had exceeded its statutory authority. The court found that the Soft Cap provision arose from the DOH's own policy determination, rather than that of the Legislature; that the provision was thus more than just interstitial rulemaking; and that the DOH did not have any specific expertise in th general regulation of executive compensation or corporate governance. Accordingly, the court held that the Soft Cap provision is unconstitutional and affirmed the uling of the Supreme Court. The Third Department noted its disagreement with a prior ruling by the Second Department, which found the Soft Cap provision to be constitutional.

Finally, the court held that Petitioners failed to meet the heavy burden of demonstrating that the Hard Cap provisions are arbitrary and capricious. The court stated that the regulations were supported by evidence obtained by the Governor's task force investigation, as well as data showing that Medicaid and other health care costs were substantially on the rise. The court further rejected Petitioners' claim that the regulation was irrational due to its application without regard to the provider's size and complexity, its geographic location, and the type of services provided, as such considerations are incorporated into the waiver provisions of 10 N.Y.C.R.R. Part 1002.

New York Supreme Court Holds That Patient Medical Records Received by Organ Procurement Organization Are Not Protected by HIPAA

McMahon v. New York Organ Donor Network, Inc., 56 Misc. 3d 467, 52 N.Y.S.3d 194 (N.Y. Sup. Ct. 2017).

Plaintiff, a former Transplant Coordinator, brought a whistleblower action under Labor Law Section 740, alleging that he was fi ed after complaining that Defendant was procuring organs from donors without performing legally required tests and, in some instances, from donors still showing signs of life.

During discovery, Plaintiff sought the production of medical records for four specific patients whom he a - leged showed signs of brain activity immediately before Defendant's procurement of their organs. Defendant obtained these records from hospitals. Unable to obtain consent from the patients' families, Plaintiff made a motion to compel Defendant to produce the patients' medical records on the basis that Defendant is not a covered entity under the Health Insurance Portability and Accountability Act ("HIPAA") or, alternatively, on the basis that Defendant could produce the records pursuant to the parties' confidentiality ag eement. Plaintiff argued that the medical records were material and necessary to his case because they demonstrate Defendant's violation of the law, which he must prove to prevail under Labor Law Section 740.

In opposition, Defendant asserted that while it is not a covered entity under HIPAA, it must maintain patient confidentiality and, also, that it had entered into memorandums of understanding with hospitals for the purpose of obtaining confidential information to facilitate the organ donor process. Defendant argued that requiring it to produce the medical records would defeat the purpose of HIPAA, and might jeopardize its status as a non-profit o gan procurement organization (OPO).

Rejecting Defendant's arguments, the court held that CPLR 3101(a) entitles parties to full disclosure of all information material and necessary in the prosecution of the action, and that the records Plaintiff sought were material and necessary because they were alleged to demonstrate a violation of law as required under Labor Law Section 740.

As to Defendant's arguments regarding HIPAA, the court noted that, in identifying "covered entities" which may not use or disclose protected health information without a valid authorization under the statute, HIPAA specifically permit a covered entity to disclose such information to an OPO, a non-covered entity, because the information is required in order to process organ donations. Holding that Defendant must disclose the requested medical records, the court noted that Defendant had not identified any federa regulation or case that would prevent the court from requiring disclosure and, also, that other courts have held that HIPAA does not prevent disclosure of documents by a non-covered entity.

The court held that if it were to deny Plaintiff's motion based on HIPAA, it would effectively be promulgating a new federal rule that the United States Department of Health and Human Services (HHS) declined to promulgate. Specificall , the court stated that, in addressing OPOs within the HIPAA context, HHS could either have included OPOs in its definition of covered entities, or directed that any protected health information received by an OPO be subject to HIPAA's privacy protections.

The court also held that the memorandums of understanding between Defendant and certain hospitals do not prevent Plaintiff from accessing the requested information. In so holding, the court noted that the risk of negative effects on the memorandums posed by disclosure of the medical records here underscores the need for additional regulations clarifying the relationship between OPOs and HIPAA. Finally, the court held that the privacy of the records was sufficiently p otected by the parties' confidentiality o der, the terms of which satisfy the criteria for a qualified p otective order under HIPAA.

Court Bars District Attorney and the Public From Attending Guardianship Proceeding of Person Charged With Murder

In re Application of Linda E., 55 Misc.3d 700, 49 N.Y.S.3d 272 (Tompkins Cty., 2017).

Justin B., an individual under indictment for murder in the 2nd degree, attempted to plead guilty to the charges during his arraignment. The court ordered a psychiatric evaluation under CPL § 730, committed Justin B. to Mid-Hudson Psychiatric Center, and suspended the pending criminal proceedings.

Justin B.'s mother filed a pet - tion under Article 81 of the Mental Hygiene Law (MHL), requesting the appointment of a guardian of the person and property of Justin B. The court appointed Mental Hygiene Legal Service (MHLS) as counsel for Justin B. and scheduled an Article 81 proceeding.

The Tompkins County District Attorney communicated his intention of having himself or other members from his office attend the Article 81 proceeding, to obtain information for use in the pending criminal case. In response, MHLS moved under MHL § 81.14(b), to seal the record and to exclude members of the public, including all members of the District Attorney's office, f om attending the proceeding.

The court noted that Article 81 proceedings are presumptively open to the public and may only be sealed by the court upon a written finding for good cause. For such determination, courts must balance the nature of the proceedings, the privacy of the person alleged to be incapacitated, the interests of the public, and the orderly and sound administration of justice.

Under this standard, the court found that Justin B. established good cause to seal the proceeding. The court explained that to fully and fairly adjudicate the allegations in the Article 81 petition, the parties had to

be able to participate without fear of adversely affecting Justin B.'s pending criminal proceedings. As the District Attorney admitted he planned to use the information from the Article 81 proceeding in the criminal matter, Justin B.'s liberty interests, including his Fifth Amendment right against criminal self-incrimination, were implicated. Therefore, the court determined that the presence of the public, including members of the District Attorney's office, would have a chilling effect on the proceeding.

The court also determined that Justin B. had medical privacy rights in the Article 81 proceeding. Although he had the right to waive such rights in the Article 81 proceeding, such waiver would not act as a waiver of his rights with respect to the public or other legal proceedings.

The court also rejected the District Attorney's argument that the proceeding should be public because a judicial determination of Justin B.'s incapacity in the Article 81 proceeding could be relevant in the pending criminal matter. The court ruled that, since the proceedings use different legal standards for incapacity, the Article 81 findings on that issue likely would not be useful or relevant to the criminal matter.

Appellate Division Reverses Order Permitting Involuntary Psychiatric Treatment of Graduate Student

In re Matter of Lucas QQ., 146 A.D.3d 92, 43 N.Y.S.3d 534 (3d Dep't 2016).

Respondent, a graduate student who had no prior history of psychiatric treatment, was involuntarily admitted to the Greater Binghamton Health Center, a psychiatric hospital operated by the Office of Mental Health. His treating physician diagnosed him with a schizophrenia spectrum disorder and prescribed a course of medications, which respondent refused to take. As a result, petitioner, the acting clinical director, commenced a proceeding pursuant to Mental Hygiene Law Article 33, seeking an order for involuntary treatment.

The Supreme Court, Broome County, held a hearing and granted the petition. The Supreme Court also issued a *sua sponte* order authorizing petitioner, and any facility to which respondent might be transferred, to administer an extensive list of medications and obtain respondent's past psychiatric and medical records as needed to facilitate his treatment. Respondent filed a notice of appeal shortly before he was discharged from the facility.

As a threshold question, the court reviewed whether the appeal had been rendered moot based on respondent's release from the facility. As the court explained, an exception to the mootness doctrine applies where the issue could readily recur, will typically evade review, is of public importance, and represents a substantial and novel issue yet to be decided by the court.

The court found that the exception to the mootness doctrine applied. The court determined that respondent adequately demonstrated that proceedings of this nature will readily recur because, as he pointed out in his brief, there were 322 applications for authorization to forcibly treat patients within the Third Department in 2014. The court also agreed that these proceedings typically evade review because the patients may be discharged before an appeal is perfected, thus terminating the order for involuntary treatment. The court also found that the proceeding is of a public importance because it implicates a patient's fundamental interest to reject antipsychotic medication.

The court also explained that although there is a well-established legal standard that governs the state's ability to forcibly administer medicine, there was a substantial and novel issue in this case with respect to how that legal standard applied to the formulation of a medication treatment plan.

The court found that a fundamental flaw with the lower court's order was that it was overbroad —it authorized use of 28 medications, even though only one was recommended and many of the medications were for symptoms or illness that respondent did not have. An additional flaw was that the lower court granted the petition without explanation other than "based on what [the treating physician] has testified to," and the treating physician's testimony did not explain the basis for the medications listed in his medication treatment plan.

Accordingly, the court held that petitioner did not meet its burden to show by clear and convincing evidence that the patient lacks "the capacity to make a reasoned decision with respect to proposed treatment," and "the proposed treatment is narrowly tailored to give substantive effect to the patient's liberty interest, taking into consideration all relevant circumstances, including the patient's best interests, the benefits to be gained from the treatment, the adverse side effects associated with the treatment and any less intrusive alternative treatments."

In addition, the court held it was error for the lower court to *sua sponte* authorize petitioner, and any facility to which respondent might be transferred, to obtain respondent's past psychiatric and medical records as needed to facilitate his treatment. The court determined that, under the Health Insurance Portability and Accountability Act, respondent was clearly entitled to advance notice of any request or directive to release his medical records.

Appellate Division Holds That Physician Adequately Pled Retaliatory Termination Whistleblower Claims Under Labor Law §§ 740 and 741

Ruiz v. Lenox Hill Hosp., 146 A.D.3d 605, 45 N.Y.S.3d 427 (1st Dep't 2017).

Plaintiff, Carlos E. Ruiz, a physician employed by Lenox Hill Hospi-

tal (the "Hospital"), filed this action against the Hospital and the Chair of the Hospital's Department of Cardiovascular and Thoracic Surgery. Plaintiff alleged that he was subject to retaliatory termination in violation of Labor Law §§ 740 and 741. Plaintiff also sought a declaratory judgment that he was entitled to the severance package set forth in his employment contract.

In support of his §§ 740 and 741 claims, Plaintiff alleged that the Chair began signing medical procedure reports for procedures which he had neither performed nor witnessed, and that contrary to accepted post-operative protocol, the Chair improperly reported to patients the results of valve implant procedures on which Plaintiff had been the lead physician. According to Plaintiff, after he reported this information to the Hospital's human resources department, he was terminated. Defendants moved to dismiss all claims pursuant to CPLR 3211.

The Appellate Division found that Plaintiff adequately pleaded a § 740 claim against the Hospital by alleging falsification of medical ecords, specificall , a physician's false claim to have performed a procedure. With regards to the sufficiency of Plai - tiff's § 741 claim, the court found that at the motion to dismiss phase, it was too early to decide whether the Chair's reports to a patient's family constituted improper care of the patient as required for a § 741 claim. The court noted that Plaintiff was not required at the pleading stage to identify the specific ule that was allegedly violated. The court also explained that under § 741, Plaintiff need only allege that he reasonably believed there was a violation of a law, rule, or regulation, not that there was an actual violation. The court explained, however, that the Supreme Court should have dismissed the §§ 740 and 741 against the Chair because he was not an "employer" as required to maintain a claim under those statutes.

Finally, the court held that the Plaintiff was not entitled to a severance payment under his employment contract or severance agreement unless he executed the general release provided in the severance agreement. In so holding, the court explained that the Supreme Court should not have dismissed the declaratory judgment claim, but instead, should have issued a declaratory judgment in favor of the Defendants.

Appellate Division Holds That Adverse Event Reports Sent by Physician to a Medical Device Company Is Not Protected By 21 U.S.C. § 360i(b) Unless It Reasonably Suggests the Device Caused Injury

Borgia v. Rothberg, 148 A.D.3d 1109, 50 N.Y.S.3d 452 (2d Dep't 2017).

This medical malpractice action arose from two cataract procedures performed by Defendant. Defendant moved for a protective order in response to Plaintiff's request to produce correspondence between Defendant and Alcon Research, Ltd. The correspondence related to Alcon lenses that Plaintiff used in two cataract procedures. Defendant asserted that the correspondence were voluntary adverse event reports by a physician ("User Reports"), and thus protected from disclosure by federal law. 21 U.S.C. § 360i(b) prohibits the civil disclosure of reports which a user device facility is required to make regarding "information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility, or… other significant adverse device experiences as determined by the Secretary by regulation to be necessary to be reported." The lower court held, after *in camera* inspection, that the Alcon documents were entitled to protection from disclosure pursuant to 21 U.S.C. § 360i(b). Plaintiff moved for leave to renew his opposition to Defendant's prior motion. The lower court denied Plaintiff's motion for leave to renew.

After the lower court granted the protective order motion, Defendant testified at his deposition that the firs lens implanted did not cause serious illness or injury to the Plaintiff and had no opinion with regard to the second lens. Based on Defendant's deposition testimony, the Appellate Division reversed, holding that since the Defendant's reports did not reasonably suggest that the implants caused or contributed to a serious illness or injury, the reports did not qualify as a protected User Report under paragraph (1) of 21 USC § 360i(b).

New York Surrogate's Court Holds That Constitution Mandates Appointment of Counsel for Respondent in SCPA Article 17-A Guardianship Proceeding

Matter of Zhou, 53 Misc.3d 1121, 42 N.Y.S.3d 530 (Sur. Ct., 2016).

Petitioner filed a petition see - ing appointment as guardian of Respondent pursuant to Article 17-A of the Surrogate's Court Procedure Act (SCPA), on the basis that Respondent was incapable of autonomous decision-making due to an intellectual disability.

Because such guardianship appointment would deprive Respondent of all legal authority and control over decisions regarding herself and her affairs, including medical decisions and placement in residential facilities, the court held that its assignment of counsel for Respondent pursuant to SCPA 407 was constitutionally mandated. SCPA 407 provides that upon a court's determination that representation by counsel is mandated by either the state or federal Constitution, the court may assign counsel for persons financially unable to obtain an attorney.

The court's analysis centered on the fact that the constitutional guarantee of due process requires notice, access, and a meaningful opportunity to be heard where the State acts to remove an adult's decision-making

power, depriving her of control over choices affecting her life, liberty and property. The court held that individuals living with disabilities are no less entitled to constitutional guarantees than non-disabled individuals, and that states have an affirmative obligation to fulfill the p omise of the Americans With Disabilities Act.

The court cited *Powell v. Alabama* to support its holding that the right to be heard would be of little avail without the right to counsel. The court also cited *Gideon v. Wainwright*, holding that the assistance of counsel is a fundamental right when one's liberty is threatened in criminal proceedings, and noting that *Gideon*'s due process mandate has been extended to civil proceedings when fundamental interests no less important than freedom from incarceration are at stake.

The court applied a three-factor test to determine the requirements of procedural due process when physical liberty is not at stake: (i) the private interest that will be affected; (ii) the risk of an erroneous deprivation of such interest through the procedures used; and (iii) the government's interests.

First, the court held that Respondent's fundamental liberty interests would be profoundly affected by the imposition of guardianship, as she would lose the freedoms to shape her own life as she thinks best, participate fully in society without the permission of her guardian, and make decisions that define the essence of an individual.

Second, the court held that in the absence of assigned counsel, the procedure used might lead to an erroneous determination regarding guardianship. Specificall , the court held that Article 17-A proceedings do not uniformly require the respondent's presence in court, require a hearing for all respondents, or provide adequate notice so as to ensure the respondent understands the nature, consequences and impact of the proceeding. Noting that 17-A guardianships are of unlimited duration and scope, with no provision for independent review or examination, the court held that an erroneous determination might have substantial and likely permanent consequences.

Third, the court held that the government's interest in avoiding the expense of appointed counsel and the costs of litigation is not controlling in determining whether due process requires a particular procedural safeguard. Specificall , the court held that the New York State Legislature has determined that the cost of assigned counsel under SCPA 407 should be paid by public funds when the assignment is constitutionally necessary, pursuant to article 18-B of the County Law.

In appointing Respondent's counsel, the court distinguished between the role of a guardian ad litem (GAL) and counsel, holding that while the GAL services in a limited capacity as neutral evaluator and consultant regarding the respondent's best interests, counsel is a vigorous advocate, safeguarding Respondent's rights, advising her, and explaining the consequences of guardianship.

Appellate Division Holds That a Certificate of Merit by a Physical Therapist Is Inadequate to Attest to the Standard of Care for Physicians And Surgeons

Calcagno v. Orthopedic Associates Of Dutchess County, 148 A.D.3d 1279, 48 N.Y.S.3d 832 (3d Dep't 2017).

In April 2013, Plaintiffs commenced a medical malpractice action alleging that Defendants were negligent in failing to address during surgery certain injuries to the injured Plaintiff's ankle. Defendants moved for dismissal based on Plaintiff's failure to file a certificate of merit. I response, Plaintiff filed a certificate o merit supported by an affidavit f om Plaintiff's physical therapist.

CPLR 3012-a requires that in medical malpractice actions, plaintiff's counsel submit a certificate of merit declaring that counsel has consulted with at least one licensed physician who (i) is knowledgeable regarding the relevant issues in the action; (ii) has reviewed the facts of the case; and (iii) has thus concluded that such a reasonable basis exists. The purpose of the certificate is to ensure that there is a reasonable basis for the commencement of an action.

The lower court granted Defendants' motion to dismiss the action, finding that Plainti f's certificate of merit was inadequate. The Appellate Division affirmed, holding that by definition, a physical therapist cannot diagnose and is incompetent to attest to the standard of care applicable to physicians and surgeons.

Legislative Update

By James Lytle

While health policy debate and drama have been focused on Washington, D.C. over the past several months, the New York State Legislature concluded its regular 2017 session in late June and will be sending a host of health-related bills to the Governor for his consideration over the weeks and months ahead. At the time of this writing in early July, the Governor had only acted on a relatively small number of bills. Nevertheless, it is worth reviewing a few of the health-related bills that have passed both houses, most of which might be expected to be enacted into law.[1]

In the spirit of David Letterman, here is an arbitrary top ten list of health-related legislation that might be of interest to the New York State health lawyer:

Medical malpractice statute of limitations, A. 8516 (Weinstein)/S.6800 (DeFrancisco): The bill would allow for medical malpractice actions premised on the negligent failure to diagnose a malignant tumor or cancer to be commenced within two-and-one-half years from when the plaintiff knew or reasonably should have known of the negligence, provided that the action is commenced no more than seven years after the negligence occurred. The bill, introduced during the closing days of the legislative session, was a somewhat scaled back version of so-called Lavern's Law, which (named for a New Yorker who died after a missed cancer diagnosis and was foreclosed by existing law from commencing a medical malpractice action) would have adopted a "discovery" standard across the board for all malpractice allegations.

Substitution and dispensation of interchangeable biological products, A.7509-A (Gottfried)/S.4788-A (Hannon): This bill, which was of interest to the Health Law Section and other components of the New York State Bar Association, would define "bi - logical product" and "interchangeable biological product" in the pharmacy provisions of the Education Law and would require the substitution of a less expensive biological product if it is interchangeable and has not otherwise been prohibited by the prescriber.

Expanded diagnoses for medical marijuana, A.7006 (Gottfreid)/S. 5629 (Savino): The bill would add post-traumatic stress disorder (PTSD) to the conditions that might warrant a prescription for medical marijuana. Although the statutory diagnoses could be expanded by the Commissioner, the Legislature statutorily seeks to include PTSD among the covered conditions for a program that has not generated as many prescriptions as might have been anticipated.

***Sepsis awareness, A. 6053-A (Nolan)/S. 4971-A (Marcellino)*:** The bill would require the Commissioner of Education, in consultation with the Commissioner of Health and sepsis awareness organizations to establish a sepsis awareness, prevention and education program. The initiative was prompted by the tragic death of healthy 12-year-old boy after he injured himself in gym class.

Insurance coverage of tomosynthesis, A. 5677 (Seawright)/S.4190 Griffo): The bill would clarify that the existing requirement on health insurers to cover mammography screening would be extended to include tomosynthesis, which provides three-dimensional imaging to detect potential breast cancer. The Department of Financial Services has already required insurers to cover tomosynthesis, at least under certain circumstances, under a 2017 directive clarifying the existing mammography mandate.

Clotting factor and Medicaid managed care, A. 7581 (Gottfried)/S. 5774 (Hannon): The bill had been intended to prevent "carving in" blood clotting factor and related services, on which persons with hemophilia and other bleeding disorders rely, into Medicaid managed care. Coverage of clotting factor has been provided on a fee-for-service basis for the approximately 200 Medicaid beneficiaries who equire the product since the inclusion of pharmacy benefits into Medicaid managed ca e, but the State's Medicaid program planned to incorporate the benefi into Medicaid managed care on July 1. The Governor vetoed the bill a few days before the carve-in was scheduled to occur, citing the State's commitment to care coordination for all.

Certificates of Public Advantage, A.7748 (Gottfried)/S. 5342 (Hannon): The bill would extend the authority of the Commissioner of Health to issue Certificates of Authority to facilitate collaboration among health care facilities, under state supervision, without incurring antitrust liability. The existing authority to issue COPAs expired on December 31, 2016; under the bill, the authority will be extended another four years, until December 31, 2020.

Certificate of need for assisted living programs, A. 7727-A (Lupardo)/S. 5840 (Hannon): The bill would replace a competitive solicitation process for assisted living programs with a new certificate of nee program, which would award beds based on demonstrated community

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need. The bill would also authorize the Director of the Division of the Budget to impose a moratorium on the approval of new beds if their approval would result in a net increase in Medicaid expenditures.

Telehealth expansions of originating sites, A. 4703 (Jenne)/S. 3293 (Hannon) and A. 1464-B (Jenne)/S. 4285-A (Serino): These bills both expand the "originating sites" from which patients may receive telehealth services. The first woul include public, private and charter elementary and secondary schools, school-age child care centers and day care centers as originating sites. The second would include licensed adult care facilities licensed under Article VII, Title II of the Social Services Law.

Excluding Nurse-Family Partnership from regulation as a home care agency, A. 8388 (Gottfried)/S. 6656 (Hannon): The bill would clarify that the Nurse-Family Partnership (NFP) program—an evidence-based nurse home visiting program for at-risk first-time mothers that is under wa at several sites across the State—would not be required to satisfy the requirements applicable to home care agencies. The bill was introduced in response to Department of Health directives that sought to require the issuance of medical orders for these services.

Endnote

1. In the interests of full disclosure, my firm was engaged in either supporting or opposing several of the bills on this list. The descriptions of the legislation contained in this column are intended to be objective discussions of the bills and are not intended to reflect the views of our firm or our clients

In the New York State Agencies

By Francis J. Serbaroli

Direct Clinical Services—Supervised Individual Residential Alternatives (IRAs), Community Residences (CRs) and Day Habilitation

Notice of Adoption. The Department of Health amended section 86-10.5 of Title 10 NYCRR to exclude direct clinical services from the reimbursement for Supervised IRAs, CRs and Day Habilitation. Filing date: February 22, 2017. Effective date: March 15, 2017. *See* N.Y. Register March 15, 2017.

Medical Use of Marihuana—Physician Assistants

Notice of Adoption. The Department of Health amended sections 94.2(e)(6) and 1004.1(a)(2) of Title 10 NYCRR to authorize physician assistants to register with DOH in order to issue certifications to patients with qualifying conditions. Filing date: February 22, 2017. Effective date: March 15, 2017. *See* N.Y. Register March 15, 2017.

Repeal 14 N.Y.C.R.R. Part 823 (Outpatient Chemical Dependency Services for Youth Programs and Services)

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 823 of Title 14 NCYRR to repeal obsolete rules. Filing date: March 6, 2017. Effective date: March 22, 2017. *See* N.Y. Register March 22, 2017.

Repeal Parts 321 and 1055; Add New Part 813 Regarding Financial Capital Improvements

Notice of Revised Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Parts 321 and 1055 and adding Part 813 to Title 14 NYCRR to repeal DSAS/DAAA regulations and consolidate provisions into new Part 813. *See* N.Y. Register March 22, 2017.

Medical Use of Marihuana—Chronic Pain

Notice of Adoption. The Department of Health amended sections 1004.1 and 1004.2 of Title 10 NCYRR to add any severe debilitating or life-threatening condition causing chronic pain. Filing date: March 7, 2017. Effective date: March 22, 2017. *See* N.Y. Register March 22, 2017.

Hearing Procedures Update

Notice of Adoption. The Office for People with Developmental Disabilities amended section 602.5 of Title 14 NYCRR to correct a grammatical error. Filing date: March 21, 2017. Effective date: April 6, 2017. *See* N.Y. Register April 4, 2017.

Expansion of Minor Consent for HIV Treatment Access and Prevention

Notice of Adoption. The Department of Health amended sections 23.1 and 23.2 of Title 10 NYCRR to allow qualified clinicians to p ovide antiretrovirals for treatment and prophylaxis. Filing date: March 28, 2017. Effective date: April 12, 2017. *See* N.Y. Register April 12, 2017.

Valuation of Individual and Group Accident and Health Insurance Reserves

Notice of Proposed Rulemaking. The Department of Financial Services proposed a consensus rulemaking amending Part 94 (Regulation 56) of Title 11 NYCRR to adopt the 2013 Individual Disability Income Valuation Table. *See* N.Y. Register April 26, 2017.

Financial Risk Transfer Agreements Between Insurers and Accountable Care Organizations

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending section 101.3 (Regulation 164) of Title 11 NYCRR to permit insurers to enter into fina - cial risk transfer agreements with Accountable Care Organizations. *See* N.Y. Register May 3, 2017.

Residential Health Care Facility Quality Pool

Notice of Emergency Rulemaking. The Department of Health added section 86-2.42 of Title 10 NYCRR to reward New York State facilities with the highest quality outcomes as determined by a methodology developed by regulation. Filing date: April 18, 2017. Effective date: April 18, 2017. *See* N.Y. Register May 3, 2017.

Repeal Parts 321 and 1055; Add New Part 813 Regarding Financing Capital Improvements

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Parts 321 and 1055 and added Part 813 to Title 14 NYCRR to repeal DSAS/DAAA regulations and consolidate provisions into new Part

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 Edward J. Ohanian, respectively of counsel and associate of Greenberg Traurig's Health and FDA Business Group, in compiling this summary is gratefully acknowledged.

813. Filing date: May 1, 2017. Effective date: May 17, 2017. *See* N.Y. Register May 17, 2017.

HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information

Notice of Adoption. The Department of Health amended Part 63 of Title 10 NYCRR to simplify HIV testing consent and improve linkage to care. Filing date: April 26, 2017. Effective date: May 17, 2017. *See* N.Y. Register May 17, 2017.

Federal Conditions of Participation

Notice of Adoption. The Department of Health amended Part 405 of Title 10 NYCRR to reflect amen - ments consistent with updated Federal Conditions of Participation. Filing date: April 27, 2017. Effective date: May 17, 2017. *See* N.Y. Register May 17, 2017.

Lead Testing in School Drinking Water

Notice of Proposed Rulemaking. The Department of Health proposed adding Subpart 67-4 to Title 10 NYCRR to require lead testing and remediation of potable drinking water in schools. *See* N.Y. Register May 17, 2017.

Charges for Professional Health Services

Notice of Revised Rulemaking. The Department of Financial Services proposed amending Part 68 of Title 11 NYCRR to limit reimbursement of no-fault health care services provided outside New York State to highest fees in fee schedule for services in NYS. *See* N.Y. Register May 24, 2017.

Physician and Pharmacies; Prescribing, Administering and Dispensing for the Treatment of Narcotic Addiction

Notice of Emergency/Proposed Rulemaking. The Department of Health proposed amending section 80.84 of Title 10 NYCRR to allow any authorized practitioner to prescribe, administer and dispense buprenorphine for the treatment of narcotic addiction. *See* N.Y. Register May 24, 2017.

Updating Certificate of Need Thresholds

Notice of Proposed Rulemaking. The Department of Health amending section 710.1 of Title 10 NYCRR to update Certificate of Need eview thresholds. *See* N.Y. Register May 31, 2017.

General Service Standards for Chemical Dependence Outpatient (CD-OP) and Opioid Treatment Programs (OTP)

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 822 of title 14 NYCRR to conform HIV and Hepatitis testing in accordance with the Public Health Law and clarify the services a peer may provide. *See* N.Y. Register June 14, 2017.

Residential Services

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 820 of Title 14 NYCRR to conform HIV and Hepatitis testing requirements in residential settings with Public Health Law. *See* N.Y. Register June 14, 2017.

Ancillary Services and Therapies

Notice of Withdrawal. The Office of Alcoholism and Substance Abuse Services withdrew proposed rule making, I.D. No. ASA-52-16-00012-P, from consideration. The notice of proposed rule making was published in the State Register on December 28, 2016. *See* N.Y. Register June 21, 2017.

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

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 361 of Title 11 NYCRR to allow for the implementation of a market stabilization pool for the small group health insurance market. Filing date: June 2, 2017. Effective date: June 2, 2017. *See* N.Y. Register June 21, 2017.

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

Notice of Emergency/Proposed Rulemaking. The Department of Financial Services amended of Part 52 (Regulation 62) of Title 11 NYCRR to ensure coverage for essential health benefits in all individual, small group, and student accident and health policies. Filing date: June 5, 2017. Effective date: June 5, 2017. *See* N.Y. Register June 21, 2017.

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 sections 52.1(p), 52.2(y) and 52.16(o) to Title 11 NYCRR to ensure that medically necessary abortion coverage is maintained for all insureds. Filing date: June 5, 2017. Effective date: August 4, 2017. See N.Y. Register June 21, 2017.

Lead Testing in School Drinking Water

Notice of Emergency Rulemaking. The Department of Health added Subpart 67-4 to Title 10 NYCRR to require lead testing and remediation of potable drinking water in schools. Filing date: June 1, 2017. Effective date: June 1, 2017. *See* N.Y. Register June 21, 2017.

Hospital Indigent Care Pool Payment Methodology

Notice of Emergency/Proposed Rulemaking. The Department of Health amended section 86.1-47 of Title 10 NYCRR to extend the methodology for indigent care pool payments to general hospitals for another 3 year period—1/1/16 – 12/31/18. Filing date: June 6, 2017. Effective date: June 6, 2017. *See* N.Y. Register June 21, 2017.

Communication Between Clinical Laboratory Physicians and Patients

Notice of Proposed Rulemaking. The Department of Health proposed amending section 34-2.11 of Title 10 NYCRR to allow lab physicians to discuss the meaning and interpretation of test results with patients under certain circumstances. *See* N.Y. Register June 21, 2017.

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 sections 52.17(a)(36), (37) and 52.18(a)(11), (12) to Title 11 NYCRR to allow coverage for the dispensing of contraceptives and codify additional guidelines. Filing date: June 5, 2017. Effective date: August 4, 2017. *See* N.Y. Register June 28, 2017.

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health Medicaid Decisions[1]

Compiled by Margaret Surowka Rossi

Persistent Car Service Corp. (DOH Administrative Hearing decision not dated, record closed February 10, 2017, Dawn MacKillop-Soller, ALJ). The ALJ rejected a transportation provider's defense of inadequate documentation due to loss in Hurricane Irene under the circumstances presented and other defenses, finding instea that the OMIG was entitled to recover $575,325.00 despite the undisputed fact that "medically necessary services" were provided. The OMIG audited a sample of 150 claims for transportation services for the period January 1, 2008 through December 31, 2010, and disallowed payment for 133 of those claims based upon missing information or no documentation. In response to the Draft Audit Report, the provider objected to the 76% error rate and to the statistical sampling employed by OMIG. The provider also claimed that its records were "damaged, destroyed and/or rendered unreadable as the result of a flood on or about August 28, 2011 [Hurricane Irene]" resulting in "a total loss of documentation." In response to the Draft Audit Report, the provider produced dispatch rosters to show that the 133 Medicaid transportation trips did occur. The OMIG rejected the defenses and issued its Final Audit Report with extrapolated damages in the amount of $575,325.00. The ALJ first exa - ined the documentation destruction defense and found it unpersuasive. The ALJ noted that The Medicaid Update provides that records proven "damaged by fi e, flood, or othe disaster" will be determined to meet the record-keeping requirements for Medicaid purposes" after the provider properly reports the "loss of their records to the Department." Here, the provider never reported any alleged loss. Second, the ALJ found that even if a report had been made, it would not excuse the failure to produce documentation in this case since the entrance conference and audit took place in June 2011, prior to the flood itself The provider rendered the "unforeseen incident explanation" moot at the hearing when the owner testified that he had submitted all clai documentation "prior to the flood. The provider then argued that it was somehow "understandable" that it had incomplete documentation because it never received proper training from Medical Answering Services, LLC ("MAS") on the proper Medicaid program documentation requirements. The ALJ found such an excuse "unavailing" as the requirements are in the Provider Manual for Transportation and published on the eMedNY website. Finally, the ALJ rejected the provider's attempt to dispute the sampling and extrapolation. No expert was presented to refute the certifications of statisticia Karl W. Heiner and OMIG Deputy Inspector General Kevin Ryan confirming the validity of the statistica sampling methodology. As such, the ALJ upheld the OMIG's determination to recover overpayments in the amount of $575,325.00.

Springville Pharmacy Infusion (DOH administrative hearing decision not dated, record closed December 12, 2016, Dawn MacKillop-Soller, Administrative Law Judge). The ALJ rejected post-response documentation from a pharmacy to substantiate authorization of refills that we e not documented on the original oral prescription form and upheld the OMIG's determination to recover overpayments. This was an audit of Appellant's home infusion pharmacy claims for the period April 13, 2013 through September 30, 2013. At issue was OMIG's disallowance of two refills totaling $113,268.40. The pharmacy disputed the disallowance. In response to the Draft Audit Report, the pharmacy submitted a printout from its computer records confirming the refill under the p escriptions in question. The orders for each prescription had been made by telephone order. Following the submission of its re-

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The Editor would like to thank Barclay Damon's Law Clerk **Dena DeFazio** for her assistance with this edition.

sponse to the Draft Audit Report, the pharmacy submitted a telephone prescription order that appeared to authorize the refills at issue. The ALJ set forth the pharmacy's recordkeeping obligations to prepare and maintain contemporaneous records demonstrating its right to receive payment under the Medicaid Program. In addition, the ALJ summarized the requirements of an oral order, explaining that refills may be authorized in an oral order but must be properly documented by the pharmacist. That is, in accordance with Education Law 6810(4): "the pharmacist shall write on the reverse side of the original prescription the date, time and name of the practitioner authorizing the refill of the prescription." The ALJ cited the regulations allowing a provider to provide additional information but stated that a provider may not raise in a hearing any new matter not submitted in response to the Draft Audit Report. The issue was limited to whether the refill p escription is supported by a contemporaneous written order authorized by the practitioner. Leaving aside the timing of the additional documentation, the ALJ found that the additional documentation was not on the original prescription. The pharmacy argued that at the time of the original telephone order, the pharmacist forgot to note the refill, but prior to dispensing the product "corrected the missing refill information" on a copy of the original prescription. The ALJ ruled that even if the additional post-audit documentation was to be accepted, it would still fail because the refill authorization was not noted on the original telephone order. The computer printout likewise was rejected as it "fail[ed] to contain complete and accurate information recorded at the time of the medical services to show the refill was o dered." As to the documents submitted after the response to the Draft Audit Report, the ALJ stated that the timing "raised questions of its authenticity" and otherwise was prohibited as it was "new material" under 18 NYCRR 519.18(a). As such, the refills we e disallowed and OMIG's determination to recover $113,268.40 was upheld.

New York State Attorney General and New York State Comptroller's Press Releases

Compiled by Joseph Murphy, Caitlin Monjeau, Bridget Steele, Eric Dyer, and Dena DeFazio

Unlicensed Dentist and Nurse Separately Convicted for Providing Patient Care as Unlicensed Medical Professionals—June 9, 2017—A former dentist was convicted by a Kings County Supreme Court jury of Unauthorized Practice of a Profession (Dentistry), a class E felony. The former dentist lost the authority to practice dentistry in June of 2000, following multiple felony convictions for Medicaid fraud. The dentist is scheduled to be sentenced on August 15, 2017 and faces a maximum of four years in state prison on each count. A former nursing home employee was convicted by a Queens County jury of Unauthorized Practice of a Profession (Nursing), a felony, and Unauthorized Use of a Professional Title, a misdemeanor. The employee provided medical care to patients at a nursing home without a license for 18 months. The nursing home employee is scheduled to be sentenced on August 4, 2017. The two cases are unrelated. https://ag.ny.gov/press-release/operation-toothache-ag-scnheiderman-announces-separate-convictions-unlicensed-dentist.

Brooklyn Medical Supply Company Owner Indicted and Arraigned for Alleged Medicaid Fraud—June 7, 2017—The owner of a medical supply company was indicted and arraigned for allegedly billing Medicaid and Healthfirst, a Medicaid managed care organization, for a higher-priced nutritional formula used via a feeding tube, while allegedly supplying consumers with an inexpensive substitute or no substitute at all. The alleged fraud totals over $1 million. The owner was also indicted and arraigned for an alleged history of identity and welfare fraud, including alleged use of two different dates of birth, countries of origin, and social security numbers to obtain welfare benefits and en oll the medical supply company in the Medicaid program. The owner was charged with Health Care Fraud in the First Degree, three counts of Grand Larceny in the Second Degree, Welfare Fraud in the Third Degree, and two counts of Offering a False Instrument for Filing in the First Degree, all felonies. The owner faces between 4 to 25 years in prison, if convicted. https://ag.ny.gov/press-release/ag-schneiderman-announces-indictment-brooklyn-medical-supply-company-owner-stealing.

Senior Living Facilities Settle $328,000 in Wage Theft Allegations—June 1, 2017—A company that owns seven senior living facilities in the greater Rochester area settled allegations of wage theft for failing to pay employees the minimum wage. Fifteen live-in safety coordinators, who were responsible for answering overnight emergency calls and performing housekeeping and light maintenance work, were given housing and utilities at a free or reduced rate, but were not paid wages for their work. The $328,000 settlement includes $238,000 in back pay to the 15 current and former employees; $89,000 in damages, interest, and penalties to New York State; and other requirements including improving recordkeeping practices, clearly informing workers of their rights, and submitting to compliance monitoring for a two-year period. https://ag.ny.gov/press-release/ag-schneirderman-announces-328k-wage-theft-settlement-rochester-senior-living.

Substance Use Treatment Provider Pleads Guilty to Medicaid Fraud and Reaches Multi-Million Dollar Civil Settlement—May 31, 2017—A Bronx-based not-for-profit p ovider of substance abuse treatment pled guilty to one count of Enterprise Corruption, three counts of Grand Larceny in the First Degree, and two counts of Offering a False Instrument for Filing in the First Degree, in connection with claims that the agency violated patients' rights, submitted

claims for excess services, and operated an unregulated residential treatment program. The agency filed for bankruptcy in January of 2016, and a $118 million settlement for outstanding government claims was approved by the bankruptcy court. https://ag.ny.gov/press-release/ag-schneiderman-announces-criminal-guilty-plea-and-multi-million-dollar-civil.

Long Island Resident Sentenced for Stealing Medicaid Funds—May 26, 2017—A Long Island resident was sentenced for stealing approximately $75,000 in Medicaid funds from the Consumer Directed Personal Assistance Program, funded by Medicaid. The woman pled guilty in March 2017 to Forgery in the Third Degree and Petit Larceny, both class A misdemeanors, for filing false claims for two relatives, including submitting false timesheets and forging signatures. The defendant was sentenced to one week in jail, three years' probation, 150 hours of community service and a $1,000 fine. https://ag.n .gov/press-release/ag-schneiderman-announces-sentencing-long-island-resident-who-stole-75k-medicaid.

Former Nursing Home Counselor Convicted of Sexual Abuse—May 23, 2017—A former employee of a residential facility was convicted by an Ulster County Court jury for sexual abuse-related charges. The former employee forcibly performed sex acts with six residents of the facility, all of whom were rehabilitating following traumatic brain injuries. His employment was terminated based on the sexual abuse allegations and he was subsequently arrested in July 2016. The defendant was convicted of one count of Criminal Sexual Act in the First Degree, seven counts of Sexual Abuse in the First Degree, and 16 counts of lesser charges. Sentencing will occur on July 28 and the former counselor faces up to 25 years in prison. https://ag.ny.gov/press-release/ag-schneiderman-announces-trial-conviction-former-nursing-home-counselor-sexual-abuse.

Pharmaceutical Company Reaches $33 Million Multi-State Settlement Resolving Deceptive Marketing Claims—May 24, 2017—41 states and the District of Columbia reached a $33 million settlement with Johnson & Johnson. The settlement resolved allegations that a subsidiary company, McNeil-PPC, Inc., used deceptive practices in marketing and promoting popular over-the-counter drugs. A number of drugs and manufacturing facilities owned by McNeil-PPC, Inc. failed to comply with current Good Manufacturing Practices, mandated by federal law, resulting in the recall of ten over-the-counter medications. In addition to the monetary settlement, the company has agreed to reform its marketing and promotional practices. New York State will receive $1.3 million of the settlement. https://ag.ny.gov/press-release/ag-schneiderman-announces-33-mil lion-multi-state-settlement-johnson-johnson-end.

Two Individuals Plead Guilty to Stealing Medicaid Dollars Related to Home Health Services—May 19, 2017—In unrelated investigations, two individuals pled guilty to Grand Larceny for stealing from a Medicaid funded program, known as the Consumer Directed Personal Assistance Program (CDPAP). CDPAP allows certain service recipients or their designated representatives to select and manage their personal assistant home care workers. Both individuals knowingly submitted false timesheets to fiscal intermediaries of CD AP for home care services that were never delivered to their relatives, the service recipients. The investigations revealed that neither service recipient was present in the county when the services were purportedly delivered; in fact, in one of these cases, the service recipient was out of the country entirely. Accordingly, the individual in that case pled guilty to Grand Larceny in the Fourth Degree, a class E felony and was sentenced to five years' p obation, 300 hours of community service, and required to pay $75,812 in restitution, while the individual in the other case pled guilty to Grand Larceny in the Third Degree, a class D felony, and was sentenced to five years' p obation and required to pay $113,584 in restitution. https://ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-and-sentencing-two-individuals-stealing-medicaid.

New York Moves to Intervene in ACA Case That Could Block Subsidies—May 18, 2017—New York, along with 14 other states and the District of Columbia, filed a motion to intervene in the *House of Representatives v. Price* case, which is currently on appeal. The case challenges the subsidies that provide for cost-sharing reductions required under the Affordable Care Act (ACA). The New York Department of Health and Department of Financial Services supported the motion with affidavits asserting that failure to continue the cost-sharing reductions will harm insurance coverage and the insurance markets in New York. https://ag.ny.gov/press-release/attorneys-general-schneiderman-and-becerra-governor-cuomo-announce-motion-intervene.

Former Home Health Worker Indicted for Endangering the Welfare of Two Developmentally Disabled Residents—May 15, 2017—A former Direct Support Assistant at a state-run group home was indicted on two charges of Endangering the Welfare of an Incompetent or Physically Disabled Person in the First Degree, a class E Felony. The former home health worker allegedly failed to perform required bed checks every 15 minutes to ensure two physically impaired and intellectually disabled residents were safe. According to the allegations, the former worker tied up one of the residents in bed; the resident was found the following morning soaked in urine and suffering from skin injuries. If convicted, the former worker faces up to one and one-third to four years in prison. https://ag.ny.gov/press-release/ag-

schneiderman-announces-indictment-former-group-home-health-care-worker-charged.

A Joint State-Federal Settlement with CareCore Results in $7.6 Million in Restitution to the New York Medicaid Program—May 11, 2017—The federal government agreed to a settlement with CareCore National LLC, formerly a utilization management services company, for $54 million as a result of false claims submitted to government health care programs. Numerous states, including New York, have agreed to join the federal government's settlement, and New York will receive $7.6 million out of the $54 million. In the settlement agreement, CareCore accepted responsibility for submitting false and fraudulent claims to New York's Medicaid program and through Managed Care Organizations by using its auto-approved program known as "Process As Directed" (PAD). PAD improperly approved prior authorizations by failing to have a Medical Director review the requests for radiology services to ensure they were reasonable and medically necessary. The purpose of PAD was to handle the hundreds of daily requests for preauthorization and to avoid contractual monetary penalties for untimely reviews. https://ag.ny.gov/press-release/ag-schneiderman-announces-joint-54-million-settlement-carecore-resolving-allegations.

Audit Questions Payments Made to Supportive Housing Provider—May 7, 2017—The New York State Comptroller audited a supportive housing provider, and identified $32,271 in unallowable expenses and $489,616 in questionable costs paid by the New York State Office of Mental Health (OMH). Unallowable expenses included nearly $17,000 for a company board retreat and $14,000 on a holiday party. Questionable expenses included contracts not competitively bid, food for clients and staff, unnecessary storage units, and gift cards. The State Comptroller made several recommendations to OMH, including suggesting OMH recover the unallowable expenses, review the questionable expenses, evaluate the performance of program service providers, require service providers to rebid competitively bid contracts periodically or demonstrate that the contracts remain competitively priced, and ensure service providers obtain pre-approvals for clients to pay more than fair market value for rent. https://www.osc.state.ny.us/press/releases/may17/050417.htm.

Attorney General Issues a Statement in Support of the Court's Decision to Deny the Appeal for a Major Insurance Company Merger—April 28, 2017—The Attorney General issued a statement in support of the D.C. Circuit decision denying Anthem's continued attempt to acquire Cigna. According to the statement, the merger would have violated antitrust law, and the court's decision was a win for consumers in New York. The Department of Justice, along with New York, ten other states, and the District of Columbia filed a join lawsuit in July 2016 to block the attempted merger. https://ag.ny.gov/press-release/statement-ag-schneiderman-decision-regarding-merger-between-health-insurers-anthem-and.

Dentist Indicted for Alleged Medicaid Fraud Scheme Involving Unlicensed Individuals—April 21, 2017—A Brooklyn dentist was indicted for allegedly hiring individuals with no dental licenses and billing Medicaid for their services. Based on the allegations, 110 Medicaid recipients received services from individuals that did not have a dentistry license, which resulted in Medicaid paying the dentist over $48,000 directly or through managed care providers. In addition to the dentist's indictment, the corporation and four unlicensed individuals were indicted. Three of the unlicensed individuals were arrested in 2014 for allegedly performing unlicensed dental procedures. The dentist, along with the other defendants, was charged with Healthcare Fraud in the Third Degree, a class D felony. Charges of Unauthorized Practice of a Profession (Dentistry), Offering a False Instrument for Filing in the First Degree, and Falsifying Business Records in the First Degree—all class E felonies—were also included against the dentist, the corporation and one of the unlicensed individuals. These charges carry up to seven years' incarceration for each defendant. https://ag.ny.gov/press-release/ag-announces-indictment-brooklyn-dentist-allegedly-billing-medicaid-dental-work.

Nurse Arrested for Allegedly Pushing and Injuring a Nursing Home Resident—April 13, 2017 —An 89-year old nursing home resident was allegedly pushed down a hallway by a Licensed Practical Nurse (LPN). The push led the resident to fall and fracture a rib. The LPN was charged with Endangering the Welfare of a Vulnerable Elderly Person or an Incompetent or Physically Disabled Person in the Second Degree. If convicted, the LPN faces up to seven years in prison. https://ag.ny.gov/press-release/ag-schneiderman-announces-arrest-oswego-nurse-allegedly-causing-nursing-home-residents.

A.G. Schneiderman Announces Settlements With Three Mobile Health Application Developers for Misleading Marketing and Privacy Practices—March 23, 2017—The Attorney General announced settlements with three mobile health application developers. These companies allegedly made deceptive statements about their mobile health apps and marketed them without possessing sufficient information to back u their marketing claims. Two of these developers claimed that their apps accurately measured heart rate after vigorous exercise, despite failing to properly test accuracy with users after vigorous exercise. The third developer claimed its app functioned as a fetal heart monitor, even though it had never received approval from the U.S. Food & Drug Administration (FDA). The app developers have agreed to provide additional information about testing of the apps, revise their ads

to make them non-misleading, pay $30,000 in combined penalties to the Attorney General, and require affirmative consents to their privac policies for use of the app as a result of the settlements. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlements-three-mobile-health-application-developers.

A.G. Schneiderman Announces Indictment of Queens Woman Charged With Stealing the Identities of Three Nursing Home Residents—March 7, 2017—A woman from Queens was indicted for three counts of Identity Theft in the First Degree and two counts of Scheme to Defraud in the First Degree for allegedly stealing the identities of three nursing home residents. Prosecutors allege that in the fall of 2013, the defendant stole the identity of three elderly nursing home residents and made unauthorized purchases on their credit cards. The woman was recorded by video surveillance using credit cards in several stores at times the credit cards showed victims' use of such credit cards. The defendant pled not guilty to the charges; if convicted, she faces up to twenty-one years in state prison. https://ag.ny.gov/press-release/ag-schneiderman-announces-indictment-queens-woman-charged-stealing-identities-three.

Audit Faults Justice Center Records, Raises Questions on Accountability—March 7, 2017—The New York State Comptroller audited the Justice Center for the Protection of People with Special Needs to determine whether the Justice Center—which began operations in June 2013—met its responsibility to operate a hotline, establish a database of reported allegations and state exclusion list, and ensure that allegations of abuse and neglect were investigated in a complete and timely manner from July 2013 to May 2016. Auditors found a number of inaccuracies in the database, including different identifiers assigned to suspected o - fenders. Additionally, auditors raised concerns regarding accountability due to the Justice Center's failure to grant auditors appropriate access to relevant information necessary to achieve audit objectives. The Justice Center has also refused to grant complete record access to its designated monitoring agency, Disability Rights New York (DRNY); DRNY has filed a lawsuit to force the Justice Center to give full access to records. https://www.osc.state.ny.us/press/releases/mar17/030717.htm.

State Missing Out on Millions in Medicare Payments for Kidney Patients—March 1, 2017—A New York State Comptroller audit determined that the New York State Department of Health (DOH) could have saved the Medicaid program as much as $146 million over the six year audit period if it had helped Medicaid patients with end-stage renal disease (ESRD) who qualified for Medica e apply for and enroll in Medicare. Auditors determined that from January 1, 2010 through December 31, 2015, there were 3,015 Medicaid recipients with ESRD who were eligible for but not enrolled in Medicare. The New York State Comptroller recommended DOH identify and notify Medicaid recipients with an ESRD diagnosis to apply for Medicare, develop an outreach program, follow up with recipients who do not apply for Medicare, and recover Medicaid claims for any retroactive Medicare enrollments of ESRD patients. DOH indicated that it has taken actions to address these recommendations. https://www.osc.state.ny.us/press/releases/mar17/030117.htm.

New York State Office of the Medicaid Inspector General Update

Compiled by Eric Dyer

OMIG Seeking Deputy Medicaid Inspector General for Investigations—May 26, 2017—https://www.omig.ny.gov/latest-news/1051-omig-seeking-division-of-medicaid-investigations-deputy-medicaid-inspector-general.

UPDATE: Ringleader of Massive Brooklyn-based Fraud Scheme Sentenced in Federal Court—May 12, 2017—https://www.omig.ny.gov/latest-news/1049-update-ringleader-of-massive-brooklyn-based-fraud-scheme-sentenced-in-federal-court.

OMIG Issues 2017-2018 Work Plan—April 13, 2017—https://www.omig.ny.gov/latest-news/1041-omig-issues-2017-2018-work-plan.

Endnote

1. The decisions are summarized after they are posted on the Department of Health's website, which is often many months after the date of the decision.

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By Mishka Woodley

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For Your Information

By Claudia O. Torrey

As I sit down to pen a few words for this column—I have a parent in the hospital trying, with God's help, to recover from a second case of aspiration pneumonia; there seems to be improvement, but it is a delicate balance of medications and other pulmonary techniques! I had not planned to extend my commentary that was in the Spring 2017 issue of our *Health Law Journal*,[1] but my personal current situation and the current debacle over health care in our country begs the question—Why is it that only one relatively wealthy, industrialized country in the world **does not** have a health care system that ensures health care access to all of its citizens? Of course, the country spoken of is the United States.

I suspect we would all agree to the basic premise that health care and health coverage **are not** one and the same. Some of the coverage terms utilized are: universal health care coverage, single payer, and socialized medicine. Universal coverage **does not** mean that the government necessarily pays for the care; there can be a combination of private and public coverage. Germany is an example of multi-payers and universal coverage, as well as the Netherlands and Singapore. Some scholars suggest that Singapore is a wonderful example of a very successful health care system that boasts low infant mortality rates and long life expectancies; simply put, universal coverage is coverage for everyone.

A single payer system provides coverage wherein the government typically pays for access to the care; the facilities and providers may not be "owned" by the government, but the government pays for coverage. Of course, some single payer healthcare services are government administered (example—the Veterans' Administration). Socialized medicine usually has government providing the health care: services, providers, and payments.

This author contends that health care in the United States should have a more patient-centered focus by providers (physicians, specialists, etc.), especially when that patient is in the hospital. A patient's primary physician and family should be "at the table," as well as all appropriate specialists, so that decisions are made with communication as a minimal problem (many hospitals use hospitalists, but in my opinion such usage tends to create "communication" issues because of no patient relationship), thus leading to less fragmented care and lower costs. Instead of optimizing a health care system around profits and evenue, this author is certain there are enough bright people in America who can collectively come together to create a health care system that will provide universal coverage, optimizing health care quality and patient safety! Quoting words attributed to Abraham Lincoln, our Sixteenth President, "[n] early all men can stand adversity—but if you want to test a man's character, give him power."

Claudia O. Torrey, Esq. is a charter member of the Health Law Section.

Endnote

1. *NY Health Law Journal*, Vol. 22, No. 1, p.13 (Spring 2017).

The Painful Reality of Caution in the Context of Managing Pain During Pregnancy

By Cassandra Rivais

We all have heard the pharmaceutical commercials say "if you are pregnant or planning to become pregnant, do not take this medication" or "talk to your doctor." This warning should cause society to think more deeply about medication use during pregnancy. Currently, a lack of U.S. Food and Drug Administration (FDA) approved pain management options[1] for pregnant women[2] during the nine months of pregnancy leaves women without acceptable prescription and over-the-counter medications. This exists because of our legal regulations of clinical trials used for the approval of medications during pregnancy. As a result, we have created an unreasonable standard of care for physicians.

A. Medications Taken During Pregnancy and the Information Gap

Over the past several decades, the number of medications consumed by pregnant women has increased for several reasons.[3] Women have had the opportunity to delay childbirth until later in life, which may result in more complications and a greater need for medicated treatment.[4] Women with poor overall health can now get pregnant due to improvements in management options and survive. As Francoise Baylis phrased it, "'pregnant women get sick, and sick women get pregnant.'"[5] Currently, more than 90% of pregnant women in the United States take one or more medication[6] and almost half use four or more drugs.[7] Women are taking medications for pregnancy-related conditions such as gestational diabetes but also for conditions unrelated to pregnancy such as depression and pain. A major reason women take pain medications during pregnancy is for back pain. As 2013 statistics from the Centers for Disease Control and Prevention (CDC) reported, "65% of pregnant women take acetaminophen,"[8] commonly known as Tylenol.

Even though more pregnant women take medications, "over 90% of clinical approved drugs lack appropriate information on efficac , safety, teratogenicity[9] and pharmacokinetics[10] in pregnancy."[11] Due to this lack of data, pregnant women are labeled as "therapeutic orphans."[12] This is not an unknown fact to society. In fact, the CDC admitted to the lack of clinical information. Their information webpage meant to educate the public about "Medication and Pregnancy" stated at the very beginning:

> We know little about the effects of taking most medications during pregnancy. This is because pregnant women are often not included in studies to determine safety of new medications before they come on the market. Less than 10% of medications approved by the U.S. Food and Drug Administration (FDA) since 1980 have enough information to determine their risk for birth defects.[13]

The American College of Obstetricians and Gynecologists (ACOG) also acknowledges this information gap.[14] Yet, despite all the lack of scientific data, the number of medications taken during pregnancy has increased. This lack of information poses a huge problem for our society, especially as the numbers of medications pregnant women take increases.

The main reason for the lack of information about drug safety and efficacy for p egnant women is the lack of clinical trials conducted using pregnant participants. Women have been historically excluded from clinical trials based on sexism, perceived complications studying the female body, and fear of legal liability if a potential fetus gets harmed.[15] Prior to 1993, studies using women were thought to be more complicated due to hormonal changes and menstrual cycles, and more complicated studies meant more expensive.[16] For example, a scientist would need to get a larger sample size to ensure scientific validity due to the increased potential for differentiation between women bodies.[17] An increased sample size costs more money. Society also experienced publicized events such as the thalidomide tragedy where birth defects and fetal deformities were the result after pregnant women took thalidomide.[18] This sparked erring on the side of caution due to perceived risk to the fetus and fear for legal liability if an event like thalidomide ever happened again. If women were included in a study, they had to have a negative pregnancy test or be taking contraceptives during the study.[19] Starting 1993, the FDA shifted its stance and attempted to make changes to include women in trials.[20] Other organizations such as the National Institutes of Health, Office of Resea ch on Women's Health have

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also pledged for increased inclusion of women in clinical trials.[21] However, the exclusion of pregnant women has persisted.

Recent statistics demonstrate that society is still excluding pregnant women from clinical trials. One 2013 national study surveyed industry-sponsored clinical studies from Clinical-Trials.gov and found that only five studies of 558 (1%) we e specifically designed for pregnant women for pregnancy-related conditions.[22] Of those studies, 367 were Phase IV and 95% of those Phase IV trials specifically excluded p egnant women.[23] This study found no studies specifically designed to evaluate the treatment of non-obstetric illness in pregnant women, such as pain.[24] This study made the point to state, "phase IV trials are potentially the most appropriate and least controversial for inclusion of pregnant women[,]" due to the information already gathered from the prior phases.[25] Another more recent 2016 international study surveyed clinical trial registries for over 70 countries and found overall only 0.48% of all studies evaluated use of a therapeutic medication in pregnancy.[26] The United States registry only had seven studies for pregnancy-related drug trials out of 109 (6.42%).[27] This is only a minor improvement from the previous survey.

"Research studies are the best way to determine effectiveness and safety of drugs. There is no other way to obtain such information other than human experimentation; it becomes a necessary evil in some ways."

B. Information Physicians Use in Prescribing Medications to Pregnant Women

Currently, physicians use animal studies, clinical studies using non-pregnant participants, case reports (individual cases reported in literature), retrospective observational studies, and adverse event registries as sources of clinical data to advise their patients of the possible risks and benefits of taking a particular medication du - ing pregnancy.[28] This post-marketing research does not go through the same process as the pre-FDA approval research process does, which limits known safety and efficacy as the FDA process is specifically designed to ensu e safety and efficac .[29] Retrospective observational studies and adverse event registries are not scientific studies and are mere collections of data.[30] They are voluntary systems where either the physician or the consumer reports the perceived adverse event. The information is limited to whatever details the reporter includes and the information may not be helpful.[31] One example of a registry would be the FDA Adverse Events Reporting System (FAERS) maintained by the FDA and available to any consumer for a perceived adverse event to drug.[32] Based on the 2007 Food and Drug Administrative Amendment Act (FDAAA), the FDA requires that pharmaceutical companies maintain pregnancy exposure registries, a version of adverse event registries specifically designed for p egnant women.[33]

One of the biggest issues with these registries is lack of public awareness. Reporting remains voluntary, resulting in another concern about a lack of reporting to these registries by physicians.[34] Consequently, this information is not considered creditable scientific information b - cause a recall bias of the reporter exists, there are a lack of control groups, and overall poor documentation.[35] Also, the information in these registries and studies is often inconsistent.[36] Since the information is not from scientific studies, it cannot be generalized for the rest of the public, which makes this information useless for providers.[37]

Research studies are the best way to determine effectiveness and safety of drugs. There is no other way to obtain such information other than human experimentation; it becomes a necessary evil in some ways. Reactions to drugs during pregnancy cannot be accurately determined using animal research, research on men, or even research on non-pregnant women. There are different reactions to drugs across genders and different reactions that are only experienced during different stages of pregnancy due to physiological, hormonal, and anatomical changes.[38] Some physiological changes during pregnancy that impact drug interactions include increased plasma volume, body weight, body fat, metabolism, and hormone levels.[39] Clinicians would need information about how the drug interacts with these changes and whether the drug crosses over the placenta to the fetus.[40] Without such information, there is an information gap that is negatively harming pregnant women.

C. Role of Clinical Trials in Standard of Care

Clinical trials are our current standard for legal and societal approval of medications. The goal of clinical trials and research in general is to improve quality of life of individuals and increase generalizable knowledge. Our practice of medicine is an evidence-based and evidence needs to support the validity of a practice in order for that

practice to be justified. If a medication is not app oved, then it is not officially on the market for that use. This is true even though we allow physicians discretion to prescribe off-label use of medications.

Legally, the regulation of drugs is controlled by the FDA and federal law. The FDA oversees the process for medication approval through the use of clinical trials. Clinical trials are research studies on humans and there is a four-phase approval process. Prior to beginning a clinical trial in general, there must be animal studies first to show initial data about the effectiveness and safety of medication. For clinical trials in pregnant women, there must also be clinical trials in non-pregnant individuals.[41] Researchers then submit an Investigational New Drug Application (IND) to the FDA for approval and seek approval from a local institutional review board (IRB). Phase I studies are focused on safety while Phase II focuses on effectiveness.[42] The amount of participants increases as the study progresses between the phases. After completion of Phase III, researchers can submit a New Drug Application (NDA) and receive FDA approval. If approved, the medication can be on the market prior to Phase IV.[43]

One of the reasons for the lack of clinical trials with pregnant women is the restrictive nature of the federal regulations governing research on pregnant women.[44] The proposed research has to meet 10 requirements[45] and it becomes 10 chances for the study to fail. The intent of the regulations is to protect both the woman and the fetus but this list may be too burdensome and too much of a barrier for inclusion. However, there has been an overinterpretation of these regulations, due to perceived risk and caution.[46] These requirements analyze appropriateness of the potential study based on whether the research is proposed to benefit or harm the woman, both woman and the fetus, or only the fetus. Two of the more limiting requirements are knowledge about the level of risk to the fetus and the possibility of father consent.

When it comes to acceptable level of risk to the fetus, it has to be "not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means."[47] The regulations further explain minimal risk to mean "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."[48] This requirement involves knowing information about the level of risk to the fetus prior to even starting the study. However, society does not have that information because the studies have not been done to gather that information and this requirement prevents the studies from happening. It requires a heightened knowledge about the risks involved in the study when the purpose of clinical studies is to determine risks. It is also not clear if whether "risk encountered in daily life" for fetus is referring to risks encountered in a normal pregnancy or risks a baby may face outside the womb. The minimal risk encountered for a fetus during "daily life" is arguably always going to be lower than that risk during a clinical trial because there is a perception of risk based on the unknown.

"When it comes to acceptable level of risk to the fetus, it has to be 'not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.'"

Another one of the more limiting requirements for inclusion in clinical studies is paternal or father consent when the research is projected to only benefit the fetus. This presents concerns about the possible authority the man may have over the woman's body, as the fetus would still be in the woman's body during these studies.[49] This is counter inituitive in relation to the national acceptable constitutional right for a woman to have control over her own body. However, paternal consent is not required when the man is unable to consent because of unavailability, incompetence, temporary incapacity, or when the pregnancy resulted from rape or incest.

Overall, these requirements have created a cyclic dilemma. Society started with a lack of information about the risks and benefits for p egnant women in research. Without knowing enough information about the potential risks and benefits, we then err on the side of caution and not conduct these clinical trials. We then have a lack of clinical trials, which is where we would gather our information about risks and benefits. e circle back to still having a lack of information, which again leads us to err on side of caution and not recommend pain medications for pregnant women. Even for the drugs that we do have some information, it is often incomplete or we do not know the degree to which there are fetal drug interactions. Our current legal structure does not seem to break this cyclic dilemma.

D. FDA Labeling of Medications: Old and New Systems

In 1979, the FDA created a five-category letter class - fication syste [50] based on fetal risk for medications. This system was used as part of medication labeling required by federal law. If a medication was labeled as Category A, it was considered the safest for the fetus, and Category X was considered the most dangerous. There were no pain medications that were labeled as Category A and this left our physicians with a standard of care that was less than optimal. Acetaminophen is one of more commonly recommended pain medications for women during pregnancy and it was a Category B in the old FDA classific - tion system.[51]

After years passed, limitations to this letter classification system arose. One issue was this letter classific - tion system oversimplified risk information. It primarily focused on fetal risk, not other factors such as maternal benefit, despite our societal assumption that the maternal interests outweigh fetal interests if they were in conflict [52] Most of medications were in Category C and providers came to assume that they were safe.[53] Providers came to rely on this letter system, instead of learning the risks and benefits of the medication itself [54] In addition, drugs within the same category did not have the same fetal risk.[55] The risks were written by the pharmaceutical company and intended to waive corporate liability, not properly inform anyone about the risks.

In May 2008, the FDA proposed a new rule for labelling and classifying medications in regards to risk during pregnancy and lactation. The final ule became known as the "Pregnancy and Lactation Labeling Rule" and it has three sections of labels: 8.1 pregnancy, 8.2 lactation, and 8.3 females and males of reproductive potential.[56] Under section 8.1, there are four sub-headings: 1) pregnancy exposure registry, 2) risk summary, 3) clinical considerations, and 4) data. The information gets provided in a more narrative format, including more information than the old system.[57] This rule eliminated the letter system and the new system gets gradually phased in over a three-year period for drugs approved after June 30, 2001. By 2018, this transition should be complete, though this transition may cause confusion for providers.[58]

The purpose of this new system is to put the burden back on providers to learn and understand the risks and benefits of medications when it comes to p egnancy.[59] This may prove troublesome because physicians may be forced into a position of admitting their own ignorance about drug safety and efficacy based our society's failu e to have that information. This may also cause tension between the patient-physician relationship and cause patients to lose trust in physicians. It may be unrealistic to expect physicians to be able to navigate the information about the medications since it is not in a systematic location (adverse event registries are not located on one database). Additionally, this new system may involve research that physicians may not have been doing historically. The easier solution for the physician would be to simply not recommend or prescribe the pain medication.

There was hope that this new system would encourage more research and thereby eliminate this information gap.[60] However, the new rule does not change the labelling for over-the-counter medications, which are likely the majority of pain medications pregnant women take.[61] This new rule encourages more data collection regarding adverse events using pregnancy registries but this is still post-market information outside scientific integrit . Consequently, the FDA's new labeling system does not solve the underlying issue of lack of clinical data about the risks due to under-inclusion of pregnant women in clinical trials.

E. Unreasonable Standard of Care Using New York Medical Malpractice Law

A physician is only liable for medical malpractice when the physician deviates from the accepted medical practice, known as the standard of care.[62] In New York, we use the locality rule for determining standard of care for medical malpractice cases articulated in *Pike v. Honsinger*.[63] This rule stated that a physician must have a "reasonable degree of learning and skill that is ordinarily possessed by physicians and surgeons in the locality where [the physician] practices[.]"[64] This is measured by the abilities "possessed by the average member of the medical profession in good standing."[65] Several years later, *Nestorowich v. Ricotta* affirmed this standa d.[66] When it comes to prescription of medications, New York case law established "[t]he standard of care [to] include [] a physician's knowledge and appropriate use of medication, including the risk associated with their use[ ]" but this knowledge is still measured against what a peer in that practice would have known.[67] Physicians are supposed to act as the "informed intermediary" between the pharmaceutical manufacturer and the patient, balancing the known risks and benefits [68]

Standard of care is primarily left to the medical profession to define, even in the case of app opriate medications.[69] Concern arises when our own medical professional has a standard of care that is unreasonable due to factors beyond their control. For example, the question arises of what is the standard of care when there is no known information about the risks and benefits of a medication. This is exactly the case for the treatment of pain for pregnant women. One physician approach could be that less is best and not prescribe the medication.[70] Another physician approach could be to maintain status quo,

meaning that the pregnant patient should only continue taking medications that she was taking prior to becoming pregnant, such as epileptic medication.[71] However, in the event a patient develops a new pain, such as back pain, a condition that the patient did not have prior to pregnancy, neither approach would help treat the patient's pain.

When physicians are prescribing medications, it is off-label to pregnant women. Off-label prescription is when the medication is FDA-approved medication but it is being prescribed for a condition that it is not approved for or for a patient population that is unapproved.[72] In this case, it is likely the medication would not be approved for this patient population, pregnant women. Off-label prescription is currently unmonitored and unregulated, which raises concerns about safety and efficac .[73] This lack of information leads to over- or under-dosing of medication because a physician has no creditable data to determine what dosage is best. This under- or overdosing reduces safety and efficacy of medications [74]

The main reason this current standard becomes an unreasonable standard of care is that it makes it impossible for physicians to properly inform their pregnant patients of the risks and benefits of taking a particular medication. Physicians cannot inform patients because there is nothing to tell. This then leads to inability of patients to properly make an informed choice because there is no known information when there could be information if there were studies.

We trust physicians to make reasonable standards of care and to properly inform patients about risks and benefits. In many ways, it is not the fault of physicians that we have come to this unreasonable care of standard; it is a broader societal fault based on the legal and social reasons pregnant women have been excluded from clinical trials. Erring on the side of caution has thus created inequality in adequate pain control for women, giving women fewer medical choices. Due to perceived legal barriers, there is a lack of clinical information about drug use during pregnancy and FDA-approved pain medications for pregnant women. This gap in knowledge has thus created an unreasonable standard of care for pregnant women.

F. Recommendations

As attorneys, we can help shape the medical standard of care by offering the medical community information and tools for advocacy. We can also assist with acknowledging that this is an unacceptable standard for women. One suggestion has been for legislative reform to better encourage participation in clinical trials both for women and pharmaceutical companies.[75] Another legislative reform idea has been a mandatory reporting system for adverse events.[76] Lawyers can advise physician clients on how to advocate for legislative reform ideas such as these and increase attention on this issue using our political and legal system.

As for advising physician clients, physicians should be advised to be honest to their pregnant patients about uncertainty and lack of data. Recommending no medications or status quo ignores the patient's pain and the larger societal problem. By having an open and honest conversation with the patient about our current state of information, the patient can then make an informed decision about what risk is worth taking: risk of the unknown by taking a pain medication or the risk of untreated pain for the next nine months. This respects a patient's autonomy and choice. Patients may not be happy to hear about the uncertainty as society has come to expect answers from science, but that unhappiness should be fueled toward advocacy for more clinical trials.

Physicians should also be advised that they should know how to translate our limited information for patients. This translation could include understanding that animal studies and non-pregnant human trials do not translate into known fetal risk and acknowledging that adverse event reporting systems are not generalizable due to lack of scientific integrit . There are several professional organizations that keep updated clinical data and educational material that physicians can use, including the Teratology Society,[77] ACOG,[78] and the Society for Maternal-Fetal Medicine.[79] One organization, the Organization of Teratology Information Specialists, has a service called MotherToBaby which is "dedicated to providing evidence-based information to mothers, health care professionals, and the general public about medications and other exposures during pregnancy and while breastfeeding."[80] MotherToBaby includes experts physicians could contact if they are even in need of additional guidance. Physicians should also be advised to be checking clinical trial websites, such as Clinicaltrials.gov, for updates on possible trials where their pregnant patients could participate.

Most importantly, lawyers should remind physician clients that they should not let the fear of the unknown lead to practicing bad medicine. The best defense to malpractice is practicing good medicine and good medicine involves informing patients of unknowns. As Martina Ayad concluded in her article, "physicians are faced with the dilemma of treating medical conditions with insufficient efficacy and safety information to make evidence-based recommendation or decisions regarding treatment options. While teratogenicity is usually at the center of every decision regarding medications use in pregnancy, it should not be the only concern."[81] Pain treatment during the nine months of pregnancy should

also be a concern of physicians, legislators, and society in general.

Endnotes

1. This article is not covering the issues surrounding alternative pain management options such as acupuncture, physical therapy, or massage, although some studies show that some of the same concerns addressed in this article about perceived risk to the fetus may serve as a barrier for alternative medicine as well. Helen Hall, et al., *The Effectiveness of Complementary Manual Therapies for Pregnancy-Related Back and Pelvic Pain: A Systematic Review with Meta-Analysis*, 95 Medicine 1– 9 (2016). *See, e.g.*, Jackie Waterfield, et al., *Physical Therapists' Views and Experiences of Pregnancy-Related Low Back Pain and the Role of Acupuncture: Qualitative Exploration*, 95 Physical Therapy 1234 –43 (2015).
2. Pregnant women in this article also include the post-natal period where the woman is breastfeeding, as whatever medication the woman may be taking can be transferred to the baby through breastmilk. The same concerns of fetal risk apply to this post-natal period as well and there is the same problem of lack of robust clinical data about the effects.
3. Francoise Baylis & Robyn MacQuarrie, *Why Physicians and Women Should Want Pregnant Women Included in Clinical Trials*, *in* Clinical Research Involving Pregnant Women 17, 19 (2016); Martina Ayad & Maged M. Costantine, *Epidemiology of Medications Use in Pregnancy*, 39 Seminars in Perinatology 508, 508 (2015).
4. Baylis, *supra* note 3, at 19.
5. *Id.* at 19.
6. *Id.* at 18.
7. Ayad, *supra* note 3, at 508.
8. Diana Pham, *Ethical, Legal, and Regulatory Issues Regarding the Study and Use of Medications in Pregnant Women*, 20 J. of Commercial Biotechnology 23, 24 (2014).
9. Teratogens are substances that negatively interfere with the development of the fetus. David K. James, Philip J. Steer, Carl P. Weiner, & Bernard Gonik, High Risk Pregnancy E-Book: Management Options—Expert Consult 580 (2010).
10. *See infra* note 42 for definition of pharmacokinetics.
11. J. Scaffidi, B. . Mol & J.A. Keelan, *The Pregnant Woman as a Drug Orphan: A Global Survey of Registered Clinical Trials of Pharmacological Interventions in Pregnancy*, 124 BJOG: An Int'l J. of Obstetrics & Gynaecology 132, 132 (2016).
12. Ayad, *supra* note 3, at 508.
13. *Medication and Pregnancy*, The Ctr. for Disease Control & Prevention (last reviewed Mar. 28, 2017), https://www.cdc.gov/pregnancy/meds/index.html.
14. The American College of Obstetricians and Gynecologists, Committee on Ethics, Committee Opinion 646, at 1 (Nov. 2015) [hereinafter ACOG Ethics Opinion].
15. Pham, *supra* note 8, at 25.
16. *Id.*
17. *Id.*
18. *Id.* at 23.
19. Ayad, *supra* note 3, at 509.
20. Pham, *supra* note 8, at 26.
21. *Inclusion Policy*, Nat'l Inst. of Health, Off. of Res. on Women's Health, https://orwh.od.nih.gov/clinical/women-and-minorities/policy/ (last visited Apr. 26, 2017).
22. Kristine E. Shields, et al., *Exclusion of Pregnant Women from Industry-Sponsored Clinical Trials*, 122 Obstet. Gynecol. 1077, 1078 –79 (2013).
23. *Id.*
24. *Id.*
25. *Id.* at 1078.
26. Scaffidi, *supra* note 11, at 135.
27. *Id.*
28. Baylis, *supra* note 3, at 23.
29. *Id.* at 20.
30. *Id.* at 20– 22.
31. Michael F. Greene, *FDA Drug Labeling for Pregnancy and Lactation Drug Safety Monitoring Systems*, 39 Seminars in Perinatology 520, 522 (2015).
32. *Id.* at 522.
33. *Id.* at 523.
34. Pham, *supra* note 8, at 26.
35. *Id.*
36. Baylis, *supra* note 3, at 20.
37. *Id.* at 22.
38. Ayad, *supra* note 3, at 509.
39. Baylis, *supra* note 3, at 21.
40. *Id.* at 23.
41. *See* 45 C.F.R. § 46.204(a) (2009).
42. Effectiveness means the study will determine the pharmacokinetics, the process by which the body absorbs and distributes drug components, and pharmacodynamics, which is the effects of those components. Baylis, *supra* note 3, at 20.
43. *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. Food & Drug Admin. (last updated Nov. 6, 2014), http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm.
44. 45 C.F.R. § 46.204 (2010). These regulations can also be viewed at the U.S. Department of Health & Human Services website. *See U.S. Dep't of Health & Human Services: Office for Human Research Protections*, 45 CFR 46 (last revised Jan. 15, 2010), https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.207.
45. There is an exception to these requirements in 45 C.F.R. § 46.207, for when the research originally not approvable "presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates." This exception requires a panel of experts, public meeting, and adherence to sound ethical principles. 45 C.F.R. § 46.207.
46. Shields, *supra* note 22, at 1080.
47. 45 C.F.R. § 46.204(b).
48. 45 C.F.R. § 46.102 (i).
49. ACOG Committee on Ethics, *supra* note 14, at 6.
50. The five categories we e Category A, Category B, Category C, Category D, and Category X.
51. Shalini Shah, et al, *Pain Management in Pregnancy: Multimodal Approaches*, Pain Research & Treatment 1, 3 (2015).
52. Consider legal precedent supporting the constitutional right for a woman to have an abortion.

53. Greene, *supra* note 31, at 521.
54. Juan F. Mosley II, Lillian L. Smith, & Megan D. Dezan, *An Overview of Upcoming Changes in Pregnancy and Lactation Labeling Information*, 13 Pharmacy Practice 1, 2–3 (2015).
55. *Id.* at 2.
56. 21 C.F.R. § 201.56 (2014), https://www.gpo.gov/fdsys/pkg/CFR-2016-title21-vol4/xml/CFR-2016-title21-vol4-sec201-56.xml; *Pregnancy and Lactation Labeling (Drugs) Final Rule*, U. S. Food & Drug Admin. (Dec. 3, 2014), https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/labeling/ucm093307.htm.
57. Mosley, *supra* note 54, at 3.
58. *Id.* at 2.
59. *Id.* at 3.
60. Ayad, *supra* note 3, at 510.
61. Greene, *supra* note 31, at 521.
62. *See* N.Y.P.J.I. 2:150 Malpractice—Physician (2009).
63. *Pike v. Honsinger*, 155 N.Y. 201, 209– 10 (N.Y. 1898).
64. *Pike*, 155 N.Y. at 209 (cited by *Nestorowich v. Ricotta*, 97 N.Y.2d 393, 398 (N.Y. 2002)).
65. *Id.* at 210. *See e.g.*, Michelle Huckaby, et al., *The Locality Rule and the Physician's Dilemma: Local Medical Practices vs. the National Standard of Care*, 297 JAMA 2633–37 (2007) (information about concerns with locality rule verse national standard of care).
66. *Nestorowich*, 97 N.Y.2d at 398.
67. *Spensieri v. Lasky*, 94 N.Y.2d 231, 238, 239, 240 (N.Y. 1999) (lawsuit for malpractice of physician for error in prescribing birth control pills to control vaginal bleeding).
68. *Spensieri*, 94 N.Y.2d at 239.
69. "The law generally permits the medical profession to establish its own standard of care." *Toth v. Community Hospital at Glen Cove*, 22 N.Y.2d 255, 262 (N.Y. 1968). Standard of care is set by physicians, not drug manufacturers. *Spensieri*, 94 N.Y.2d at 238.
70. Baylis, *supra* note 3, at 23.
71. *Id.*
72. Baylis, *supra* note 3, at 21.
73. *Id.*; Pham, *supra* note 8, at 27– 28.
74. Ayad, *supra* note 3, at 509.
75. Ayad, *supra* note 3, at 510; *see also* Gerald G. Briggs, et al., *Should Pregnant Women Be Included in Phase IV Clinical Drug Trials?*, Am. J. of Obstetrics & Gynecology 810–15 (2015) (suggesting legislative change and offering specific considerations to include in Phase IV clinical trials of pregnant women).
76. Pham, *supra* note 8, at 28.
77. *Resources for Scientists and Professionals*, The Teratology Soc'y (last rev. Sept. 8, 2016), https://www.teratology.org/scientists.asp.
78. *Resources and Publications*, The Am. Congress of Obstetricians & Gynecologists, (2017), http://www.acog.org/Resources-And-Publications.
79. *Publications and Guidelines*, The Soc'y for Maternal-Fetal Medicine, https://www.smfm.org/publications (last visited Apr. 26, 2017).
80. MotherToBaby, https://mothertobaby.org/ (last visited Apr. 26, 2017).
81. Ayad, *supra* note 3, at 508.

Unfair and Inadequate: An Analysis of Transgender Health Care

By Rachel Bernzweig

Transgender individuals do not have equal access to health care. When they try to make a doctor's appointment and mention "transgender," the office esponds that no one is available to help them.[1] Doctors and medical professionals alike refuse to provide health care to them because they do not have the training or expertise to deal with their unique health care concerns.

This type of discrimination is not new. Undeniably, "[t]he history of this country is replete with instances when people, based on their . . . sex, gender, gender identity or expression, . . . or some combination thereof, have been burdened and excluded from the founding promise of equality for all."[2] These instances stem from "the idea that there are only two genders, which match two distinct physical sexes" which is presumed by most people in our society.[3] That presumption unfairly alienates transgender individuals because the "transgender umbrella" includes people who were assigned female sex at birth who now identify as men (transgender men) and people who were assigned male sex at birth who now identify as women (transgender women).[4] Transgender individuals "have long endured frustrated dreams and denials of equal access to . . . healthcare . . . [that] they seek and deserve."[5] Irrefutably, "[m]eeting the needs of current and future transgender individuals is a pressing medical concern."[6]

I. Current Day Transgender Discrimination

The majority of medical professionals know little to nothing about transgender health, meaning that "countless trans[gender] individuals across the country" are left with "incredibly restricted health care options."[7] Consequently, transgender individuals are forced to travel far distances in order "to see a doctor who has experience in transgender health care, or at least is not openly hostile."[8] They are willing to travel because the regions they come from are not only "hurting for health care options" because they lack physicians who are knowledgeable about treating them, but they also face "discrimination and abuse" by staying.[9] As the National Center for Transgender Equality has shockingly reported, "half of all trans[gender] people have had to teach the fundamentals of trans[gender] health care to their health care providers."[10]

The aforementioned discrimination is facilitated by the fact that the federal government has failed to afford the transgender community protection from this type of discrimination. Section 1557 of the Affordable Care Act (hereinafter "Section 1557")[11] was enacted to combat blatant discrimination against the transgender community by "expand[ing] the rights of all patients to equal healthcare free from discrimination."[12] Section 1557 specifies that "an individual shall not . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity"[13] which essentially "provides antidiscrimination protections greater than those of the Equal Protection Clause" because the section encompasses Title IX of the Education Amendments of 1972 and Title VI of the Civil Rights Act of 1964, which "forbid discrimination on the basis of sex."[14] Further, Section 1557's protection extends more than previous antidiscrimination laws because the U.S. Department of Health and Human Services (HHS) declared that "discrimination 'on the basis of sex' include[d] discrimination on the basis of 'gender identity.'"[15] This landmark distinction made Section 1557 the first federal law enacted to protect transgender individuals from discrimination on the basis of gender identity.

But on December 31, 2016, one day before Section 1557 was supposed to go into effect, a federal judge issued a nationwide injunction halting enforcement of the provision.[16] The lawsuit sought "to undermine critical protections against discrimination in health care."[17] In this infamous decision, U.S. District Court Judge Reed O'Connor wrote that the section's "interpretation of sex discrimination pressures doctors to deliver health care in a manner that violates their religious freedom and thwarts their independent medical judgment."[18] Pursuant to this ruling, health care providers are permitted to discriminate and subsequently "turn away" transgender patients seeking necessary care.[19]

Over the years, discrimination against transgender individuals, "the T in LGBT,"[20] arguably "the most medically vulnerable Americans,"[21] was "largely tolerated because of the lack of federal regulation . . . and inadequate nondiscrimination laws."[22] It has been noted that a central purpose of the Affordable Care Act[23] (ACA) is to "ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country."[24] However, since the injunction remains in place, transgender individuals have no law to lean on and discrimination against them in the health care industry continues.

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II. Without Change, Discrimination Continues

Aside from legal protections, to ensure that transgender individuals have equal access to healthcare, the health care community should focus on medical training because while transgender individuals cannot always rely on the law for protection, they should be able to rely on their health care professionals. This focus can have a positive effect because "[a] health care professional's humility can be a source of relief to an anxious [transgender] patient."[25] The Code of Medical Ethics "recognizes healthcare as a fundamental human good"[26] and that "physicians' attitudes can exacerbate variations in patients' access to healthcare services or the quality of health care patients receive."[27] Further, the Code provides that physicians "may not discriminate against a patient on the basis of gender identity."[28]

Without question, "[t]his area is a critical one for reform, as access to nondiscriminatory medical treatment remains a serious problem for trans[gender] people in the United States."[29] The types of discrimination that transgender individuals "across the country routinely experience," range from "health care providers" using harsh or abusive language, blaming patients for their health status, being physically rough or abusive or refusing care outright."[30] Those in the health care industry who do not understand or support transgender identities have been found to "gossip" by "asking inappropriate questions about a transgender patient's identity, joking or commenting about a patient's body or appearance, and using slang or the wrong pronoun or name when referring to a patient."[31] It is important that health care professionals respect transgender patients and stand up for patients who are being faced with "this kind of unprofessional and aggressive behavior . . . [b]y informing perpetrators of inappropriate and offensive speech, and by making it clear that their actions are insensitive and sources of potential harm to patients."[32]

In the broadest sense, a "health disparity" is "a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage."[33] These differences include "the role of bias, discrimination, and stereotyping at the individual, institutional, and health-system levels."[34] Although these types of disparities are often linked to race or ethnicity, they affect those who are discriminated against based on "gender; sexual orientation or gender identity."[35] It is well defined that transgender individuals suffer because of these disparities[36] because "LGBT health disparities largely track to a long history of societal stigma and discrimination directed at sexual and gender minorities."[37] This "[s]tigma and discrimination" affects transgender individuals directly through health care professionals who are biased and are "fueled by hatred of LGBT people."[38]

According to HHS, in order to attain "health equity," meaning the "attainment of the highest level of health for all people," it is required that everyone be valued "equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities."[39] Yet transgender individuals face "high rates of victimization coupled with limited social and cultural structural support" which inevitably "set the stage for health disparities."[40] It is impossible to attain "health equity" when transgender individuals "often delay necessary care for fear of bias" because they would rather avoid "than engage with the health care system."[41]

Physician implicit biases, such as those described earlier, are "associated with weaker communication between doctors and their minority patients" because "physicians hold shorter clinical encounters with minority patients, make less frequent eye contact, verbally dominate exchanges . . . and share less information with minority patients."[42] These biases have evident negative effects on a transgender individual's ability to access necessary types of healthcare because when transgender individuals are being discriminated against due to their gender identity, they are left with "health care options [that] are correspondingly biased, limited and therefore inadequate."[43] Despite the "demonstrable health benefits of gende - affirming health ca e interactions and accessible transition options among transgender populations[,]" countless medical professionals "struggle to provide care to people who want to transition genders"[44] because of these biases.

Access to adequate and respectful health care is important for all people. Change must be made in order to address the remaining barriers facing transgender individuals to ensure that our most vulnerable and marginalized communities will have access to adequate health care. While the "lack of access to appropriate care (due to lack of clinicians knowledgeable about transgender patients' specific needs and vulnerabilities) is the biggest barrier," they face other barriers such as "financial and socioeconomic obstacles, physicians lack of awareness or education about physicians' roles in transgender health care, and discrimination."[45] Transgender individuals are one of "the most stigmatized and medically underserved groups, facing barriers at every phase of accessing care, from getting into the doctor's office to paying for ca e."[46]

While "LGBT health centers do exist . . . they are generally located in major cities and therefore too far for many people to travel for regular care."[47] Physicians who "are experienced in gender-affirming p ocedures are also relatively few, and, as a result, patients might have no choice but to travel great distances for expensive procedures."[48] These conditions have created a financial ha d-ship on transgender individuals[49] who "[b]ecause of dis-

crimination . . . are much more likely to be homeless, unemployed, and low income."[50] While "anti-transgender bias" can appear in any setting, it is "particularly problematic in health care because transgender individuals are 'uniquely dependent on medical treatments to realize their identities and to live healthy, authentic lives.'"[51]

Clearly, access to gender transition-related care remains an unmet need, but transgender individuals also struggle to get other types of health care as well. The reality is that "[t]ransgender patients' other health care needs are, in many respects, identical to those of cisgender (nontransgender) people."[52] This why the World Professional Association for Transgender Health "recommends that the health-care needs of transgender people be openly and properly addressed, at the same level of quality and thoroughness as is afforded to any other person."[53]

Yet, transgender individuals are not afforded the same quality because numerous transgender individuals are denied access to preventative health care and routine services "due to the gender marker on file with their insurance provider."[54] Transgender males "who have a uterus, ovaries, and/or breasts, can be at risk for cancer in these organs" and will need services such as a "Papanicolaou (Pap) smear to screen for cervical cancer."[55] These males are denied access to "Pap smears and other reproductive health-related preventive services even though they need this care."[56] Comparably, transgender females are often denied access to prostate exams despite their risk for prostate cancer.[57] Where a transgender male was diagnosed with cervical and ovarian cancer, "more than twenty gynecologists refused to treat him over a ten-month period" because the physicians were "uncomfortable with his transgender status and feared that treating him would harm the reputation of their medical practices."[58] Unfortunately, because the cancer had gone untreated for so long, the cancer metastasized and became fatal.[59] Therefore, it is necessary that "[c]linicians . . . understand how to validate and support [transgender] patients by providing gender-affirming ca e."[60]

III. Focus on Medical and Legal Professionals

1. Medical Professionals

There is no debate "that the actions and inactions of health professionals have had a significant e fect on the health of LGBT people."[61] In order to "end[] LGBT invisibility, it is important to understand the terminology used."[62] Understanding and valuing "gender" is "[a] foundational concept" that allows medical professionals to "focus on optimizing interactions with individual patients."[63] It is important to "understand and value the diversity embedded within the term 'gender' and the panoply of ways people may choose to describe and express their gender."[64] An example of this understanding is the use of preferred pronouns in order to avoid "misgendering"[65] because "clinicians' nonjudgmental use of this language assists with establishing rapport and cultivating respectful relationships."[66]

Further, "[h]ospitals and medical practitioners can create a more welcoming environment for this marginalized population of patients by adopting inclusive intake procedures, asking about gender identity, and conducting a physical exam in a manner that is most comfortable for patients."[67] Additionally, "[w]hile a patient's gender identity may not appear relevant to a diagnosis and treatment of many medical conditions, familiarity with transgender medicine will lead to better informed medical care and provide a singular opportunity for teaching."[68] Gender-affirming ca e can and should be provided to all patients because "[e]veryone, no matter their gender identity . . . appreciates friendly and courteous service"[69] and "[m]eeting the needs of these patients is an ethical obligation that the medical profession must assume."[70]

Whether patients have identified themselves as tran - gender or not, it is advised that health care providers ask them if they have "a preferred pronoun" because "this small act . . . has the potential to enhance the therapeutic alliance between doctor and patient and may enable the patient to be more forthcoming about sex and gender issues that could be relevant to the clinical presentation."[71] Further, "clinicians can try more mindfully to notice that they have biases or make judgments that impede the formation of strong patient-clinician relationships."[72] For example, "[i]n the transgender population, gender variant bodies are common, and this 'difference' should be respected by members of the medical community."[73] Learning about these biases and working to "mitigate reactions" are critical to improving "gender-affirming and responsible care."[74]

In order to obtain "[t]ransgender health literacy[,] . . . ongoing education and training" is required.[75] As "any area of medicine, . . . standards of care and best practice guidelines are continually being updated" and "it is important to stay up to date on current research and literature pertaining to transgender identities."[76] Moreover, it is important to note that "although the acronym LGBT is used as an umbrella term, and the health needs of this community are often grouped together, each of these letters represents a distinct population with its own health concerns."[77] Additionally, "[i]t is not always possible to know a person's gender identity based on their name, their appearance, or the sound of their voice."[78]

The "Fenway Approach" is "'a philosophy of accessible, patient-centered care that views gender affirmation as routine part of primary care service delivery, not a psychological or psychiatric condition in need of treat-

ment."[79] Arguably, using this approach could lead to decreased discrimination towards transgender patients, because physician biases would not come to fruition. Medical schools should be incorporating this approach into their curriculum because it is well established that education "represents an opportunity to not only help [medical professionals] develop LGBT-care competence but also to help improve the care received by that learner's future patients, and, perhaps on a grander scale, to improve overall social equity for LGBT people."[80]

Commonly, "medical, nursing, and other health professional school curricula have contained very little LGBT-specific content . . . because of pervasive homophobic attitudes among educators, the health care professions as a whole, and the population at large."[81] But, "as cultural attitudes are shifting to regard LGBT people in the United States more positively, so have attitudes in health care and health care education."[82] For example, Vanderbilt University School of Medicine has recently established "The Trans Buddy Program" as part of its medical education, where students are trained as "peer advocates" to "streamline communication between patients and providers" and to "reduce patient anxiety."[83] Further, the school offers lesbian, gay, bisexual, transgender and intersex (hereinafter "LGBTI") curriculum components, internships and a graduate certificate p ogram.[84]

The Association of American Medical Colleges has encouraged the inclusion of LGBTI health in medical schooling because "LGBTI individuals face documented health disparities, perpetuated in part by limited LGBTI-related education and cultural competency training in medical curricula."[85] Further, the Accreditation Council for Graduate Medical Education program requirements provide that medical curriculum must include "Patient Care and Procedural Skills," meaning that "[f]ellows must be able to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health."[86]

There remains a continued need for these types of programs. A recent study of medical school curricula showed "that more than 33% of medical schools reported 0 hours of LGBT-specific content delive ed in the clinical years, and 6.8% of medical schools reported 0 hours of LGBT-specific content in the p eclinical years."[87] Further, although some schools have LGBT-specific content, "it is important to note that time devoted to subject-specific education does not necessarily equate to equality of education, nor does it necessarily lead to desirable learning outcomes (knowledge, skills, behaviors, attitudes)."[88]

2. Legal Professionals

Working to prevent discrimination against transgender individuals also applies to law practices in "both their capacity as employers and as professionals serving members of the public."[89] The National Transgender Discrimination Survey found that transgender individuals suffer from unemployment and those that are employed "make less than $10,000 per year."[90] Also, transgender individuals are being turned away from law firms who do not a - cept transgender clients.[91] Especially in New York, where a longstanding history of anti-discrimination laws is in place, legal professionals "need to be aware of this issue" and work to prevent it.[92] Combating against discrimination by promoting "an environment where all persons, including persons who do not conform to traditional gender norms, are treated with dignity and respect" effectively "sends a message to the outside world about your values, company culture, and commitment to equal treatment."[93]

For example, law firms should "[a]dd gender ident - ty/expression to the list of protected classes in application forms, recruitment materials, marketing materials, website pages and policies related to nondiscrimination, antiharassment, and equal employment opportunity."[94] Relatedly, it is advisable to "eliminate any questions related to gender (or other protected class status)" from client intake forms because it is extremely important to "[u]se appropriate pronouns . . . consistent with an employee's or client's stated gender identity."[95] Where you might be unsure, "it is acceptable to ask, provided you do so in a sensitive and open-ended manner."[96] However, it is equally important not to "out" any transgender employees or clients and to "make sure you have their permission before disclosing to anyone that they are transgender" because "protecting the confidentiality of any medical information they may provide to you . . . [will] enable you to better accommodate their needs."[97] On the other hand, "[i]t will be necessary to make sure opposing counsel and the court address your client appropriately" because "[y]ou as the representative set the tone."[98]

IV. Creating a New Antidiscrimination Law

While maintaining an active approach to mitigating and eliminating discrimination against transgender individuals in the medical and legal fields, we should begin by looking at current state laws to help determine an adequate replacement for Section 1557. Notably, despite Section 1557's failure, "[t]he state of New York has had a long history of protecting the rights of transgender persons under the provisions of the Human Rights Law."[99] In fact, "New York was the first state in the nation to enact an anti-discrimination Human Rights Law, which affords every citizen 'an equal opportunity to enjoy a full and productive life.'"[100] To show perspective, "New York [S] tate is home to more than 78,600 transgender people" who are "historically underserved" and for whom "access to a full continuum of quality, culturally competent health care is long overdue."[101]

More recently, in an effort to further protect transgender individuals in the state, Governor Cuomo issued a "statewide regulation[] to prohibit harassment and discrimination on the basis of gender identity, transgender status or gender dysphoria."[102] This regulation speaks volumes because "[i]t is intolerable to allow harassment or discrimination against anyone, and the transgender community has been subjected to a second-class status for far too long."[103] Additionally, New York City's Commission on Human Rights has one of "the most severe 'transgender rights' enforcement" laws.[104] Violations of the law include: "[1] [f]ailing to use an individual's preferred name or pronoun . . . [2] [r]estricting same-sex facilities . . . [3] [l]imiting a person's options to only 'male' and 'female' . . . [4] [s]ex stereotyping . . . [5] [i]mposing different dress codes based on sex . . . [6] [t]ransgender-inclusive health insurance . . . [and] [7] [t]reating cross-dressers differently in any way."[105] The City determined that the law was necessary because "there is no greater danger to the health, morals, safety and welfare of the city and its inhabitants than the existence of groups prejudiced against one another and antagonistic to each other because of their actual or perceived differences."[106]

Forgoing a replacement for Section 1557 will leave a chilling impact on millions of Americans because "[c]hanges to the Affordable Care Act do not just affect a small group of individuals; millions of lives are at risk."[107] Section 1557's protections were "critical to addressing the remaining barriers to . . . care that LGBT people across the country routinely experience."[108] Section 1557 was enjoined because the judge believed "that statutory prohibitions against sex discrimination under Title XI . . . do not prohibit discrimination on the basis of gender identity."[109] Judge O'Connor "justified his ruling by claiming that individual doctors' refusal to treat trans patients . . . does not limit their access to health care" because "the government doesn't seem to be too concerned about specifically trans people's access to health care anyway."[110] This ruling "will only continue to limit options for trans people" because it has "paved the way for even more discrimination on the grounds of religious freedom."[111] Therefore, a different argument must be produced in order to create a new federal law that will actually protect transgender individuals from discrimination.

While states, such as New York, offer invaluable protections from discrimination, all "[s]tate laws do not sufficiently address these concerns: currently only 18 states and the District of Columbia protect access for LGBT people to health care facilities."[112] Further, "the nondiscrimination protections offered by federal laws . . . are becoming even more critical for LGBT people across the country as states enact laws . . . that condone or even encourage discrimination on the basis of gender identity and sexual orientation, including by health care providers."[113] A law like Section 1557 has power because it "codifies substantial protections for transgender individuals in access to health care."[114] A replacement law should, among other things, "clarif[y] that a provider or other staff person persistently and intentionally refusing to use a transgender individual's correct name and gender pronoun [in communication with the patient] constitutes prohibited harassment on the basis of sex" and "require[] health care providers to provide medically necessary health care services to transgender individuals."[115]

V. Conclusion

Undoubtedly, "[t]he need to uphold transgender rights has never been more pressing or more important than today."[116] It is clear that "transgender rights stem from human rights" which are "fundamental rights belonging to every person"[117] and the "right" to have access to health care should be protected by the law. Our country protects religious freedom and "religion is quintessentially a choice."[118] Using the same rationality, all members of our communities, including transgender individuals, deserve to have that same level of protection for their choices.

Right now, there is no nationwide protection from discrimination for transgender individuals. Thus, to ensure that discrimination against transgender individuals in health care does not continue, a change to medical training is the next best step. Treating "transgender patients with the same dignity and respect that [a medical professional] would treat any other patients cannot be overstated."[119] Physicians have "responsibilities to protect their transgender patients as they would any other patient."[120] Further, "transgender patients need clinicians whom they feel safe and comfortable seeing regularly for all of their health care needs."[121]

In reality, the "majority of medical care related to transgender health can be administered by any physician willing to research best practices and create a care plan that centers on an individual patient's health care needs and priorities."[122] Transgender individuals "should have access to a gender-affirming medical home where all components of care can be discussed nonjudgmentally in an environment that minimizes stigma and discrimination."[123] Thus, "[i]t is incumbent upon health professionals to continue striving to meet the needs of individual patients" regardless of their gender identity.[124]

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The Government's Unenforceable Duty of Care to Secure Messaging

By Nathan G. Prystowsky

Would you rather be alive and embarrassed or not embarrassed…but dead? It's not a new question, but until now the answer has always been alive. Privacy, while important, must never be more important than patient safety. Now, however, the Office of the National Coo dinator for Health Information Technology (ONC) has essentially forced unreliable and underdeveloped technology to be used that creates inherent risks for outpatient care.

Under the authority granted by the Affordable Care Act, ONC created regulations requiring the adoption of a patient portal including "secure messaging" as a feature. Mandatory adoption of secure messaging has disrupted the organic adoption of technology that gives practices the discretion to safely implement and integrate technology to a responsible standard of care for outpatient procedures.

Before ONC requirements, integrating new medical information technology did not compromise safety protocols in a medical practice. Being able to avoid those compromises was and remains important. In the medical profession, we rely upon technology to monitor patient conditions and administer remote care. Ask any patient. A large part of the comfort and relief of returning home after an outpatient procedure resides in the security that a capable on-call physician can be reached in the event of an emergency.

Consider a patient who has a post-op complication following a surgical procedure. The patient takes a photo and sends it to their doctor outside of normal business hours. The photo, if seen by the monitoring doctor, would require immediate attention. If the patient submits the photo by email, the doctor will likely have uninterrupted access and can proceed to address the situation promptly. On the other hand, if the patient must use a secure messaging system on a patient portal, obstacles arise. The patient portal can only be accessed by the doctor on site using a computer connected to the practice's computer network. As a result, the message does not get evaluated until the next day or, if on a weekend, several days later. Moreover, unless the patient routinely logs onto their patient portal, the patient might not actually see a response for several more days. As a result, a minor post-operative complication risks becoming something more serious.

We know that patients will use secure messaging for anything and everything, especially if they are encouraged. Given the need to use and report secure messaging to drive new incentive payments we can also expect some level of encouragement from physicians. Moreover, even if the encouraged use comes with a caveat that secure messaging should not be used for urgent matters, we know that patients cannot be expected to understand the urgency of their conditions or the limitations of a secure messaging system. The notion that secure messaging does not get used for urgent medical needs simply cannot be accepted as realistic. So why mandate the implementation of a secure messaging system that cannot safely handle urgent medical needs?

Common Law Malpractice Codifies Realistic Patient Expectations

Any person who has gone to see a doctor can testify to the following expectations for outpatient care. A patient should expect to be able to reach the office during no - mal business hours. Outside of normal business hours a patient should reasonably expect an answering service to connect them to the doctor for urgent care needs. A patient expects that once a doctor gets paged, a prescription can be phoned in or the patient will be referred to an urgent care center. These interactions have become so commonplace that they are an unspoken expectation. This level of communication is assumed before a patient even seeks medical care or receives a treatment.

These expectations are also codified in common la malpractice. Broken down into its elements malpractice get proven by (1) a deviation or departure from accepted practice and (2) evidence that such departure was a proximate cause of injury or damage.[1] Many outpatient procedures require some degree of follow-up care. Providing a service requiring some degree of follow-up care means it will be malpractice if a doctor fails to follow up in accordance with accepted medical standards.[2] Follow-up care includes a duty to monitor a patient after an operation.[3] While monitoring a patient, a physician needs to be reachable because failing to respond to a patient could be considered patient abandonment.[4]

With abandonment claims it's well settled that a "physician who undertakes to examine or treat a patient and then abandons him may be held liable for malpractice."[5] Abandonment is also professional misconduct.[6] A physician undertaking the responsibility to be on-call for follow-up care has a duty to respond when called upon for assistance.[7] In most cases, follow up care patients are given

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post-operative instruction sheets with the number of a 24-hour answering service to page a "covering physician." It is also sufficient to p ovide a transfer of care to another qualified physician [8] and that coverage can include a referral to a hospital emergency room.[9]

Referral to a reliable answering service will also be in accord with a standard of care even if that service makes a mistake that results in the doctor failing to be reached.[10] Nonetheless, being reachable by the answering service has an impact if there is an unreasonable delay before responding to a message. The law imposes a duty to treat conditions timely.[11] Given the impact a short delay can have on treatment, a doctor needs a reliable answering service.

If a service cannot conform to the reasonable expected standard of care, it should be outright rejected. Practices need an answering service that is reachable at a number given in the discharge instructions. The discharge instructions must include instructions for emergency care and otherwise direct the patient to consult with an on-call physician for urgent matters. The doctor, upon being paged, must return phone calls timely and in the appropriate circumstances prescribe a medication or instruct the patient to schedule an appointment in the morning or go to the emergency room.

It's not difficult to operationalize these standa ds of care, provided a doctor can use any available means to comply with the standards. Take email communications. Emails are not a reliable means to reach a physician for urgent care questions. While physicians may permit scheduling or some forms of routine monitoring by email, physician practices have discretion to develop ways to deter patients from trying to use email for urgent medical consultations.

To ensure proper email usage, an email consent form setting out the office policy equiring email only be used for scheduling and non-urgent care will be signed by the patient. Additionally, a practice has the ability to set up an automatic response to ensure a patient always gets notified that emails a e not responded to immediately and that urgent matters require contacting the on-call service and emergency matters should be handled by dialing 911 or going to the emergency room. Finally, multiple clinical staff at all times can remotely monitor the email account reserved for patient email just in case an urgent matter comes up that a patient has no awareness of when submitting the email.

No doubt email has security vulnerabilities that may enable a person's information to be inadvertently disclosed and that information should be discussed with a patient.[12] However, with email, all the safety protocols discussed above are at the discretion of the physician to curb unintended misuse by patients. The problem that presently exists is that secure messaging systems are foisted upon practices and cannot be rejected, configu ed, or adapted sufficiently for patient safet .

The Mandate to Use Software Developed by the Certification Process

The office of the National Coo dinator for Health Information Technology (ONC) is the government body responsible for setting standards for health information exchange.[13] The regulations implementing the standards for certification of elect onic health records and modules are published in the Federal Register at 45 CFR 170.100 et seq. The standards for certification vary depending on the ed - tion of the criteria. The first edition of criteria was the 201 Edition for Electronic Health Record (EHR) certification but at present ONC is phasing in the 2015 Edition of EHR certification standa ds. One of the additions to the 2015 Edition standards is the secure messaging requirement. Under 45 CFR § 170.315 (e)(2) pertaining to patient engagement an EHR must "[e]nable a user to send messages to, and receive messages from, a patient in a secure manner."

If a practice has not fully opted out of Medicare, it needs an EHR that has the required 2015 Certification t be able to complete the reporting requirements pursuant to the Medicare Access and CHIP Reauthorization Act or MACRA. A large number of EHR customers are Medicare providers. Consequently, it goes without saying that an EHR must incorporate and certify this technology to remain competitive on the market. As such, it should be noted that the ONC regulations provide for a very broad scrutiny of EHRs in that the ONC has the ability to review for certification [14] conduct in-field surveillance [15] revoke certifications [16] and enact a certification ban [17] In other words, the conditions present are such that even if a practice suggested turning off a secure messaging application in the patient portal, the EHR provider would not likely be able to comply with the request.

In their present state of development, remote access and remote monitoring of patient communications using secure messaging cannot be done with mobile devices outside of the network. The messaging application only lets patients send messages to the EHR from the patient portal and the EHR only lets office personnel access messages u - ing computer in the office. Checking an email on a smar phone outside of the office does not exist for secu e messaging because email and text notifications do not compl with the secure messaging certification standa ds. That poses a problem for any practice without personnel in office 24/7. When a person is not monitoring the EHR f om his or her computer outside of office hours these notifi - tions will be missed.

Additionally, for privacy and security reasons the secure messaging function usually requires messages from a patient to populate directly within that patient's speci-

fied patient chart in the EHR. This starkly contrasts f om emails. Emails group all communications from multiple people into one list. This permits a physician to triage these messages at a glance. Secure messages are not summarily reviewable because they do not all get grouped into one list in the EHR.

Some EHRs attempt to address this by creating a pop-up notification window whe e each secure message shows up in a list. However, pop-ups are a distraction. While working on patient notes during diagnosis and treatment they often need to be disabled for a physician to focus. This presents a significant shortcoming if a pop-u notification stands as the best available softwa e mechanism for creating a secure message alert because it will always be essential for a medical office to gua d against persistent intolerable distractions placing the welfare of patients at risk.

Also, secure messaging often does not permit an automatic response or disclaimer to be configu ed by the practice. The common practice of secure messaging systems is to use an unchangeable boilerplate disclaimer above a secure message text block that states "not for emergencies, in emergences call 911." Some also add "allow two business days for response."

This kind of disclaimer does not account for a portal that will be habitually used by a patient and develop a routine of usage that eventually overlooks disclaimers of this kind. Take the average person who habitually ignores a "no parking" or "no standing" sign even though these signs have big bright red letters. The same type of response should be expected from patients, i.e., that patients will not see, potentially not read, otherwise ignore, or just not understand these directions. Patients do not know how to triage their own conditions. Patients will inquire about urgent conditions, send photos of urgent medical conditions asking for evaluations, or even request urgent prescription refills. Each one of these situations, if unn - ticed, presents a problem for the practice. Thus, having a system that can address expected misuse is necessary.

The Responsibility of an EHR Extends Beyond Certification Standards

A practice should not use a device or system that cannot configu e safeguards or protocols necessary for patient safety. However, this is exactly what must happen because ONC requires secure messaging to be part of the EHR patient portals and physicians do not get a choice in the matter.

There are good reasons to expect eventual injuries to arise out of a secure messaging system. A secure messaging system that fails to notify patients that messages are not immediately read will become susceptible to foreseeable misuses by patients who come to believe urgent matters would be responded to immediately. Additionally, a secure messaging system that cannot be remotely monitored has a dangerous design defect because a patient can reasonably be expected to send an urgent message needing immediate attention.

New York tort law potentially protects a physician by holding companies responsible for the secure messaging systems included with their EHR patient portal. While no case law directly applying a standard of liability to a patient portal secure messaging system presently exists in New York, liability for messaging systems have been developed in analogous industries like the home alarm system industry. There exists a large lineage of alarm system cases in New York with similar messaging system issues that secure messaging systems will face.

In the same fashion that an alarm service monitors conditions and transmits emergency messages to the police or fi e department, a secure messaging system takes on the risk of alerting medical practices of patient communications. This is particularly true in the case of patient portals because their operation depends upon the configuration set by the technical support staff of the EHR companies.

In *Sommer v. Federal Signal Corp.* the court announced a standard for the transmission of alarm systems that we can likewise expect be applied to secure messaging systems.[18] The *Sommers* court recognized a duty to act with reasonable care is not only a function of a private contract but also stems from the nature of its services. An alarm system gets regulated and certified by various agencie and thereby provides a service "affected with significan public interest." As discussed above, secure messaging systems are likewise becoming similarly certified for thei public health-related services and likewise the nature of their service serves the public interest.

The *Sommers* case essentially announces the following basic legal framework that would likewise to apply to secure messaging systems: (1) a legal duty independent of contractual obligations may be imposed by law as an incident to the parties' relationship; (2) while exculpatory clauses are enforceable against claims of ordinary negligence in instances of gross negligence, exculpatory clauses would be unenforceable; (3) gross negligence consists of conduct evincing a reckless indifference to the rights of others; (4) while lack of privity may mean that a duty does not get owed to a third-party, that does not preclude a claim for contribution found on a party in privities independent duty to that third-party.[19]

In the case of secure messaging systems the independent duty assumed by the manufacturer would be same duty to communicate medical information as other intermediaries in the medical sector. While in those cases the

duty to transmit information may be considered a separate obligation sounding in ordinary negligence;[20] here, since we are dealing with a contract containing exculpatory clauses we can expect a similar standard announced in the *Sommers* court. Thus, the action would remain separate but require a finding of g oss negligence rather than ordinary negligence.

Gross negligence consists of "reckless indifference to the rights of others." Here, those rights would stem from the legal obligations of medical providers to communicate medical information to patients. Where medical providers have relevant medical information they are under a duty to transmit this information and the failure to do so will make them liable for damages that result from the foreclosed opportunity to take measures to attend to the patient's condition.[21] In fields whe e interpreting and transmitting information define the physicians practice such as radiology or pathology, the duty might be limited to "properly and accurately interpreting [] dictating, signing and electronically transmitting the report."[22] Nonetheless, it still must be communicated.

If a doctor relies upon a piece of technology to transmit information to and from patients, that duty on some level must transfer to the maker of the technology. The law recognizes responsibility undertaken by the operator of a secure messaging system by recognizing liability on the part of independent contractors. The employer of an independent contractor generally cannot be liable for injury caused to a third party by an act or omission of an independent contractor.[23] When it comes to the duty to transmit information from a patient to a doctor, the maker of the secure messaging system and the technical support staff undertake a duty to ensure that system will reach the physician.

The issue that presently exists pertains to the fact most secure messaging systems do not permit physicians to receive remote communications. The security and privacy concerns inherent in providing remote notice prevent any configuration that would enable an on-call physicia to receive a redirected message or notification by emai or standard text. Assuming the EHR will not make a secondary secure mobile application that could allow secure messages to reach a mobile device, any doctor outside of the in-office network cannot monitor or eceive messages.

For a practice, knowing about the problems discussed throughout this article prior to using the secure messaging system presents its own problem because if a contractor's propensity to engage in the conduct responsible for a patient's injury was known or should have been known then a practice or hospital could be found to have negligently hired the contractor.[24] In this light, there exists a duty to "safeguard the welfare of [] patients, even from harm inflicted by thi d persons, measured by the capacity of the patient to provide for his or her own safety."[25] The contractor's secure messaging system has known shortcomings, but the government mandates the adoption of the certified system anywa . This paradoxically creates a situation where the physician seemingly without recourse must undertake liability for a situation.

The problem is further aggravated by the fact, as mentioned above, the certified secu e messaging technologies have a limitation in their ability to make any changes without being recertified by ONC. Nonetheless, the fac that the government certifies the secu e messaging system does not enable the EHR to use the certification as a shiel to protect itself from liability for harm to a patient because New York follows the rule that compliance with a statute or regulation by itself does not preclude a conclusion of negligence.[26]

Additionally, under New York law, manufacturers of secure messaging systems are strictly liable for defectively designed products. In that instance, "if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner."[27] Making this determination requires inquiry into such factors as "(1) the product's utility to the public as a whole, (2) its utility to the individual user, (3) the likelihood that the product will cause injury, (4) the availability of a safer design, (5) the possibility of designing and manufacturing the product so that it is safer but remains functional and reasonably priced, (6) the degree of awareness of the product's potential danger that can reasonably be attributed to the injured user, and (7) the manufacturer's ability to spread the cost of any safety -related design changes."[28]

Considering the required inquiry in design defect cases, it should be noted that patient portals provide a beneficial form of secu e access to patients for non-urgent matters. No doubt for non-urgent matters secure messaging should be further developed and utilized for the health and well-being of patients. Secure messaging thereby has utility both to the public and individual users, and in many instances, since the use remains non-urgent, the product will not cause injury. The use of a patient portal to share lab results, schedule appointments, share educational material, and provide better access to medical records generally improves health for all patients. The problem, and therefore, the focus of the inquiry for a defective design would be under prongs 4,5,6, and 7 outlined above.

Patients will always have their own expectations for the use of secure messaging. They expect to reach a physician. They expect the messages to be monitored and reviewed as they come in even if they have notice of a

delayed response of two days. They expect a response as needed, and for messages to not be sitting unviewed for days. In fact, if there were a disclaimer stating that the secure messaging was not actively monitored and messages might not be reviewed for several days, that would make it unusable and patients would avoid it.

Designing a safer secure messaging system would not require a large effort on the part of a developer. The ability to configu e an appropriate disclaimer, the ability to configu e an automatic response, and the ability to install a remote monitoring feature for offices that a e not staffed 24/7 are minimal safeguards that make things safer for patients. None of those design changes would change the function of the technology or its intended use and would doubtfully raise the cost and consequently the price of the product. However, these changes would be instrumental in preventing the glaring potential for a patient to misuse secure messaging for urgent care needs.

Solutions for These Problems

With EHR technology, despite many advancements, there seems to be a continuing failure to accurately consider physician and patient user preferences and how they will attempt to interact with the software. Understanding physician protocols and office p ocedures not just during a patient visit, but throughout the multiple varied interactions that occur throughout the entire portion of an outpatient managed condition, changes the paradigm for the design process of making an EHR interface.

Developers often fail to consider the actual likely interactions of a user and instead make assumptions about what a user will do. On some level this is expected and must be the case because developers do not practice medicine. However, this leads to situations where usability and user-centered design aspects of a program are often not sufficiently vetted during testing

With secure messaging, the systems deployed often fail to account for very foreseeable potential patients who would send urgent messages using the secure messaging system in a patient portal. With a system that does not enable configuration of safegua ds to ensure proper usage and monitor inadvertent deviations from acceptable uses, this becomes a danger waiting to happen. All certifie technologies should have a greater focus on having all the necessary functionality to be safely configu ed for doctor-patient interactions during their vetting process. This is especially true where that technology will be mandatory.

When factors pertaining to integration with risk management protocols are ignored, or glossed over to meet existing certification equirements, those requirements need to change. Ideally, physicians and practices would be able to disable secure messaging until it could be appropriately configu ed to acceptable safety standards. However, physicians who need to report under the incentive programs developed under MACRA do not really have that option. In fact, they need to demonstrate a functional patient portal using the secure messaging system.

Consequently, the only real option is for the secure messaging system developer to change the system and make needed improvements for a safe functional interface. Whether this happens because EHR developers recognize their legal liability under tort law or because ONC requires it does not matter so long as it happens.

Endnotes

1. *See Garrett v. University Assoc. in Obstetrics & Gynecology, P.C.*, 31 Misc.3d 1207(A) (Suffolk County 2007).
2. *See English v. Fischman*, 266 A.D.2d 6 (1st Dept. 1999).
3. *See Parnell v. Monefiore Med. Ctr.*, 63 A.D.3d 573 (1st Dept. 2009).
4. *See Dillon v. Silver*, 134 A.D.2d 159 (1st Dept. 1987) (patient abandonment can be a factor in damages).
5. *See O'Neill v. Montefiore Hospital*, 11 A.D.2d 132 (1st Dept. 1960).
6. *See* NYS Education Law § 6530.
7. *See Clarke v. Union Hosp.*, 6 A.D.3d 229 (1st Dept. 2004).
8. *See Brown v. Bauman*, 42 A.D.3d 390 (1st Dept. 2007).
9. *See Lederman v. Lawrence Hosp.*, 202 A.D.2d 198 (1st Dept. 1994).
10. *See Alvarado v. Miles*, 32 A.D.3d 255 (1st Dept. 2006).
11. *See Dallas-Stephenson v. Waisman*, 39 A.D.3d 303 (1st Dept. 2007) (delay in treatment can be responsible for damages).
12. *See* AMA Principles of Medical Ethics 2.3.1(b).
13. *See* 42 USCS § 300jj-1.1.
14. *See* 45 CFR § 170.580.
15. *See* 45 CFR § 170.556.
16. *See* 45 CFR § 170.570.
17. *See* 45 CFR § 170.581.
18. *See Sommer v. Federal Signal Corp.*, 79 N.Y.2d 540 (1992).
19. For this proposition, it is worth noting the *Sommer* case cites to a series of motel cases where contribution was available to motels against a town for failed fi e services. *See Garrett v. Holiday Inns*, 58 N.Y.2d 253 (1983).
20. *See Bleiler v. Bodnar*, 65 N.Y.2d 65 (1985).
21. *See Huntley v. State*, 62 N.Y.2d 134 (1984).
22. *See Lee v. Kamdar*, 2013 N.Y. Slip Op. 31992(U) (Suffolk County 2013).
23. *See Kleeman v. Rheingol*d, 81 N.Y.2d 270 (1993).
24. *See State Farm Ins. Co. v. Cent. Parking Sys., Inc.*, 18 A.D.3d 859 (2nd Dept. 2005).
25. *See Sandra M. v. St. Luke's Roosevelt Hosp. Ctr.*, 33 A.D.3d 875 (2nd Dept. 2006).
26. *See Yungler v. Pharmacia & Upjohn Co.*, 225 N.Y.L.J. 80 (NY County 2001).
27. *See Cover v. Cohen*, 61 N.Y.2d 261 (1984).
28. *See Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102 (1983).

Authority and Ambiguity: The Complex History of, and Current Challenges to, U.S. Administrative Agencies' Rulemaking Power

By Shawna Benston, Nolan Ritcey, Jennifer E. Miller

Introduction

In January 2017, the U.S. House of Representatives passed the Regulations from the Executive in Need of Scrutiny (REINS) Act, which—if passed by the Senate—would "limit the ability of executive agencies to adopt major regulatory initiatives without congressional approval."[1] This Act has proven politically polarizing. Some commentators fear this procedural change imbues dangerous power to Congress, which "totally lacks the technical competence to review these kinds of complex rules."[2] Others hail it as a restorative influence on "Co - gress' constitutional power as the sole lawmaking authority under the Constitution."[3, 4]

To fully understand the potential impact of the REINS Act on regulatory procedures in the U.S., we must examine the judicial history and current state of administrative rulemaking. As part of this exploration, we include a case study of a recently issued final ule by the National Institutes of Health (NIH) that aims to clarify ambiguous provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA). Following our evaluation of the successes and limitations of this final ule in clarifying certain aspects of the statute, we will reflect on the futu e of regulatory action and compliance should Congress pass the slate of regulatory revisions found in the REINS Act, Midnight Rules Relief Act, and Regulatory Accountability Act.

I. Legal History: Thirty Years of Shadowy Distinctions

Regulated entities often need guidance to fully comprehend statutes. The need for guidance can stem from vague and ambiguous language. The task for such elucidation often falls on executive agencies, which can provide formal guidance in the form of rules issued after an appropriate notice-and-comment period as codified by the Administrative Procedure Act (APA),[5] or informal guidance in the form of handbooks, opinion letters, policy statements, and even oral answers via telephone conversations.[6] The issue of which rules carry the "force of law" has become a central and critical one, refined to focus on the distinction between the two types of executive agency rules: legislative rules, which carry the force of law, and interpretive ones, which do not.[7]

The key distinction between "legislative" and "interpretive" actions must be found in their results—namely, whether they change the substance of the statute or rule about which they are providing guidance. Legislative rules carry the force and effect of law, while interpretive rules provide interpretation or clarification of an existing statute or regulation.[8] If a rule is legislative and implements changes to a statute or rule's substance, such changes require a notice-and-comment period.[9] Critically, if a legislative rule is put forward without abiding by the notice-and-comment requirement, it will be deemed "procedurally invalid."[10] Despite this distinction's apparent intrinsic clarity, however, "[t]he distinction between creating new law and construing existing law does not create bright lines, but rather results in a 'hazy continuum.' Faced with a blurred line rather than a bright line, courts have attempted to add some substance to the distinction by creating more complete tests for when an agency has engaged in legislative rulemaking."[11]

Especially since the landmark 1984 case *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*[12] (*Chevron*), courts have been obliged to grapple with the practical application of this shadowy distinction. In *Chevron*, the Supreme Court established a test for determining whether to defer to an agency's interpretation of a self-administered statute. This case was precipitated by the Environmental Protection Agency's (EPA) passage, under the Clean Air Act Amendments of 1977, of a regulation allowing states to treat all pollution-emitting devices in the same industrial grouping as though they were a single "bubble."[13] Prior to this regulation, Congress had amended the Clean Air Act to regulate—via "nonattainment"-State-established permit programs—"new or modified major stationary sources"[14] of air pollution, with the result that "several stringent conditions"[15] had to be met in order for permits to be issued for a new or modified stationary sou ce. Under the EPA's new regulation, plants could install or modify pieces of equipment without needing a permit if doing so would not increase the

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plant's total emissions. Led by the National Resources Defense Council (NRDC), several environmental groups challenged this "bubble provision" as contrary to the Clean Air Act. Following the U.S. Court of Appeals for the D.C. Circuit's decision to set aside the EPA regulation as contrary to the Act, the Supreme Court heard the case, investigating whether the "bubble provision" was "based on a reasonable construction of the statutory term 'stationary source.'"[16]

Writing for the majority, Justice Stevens established a two-part test for courts reviewing an agency's construction of a self-administered statute:

> First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.[17]

Employing this test, the Court held that the EPA's "bubble provision" was based on a reasonable construction of the statutory provisions, reversing the Court of Appeals' decision. Supporting a general understanding of agency autonomy, Stevens held:

> When a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail. In such a case, federal judges—who have no constituency—have a duty to respect legitimate policy choices made by those who do.[18]

The impact of *Chevron* reaches to this day, even as it has encountered limitations—for example, in the 2001 case *United States v. Mead*, in which Justice Souter rejected the *Chevron* doctrine. Souter limited the scope of administrative agency by stating that deference could be granted to agency interpretation only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority."[19]

II. Recent Legal Precedent: The Confusion Continues

The debate about agency authority and the scope, power, and type of agency rulemaking continued in the 2010 case *United States v. Magnesium Corporation* ("*Magnesium*"). In *Magnesium*, the U.S. government asserted that defendant U.S. Magnesium had not complied with stipulations of the Resource Conservation and Recovery Act of 1976 when handling five waste p oducts. In response, U.S. Magnesium asserted that the EPA had exempted the five wastes f om the provision at issue "in a prior interpretation of its own regulation"[20] and that the EPA could not now change that interpretation without "first complying with the notice and comment procedures of the [APA]."[21] The U.S. Court of Appeals, Tenth Circuit, vacated the district court's judgment in favor of U.S. Magnesium, instead finding that the E A was free to "change its mind and issue a new interpretation of its own regulations without assuming notice and comment obligations."[22] The court's reasoning depended on the issue of whether an interpretation of a regulation was "defin - tive," finding that it is binding—and, the efore, requiring a notice-and-comment period prior to subsequent agency changes in interpretation—only if it is definitive [23] Thus, the central issue to this case became: What constitutes a "definitive" interp etation of an agency's own regulation, such that it is binding and therefore would require a notice-and-comment period prior to subsequent agency change in interpretation?

U.S. Magnesium's defense relied on precedent from *Alaska Professional Hunters Ass'n v. FAA*[24] (*Alaska*), in which the D.C. Circuit found that the Federal Aviation Administration (FAA) had "significantly evise[d]" its previous "definitive interp etation" of its regulation, "effect[ively] amend[ing] its rule, something it may not accomplish without notice and comment."[25] The *Alaska* court's supporting precedent for its decision came from a contentious case, *Paralyzed Veterans of America v. D.C. Arena L.P.* (*Paralyzed Veterans*), which, along with *Alaska* subsequently, precipitated a circuit split as to whether an agency may alter its interpretation of its own regulation without notice and comment.[26] Ultimately, the *Magnesium* court demonstrates that the determination of whether a ruling is "definitive" must be made on a case-by-case basis.[27]

Likely aware of the controversial nature of its ruling, the *Magnesium* court notes that "one might worry that administrative law has simply abandoned regulated parties to the whims of an agency's arbitrary interpretive

reversals."[28] To quell regulated parties' fears, the court then offers a reminder that "at least two other layers of protection exist"[29] for the regulated public, which would be understood to have "reasonable and settled expectations"[30] following the enactment of relevant policies. The first is the powe , granted by the APA, of courts to review "agency action, findings, and conclusions" that they deem "arbitrary and capricious, an abuse of direction, or otherwise not in accordance with law."[31] The second is the Due Process Clauses of the Fifth and Fourteenth Amendments, which protect the right to fair notice prior to the imposition of penalties.

In 2015, the Supreme Court visited the issue in *Perez v. Mortgage Bankers Association*[32] (*MBA*), considering "whether the rule announced in *Paralyzed Veterans* is consistent with the APA."[33] Justice Sotomayor held in the negative, stating that the *Paralyzed Veterans* doctrine "is contrary to the clear text of the APA's rulemaking provisions, and it improperly imposes on agencies an obligation beyond the 'maximum procedural requirements' specified in the APA."[34] After noting that the precise meaning of "[t]he term 'interpretative rule,' or 'interpretive rule' . . . is the source of much scholarly and judicial debate,"[35] Sotomayor opts not to engage in that debate except to state that "the critical feature of interpretive rules is that they are 'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'"[36]

> *"Sotomayor adopts a reading of the APA that 'harmonizes with longstanding principles of our administrative law jurisprudence,' rather than leaning on a case-by-case approach as suggested by* Magnesium."

Sotomayor adopts a reading of the APA that "harmonizes with longstanding principles of our administrative law jurisprudence,"[37] rather than leaning on a case-by-case approach as suggested by *Magnesium*. The Court's reading is derived directly from the APA itself, with focus on Section 4, which delineates the "notice-and-comment rulemaking" process:

> First, the agency must issue a "[g]eneral notice of proposed rule making," ordinarily by publication in the Federal Register. § 553(b). Second, if "notice [is] required," the agency must "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." § 553(c). An agency must consider and respond to significant comments eceived during the period for public comment. . . . Third, when the agency promulgates the final ule, it must include in the rule's text "a concise general statement of [its] basis and purpose." § 553(c). Rules issued through the notice-and-comment process are often referred to as "legislative rules" because they have the "force and effect of law."[38]

Sotomayor notes that Section 4 of the APA states that the notice-and-comment requirement is not applicable to interpretive rules unless there is a statute requiring such notice and hearing.[39] Critically, this exemption of interpretive rules "is categorical, and it is fatal to the rule announced in *Paralyzed Veterans*."[40] *Paralyzed Veterans* had focused not on Section 4 but on Section 1, the Act's initial definition of " ule making" that included repeals or amendments of existing rules in addition to the initial issuance of new rules.[41] The *Paralyzed Veterans* court had reasoned that this definition indicated that, along with the notice-and-comment requirement for repeals and amendments, such a requirement must exist also for agency changes in interpretation of a substantive regulation in order not to violate the APA.[42] This approach, Sotomayor maintains, "conflates the di fering purposes of [sections] 1 and 4 of the Act": the former defines ulemaking, while the latter delineates rulemaking procedures that agencies must follow.[43] Thus, if an agency is required to have a notice-and-comment period prior to issuing a substantive rule initially, it must also have a notice-and-comment period prior to amending or repealing the substantive rule; conversely, if an agency is *not* required to have a notice-and-comment period prior to issuing an interpretive rule initially, such a period is not required prior to amending an interpretive rule.

The Court thereby granted executive agencies substantially more freedom to issue new interpretations of their regulations "without the detailed and time-consuming procedures or substantive standards of judicial review of the APA."[44] However, this freedom wields a double-edged sword: while one Administration might welcome it and make regulatory changes without jumping through judicial hoops, so, too, may the following Administration, which could then undo or reverse those changes.[45] Fur-

thermore, the effects of the *MBA* ruling reach likely every federal regulatory agency and their respective regulated parties, from businesses to individuals to state and local agencies.[46]

III. A Current Case Study: An Agency's Implementation of a Final Rule Following a Decade of Confusion

The U.S. Food and Drug Administration Amendments Act of 2007 (FDAAA), aimed to expand the FDA's authority to review new drugs and biologics, new uses for existing drugs, and medical devices. This Act further aimed to enhance the transparency of clinical trials by codifying requirements for registering and reporting summary results of such trials in a publicly accessible registry, like ClinicalTrials.gov, a clinical trials registry maintained by the National Institutes of Health (NIH). While this Act provided significant and valuable new requirements for the registration and reporting of clinical trial information, it also contained critical ambiguities, resulting in an inconsistent application of its provisions for almost a decade.[47]

Following critiques of FDAAA,[48] as well as a public comment period during which nearly 900 comments were submitted,[49] a Final Rule was developed and enacted by the NIH on January 18, 2017, with the goal of clarifying the guidelines for responsible parties and interpreting ambiguous clauses in FDAAA.[50]

While the Final Rule provides clarification on many ambiguities of FDAAA, reasonable minds may still disagree on some remaining points. Misconceptions could arise, for instance, regarding (1) standards for timely reporting of trial results, and (2) the criteria for extensions of certificates of dela . Furthermore, the NIH guidance put forward ahead of the Final Rule's implementation, while helpful in many respects, does not succeed in easing regulated parties' full transition to Final Rule modifications; instead, this guidance's informal p esentation and occasional divergence from the letter of the law may perpetuate select areas of ambiguity.[51]

A. FDAAA

FDAAA delineates the registration and results-reporting requirements that responsible parties[52] must fulfill when conducting applicable clinical trials (AC s). The goals of FDAAA—to greatly enhance the clinical-trial transparency and, in turn, to enhance physicians' ability to make the "most well-informed treatment choices with their patients"[53]—are extraordinarily important to public health. However, the Act's reception has not been entirely positive. Although "the primary goal of FDAAA is to enhance medical product safety,"[54] the rather quick timeline for clinical-trial reporting can result in the stark lack of accompanying discussion or conclusion. Submission of results—generally,[55] not later than one year following the primary completion date of a trial[56, 57]—may hinder full or even partial analysis by investigators.[58] Readers should note that responsible parties may (and generally do) request extensions to delay results reporting until 30 days post-FDA-approval of the indication being studied by fi ing certificates of extension (also known as certificates o delay).[59] However, many regulated entities, such as pharmaceutical companies, have been unsure as to whether FDAAA applied to trials studying unapproved drugs, particularly drugs that had never been approved before for any uses (i.e., initial-use drugs).

There was also ambiguity in the black-letter denotation of several of the Act's provisions. Indeed, enough confusion has emerged regarding certain terminology and clauses in FDAAA that the Final Rule, discussed in the next section, was enacted with the primary goal of clarification and interp etation. One example of ambiguous language in FDAAA is the definition of "applicable clin cal trial" (ACT). While, as stated above, the Act provides at least a partial definition for an ACT, not all terms in the definition we e adequately explained, with the result of many responsible parties' confusion as to which of their clinical trials were truly applicable.[60]

The Act defines an ACT as, generally, "a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of [FDAAA]."[61] In using the term "well-controlled investigations," § 505 of the Federal Food, Drug, and Cosmetic Act includes "clinical investigations, by experts qualified by scientific training and experience to evaluate the e fectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."[62] This description leaves room for confusion as to what, precisely, "controlled" denotes. The term could refer to all multi-arm interventional trials, studies measuring the impact of an intervention, a drug, or medical device, in different comparison groups. However, it was unclear if "controlled" was meant to include single-group studies in which no concurrent comparison was present.[63] For example, there might be a single-arm study without a placebo—i.e., "implicit" baseline—control; however, in the sense of the law, it could be controlled by historical—i.e., "explicit"—data.[64]

In situations in which the set of controlled trials is much narrower than the set of interventional trials, this dual connotation of "controlled" in the clinical-trial context can have widespread repercussions for public health.

Because the primary purpose of FDAAA is to enhance transparency of clinical-trial reporting, any confusion as to which trials are governed by the Act can result in underreporting of trials that, in fact, are intended to be governed by the Act, and in overreporting of trials not governed by the Act in order to "play it safe." In turn, medical practice and public health more generally will be adversely affected by incomplete reporting of the efficacy and safety of relevant drugs.[65]

B. The Final Rule

The Final Rule works to expand certain provisions in FDAAA. For example, while FDAAA stipulated an exact timeline for submission of basic results information for ACTs of products already approved for at least one use, the Final Rule broadened the requirement to apply to all ACTs, including those not yet approved.[66] By incorporating a checklist of inclusion criteria for ACTs, the Final Rule simplifies the evaluation of whether a particular trial is regulated by FDAAA.

Other important expansions in the Final Rule are its requirement that demographic information, notably study participants' racial and ethnic backgrounds, be included;[67] a requirement that additional types of adverse event information be reported;[68] and the provision of potential legal consequences for noncompliance.[69]

The Final Rule clarifies points of potential confusion in FDAAA regarding ACT results-submission deadlines. FDAAA provides a general submission deadline of one year after the earlier of (1) the estimated completion date of the ACT,[70] or (2) the actual date of completion.[71] It goes on to discuss how responsible parties might gain an extension if the ACT is studying "new drugs" or "new uses" of approved drugs:

> If the responsible party for an applicable clinical trial submits a certification that clause (iv)[new drug] or (v)[new use] applies to such clinical trial, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information . . . as required under the applicable clause.[72]

Following such a certification, a sponsor ma , in the case of a new drug, submit results 30 days following FDA marketing approval of the indication being studied. In the case of a new use of an already-approved drug, sponsors may submit results within the earlier of (a) 30 days following approval of the new use, (b) 210 days following the withdrawal of the new use from FDA consideration, or (c) 2 years following the submission of the certification.

The point of confusion concerns the need for such a certification, especially in the case of a trial studying a new drug. While many drug manufacturers generally submit trial results within 30 days following FDA approval, practices vary as to whether they signal to FDA by way of a certification their intention to do so. In a ecent article[73] discussing new drugs approved by the FDA, it was shown that certification was submitted for oughly 30% of ACTs with results submitted within 30 days of approval. One plausible reason for such omission is that, whereas clause (v) details conditions for submission in cases requiring certification, clause (iv) does not. Furthe - more, and perhaps more importantly, the above quoted clause (clause iii) is framed in the subjunctive, leading responsible parties to believe that clauses (iv) and (v) apply, but that (iii) is, at best, a courtesy, not a requirement.

Conversely, the Final Rule states unequivocally that the standard submission deadline for results recording is one year after the primary completion date (PCD),[74] defined as "the date that the final participant was ex - ined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated."[75] The Final Rule does not allow for more time between the PCD and the results-submission deadline.

However, the Final Rule does provide significant cla - ification egarding extensions of this timeline. Before the standard submission deadline has passed, a responsible party must submit a certification that an ACT is studying an FDA-regulated drug or device for an indication not yet approved, licensed, or cleared by the FDA for any use before the PCD of the ACT, and that the responsible party seeks to continue with product development or perhaps FDA approval, licensure, or clearance of the product under study.[76] Receiving an extension allows parties to submit results 30 days following the approval of the drug or indication being studied, subject to the following caveat: the Final Rule makes clear that the final deadline follo - ing an extension with certification must not exceed two years after the date on which the certification was su - mitted.[77] This two-year limitation applies to both ACTs studying a new drug and those studying a new use for an already approved drug. Therefore, the results-submission provision is appended to the new drug trials, and the submission requirements for certification a e rendered explicit.[78] This expansion serves as a simplification, allo - ing responsible parties to avoid second-guessing whether the two-year limitation applies to their ACTs.

The Final Rule also expands the procedure that responsible parties must follow when seeking a "good cause" extension under the statute.[79] FDAAA states succinctly that the Director of NIH may provide an extension

of the ACT reporting deadline if the responsible party "submits a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted."[80] It also allows the Director to grant more than one such extension for an ACT. Notably, FDAAA did not define "good cause," and so the Final Rule sought to provide clarity on that issue. The Final Rule begins by including the basic provisional allowances of FDAAA—namely, that responsible parties can request a submission-deadline extension for good cause and may make such a request more than once per ACT—and then provides further procedural guidance for both the request and an appeal of a request's denial.[81] However, even the added regulatory language excludes any definitional elaboration on the "good cause" te - minology, leaving room for confusion as to whether a requested extension properly would demonstrate "good cause."

In its overview of the proposed Final Rule, the NIH states its intention "to issue guidance on what might be considered 'good cause' under particular circumstances as soon as practicable," offering in the meantime "two situations that [it has] identified to date that [it] p oposed would constitute good cause"[82]:

> (1) The need to preserve the scientific integrity of an [ACT] for which data collection is ongoing, including situations in which the submission of results information for the primarily outcome(s) of an [ACT] would impair or otherwise bias the ongoing collection, analysis, and/or interpretation of data for secondary outcome(s) . . . ; and
>
> (2) Emergencies that would prevent timely submission of clinical trial results information, including situations in which one or more data collection sites were affected by natural disasters or other catastrophes outside the responsible party's or sponsor's control.[83]

To illustrate situations that would *not* be considered "good cause," the NIH included two other scenarios:

> (1) [A] request containing only a general statement without any specific eason for delay in data analysis (e.g., "data could not be analyzed fully within 12 months") . . . ; and
>
> (2) "[A]waiting journal publication."[84]

The NIH thereby elucidates the general categories that might, or might not, warrant a "good cause" submission-deadline extension. This approach—coupled with the NIH's stated intention to issue even more detailed guidance for the determination of what situations would constitute "good cause"—carefully avoids obfuscating a clear, yet flexible, egulatory structure.

The procedural changes to FDAAA introduced by the Final Rule have an impact on public health. For example, the certification p ocess described above is not merely an administrative formality; it has the function of signaling to researchers, and physicians responsible for choosing drugs for their patients, that the posting of results from an ACT may be delayed by FDA review. This case study illustrates the high specificity of agency guidance and ulemaking involved in delivering a substantive interpretation following a lengthy consultation process. Moreover, the intense detail within such agency guidance and rulemaking is tailored to the regulated industry. Such detail is, critically, beyond the scope of Congress' expertise and should be duly delegated to the relevant agencies.

IV. Conclusion: An Uncertain Future

The actual procedure set out in the REINS Act prioritizes speed above care and reason. For example, Senate debate concerning the approval of a regulation would be limited to two hours,[85] Senate debate concerning the disapproval of a regulation would be limited to 10 hours,[86] with the final decision by both Houses of Cong ess required within 70 days.[87] Critically, the Act would make all such regulatory decisions—which have, thus far, been shared by executive agencies and judicial review—exclusive to Congress, with courts' only role being to "determine whether a Federal agency has completed the necessary requirements . . . for a rule to take effect."[88]

Furthermore, should the so-called Midnight Rules Relief Act[89] be implemented as law, all of President Obama's regulatory acts in his last eight months of his term in office may be epealed "with one vote"[90] and "without threat of a filibuste ."[91] Yet a third act passed by the House, the Regulatory Accountability Act, would aim to "reform the process by which Federal agencies analyze and formulate new regulations and guidance documents, to clarify the nature of judicial review of agency interpretations, to ensure complete analysis of potential impacts on small entities of rules, and for other purposes."[92] This Act "would add dozens of hurdles to the regulatory process, potentially grinding all future rule-making by federal agencies to a halt."[93]

Rather than lend the purported clarity to the regulatory process, these three acts could obscure what Congress would be voting for or against. Indeed, the result—while not overtly articulated—could be obfuscation of procedure: the blockage of both the public and the judiciary from input before, during, and after Congressional decision making regarding regulations will result in height-

ened confusion among regulated parties. Furthermore, the process laid out by these three Acts lacks both expertise and ethics. Congress should not be the sole arbiter of major regulatory initiatives both because its members are not trained in the various fields of knowledge that inform regulatory development, and because such exclusive decision-making power would be intrinsically devoid of the checks and balances upon which our government was founded.

The intricate executive and judicial work done over more than 30 years, coupled with critical instances of public notice-and-comment periods, have allowed for a collaborative, ethical, and informed regulatory procedures. While Sotomayor's holding in *MBA* giving substantial rulemaking authority to agencies resulted in the potential for Administrations to undo one another's regulatory changes on a whim, the regulatory procedure itself has remained transparent and understandable. Should the Trump Administration implement the three proposed acts that would limit executive, judicial, and public influence on egulatory procedure, anyone other than Congress—i.e., the vast majority of regulated parties—can be expected never to know whether, how, or when they will be regulated in their various industries and personal choices.

Endnotes

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6. *Id.*
7. Indeed, the United States Attorney General categorized the various modes of agency action into three types of varying authoritative weight: (1) substantive, or legislative, rules, which are effectively equivalent to statutes; (2) interpretive rules, which are advisory in nature; and (3) general statements of policy, which offer advance public warning of how the agency will exercise its discretionary power. Because the latter two categories' informal direction does not require the notice-and-comment period that is required for the introduction of substantive rules, confusion can emerge in response to agencies' ostensibly varying interpretations of statutes and even their own previously implemented rules. Furthermore, confusion often arises as to whether a rule is substantive—and therefore requiring a notice-and-comment period prior to agency changes—or interpretive—and therefore *not* requiring a notice-and-comment period prior to agency changes. See for instance, Tom C. Clark, Attorney General's Manual on the Administrative Procedure Act (1947).
8. *Sweet v. Sheahan*, 235 F.3d 80 (2d Cir. 2000).
9. Breer and Anderson, *supra* note 5, citing *Shell Offshore, Inc. v. Babbitt*, 238 F.3d 622 (5th Cir. 2001).
10. Breer and Anderson, "Regulation Without Rulemaking: The Force and Authority of Informal Agency Action," citing *American Mining Congress v. Mine Safety and Health Administration*, 995 F.2d 1106 (D.C. Cir. 1993); *National Family Planning and Reproductive Health Assoc. v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992).
11. *Id.* at 14., quoting *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987).
12. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), https://www.law.cornell.edu/supremecourt/text/467/837 (last visited Jan 18, 2017).
13. *Id.* at 840.
14. *Id.* at 840.
15. *Id.* at 840.
16. *Id.* at 840.
17. *Id.* at 842–43.
18. *Id.* at 866.
19. *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001), https://supreme.justia.com/cases/federal/us/533/218/case.html (last visited Jan 18, 2017).
20. *United States v. Magnesium Corporation of America*, 616 F.3d 1129, 1131 (2010), http://caselaw.findla .com/us-10th-circuit/1535202.html (last visited Jan 6, 2017).
21. *Id.* at 1131.
22. *Id.* at 1131.
23. *Id.* at 1138.
24. *Alaska Professional Hunters Ass'n, Inc. v. F.A.A.*, 177 F.3d 1030 (1999), http://leagle.com/decision/19991207177F3d1030_11090/ALASKA PROFESSIONAL HUNTERS ASS'N, INC. v. F.A.A. (last visited Jan 12, 2017).
25. *Id.* at 1034.
26. United States v. Magnesium Corporation of America, *supra* note 20, at 1139.
27. Siding with circuits and commentators disagreeing with *Alaska*'s ruling, the *Magnesium* court focused on the distinction—as codified in section 553(b)(A) of the APA—between legislative and interpretive rules, stating, "[I]t doesn't matter whether an interpretive rule is the first or second or seventeenth in a series: on this view, none has to undergo notice and comment before taking effect." 1140. The court effectively aligns "legislative" with "definitive" and "interp etive" with "tentative," but it leaves unexplained how best to determine whether a rule is legislative/definitive or interp etive/tentative: "[t]rying to decide whether an interpretation is, in substance, definitive or tentative may in some cases prove challenging, much like the challenge that differentiating between substantive and interpretive rules has posed to courts for decades." See note 14. The court's ultimate finding that the E A had not intended its original interpretation to be definitive depended on U.S. Magnesium's inability to

demonstrate otherwise, as well as on the EPA's original report's having expressly described itself as "tentative." See note 13.

28. United States v. Magnesium Corporation of America, *supra* note 20 at 1143.
29. *Id.* at 1144.
30. *Id.* at 1143.
31. Administrative Procedure Act, 5 U.S.C. Subchapter II, 706(2)(A) (1946), https://www.archives.gov/federal-register/laws/administrative-procedure (last visited Jan 12, 2017).
32. *Perez v. Mortgage Bankers Association et al.*, 135 S. Ct. 1199 (2015), https://www.law.cornell.edu/supremecourt/text/13-1041 (last visited Jan 6, 2017).
33. *Id.* at 1203.
34. *Id.* at 1206, citing V*ermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 524, 98 S.Ct. 1197, 55 L.ed.2d 460 (1978).
35. *Id.* at 1204.
36. *Id.* at 1204, quoting *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 99, 115 S.Ct. 1232, 131 L.Ed.2d 106 (1995).
37. *Id.* at 1207.
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45. *Id.*
46. Barry M. Hartman et al., Supreme Court's Perez Decision Shines the Light on Federal Agencies' Authority to Use "Interpretations" (Often called Shadow Regulations) to Regulate Business K&LGates.com (2015), http://www.klgates.com/supreme-courts-emperezem-decision-shines-the-light-on-federal-agencies-authority-to-use-interpretations-often-called-shadow-regulations-to-regulate-business-03-19-2015/ (last visited Jan 18, 2017).
47. Miller, 2015.
48. *See, e.g.*, Curtis L. Meinert, *The US requirement to deposit trial data within a year is unworkable*, 347 BMJ f6449 (2013).
49. HHS takes steps to provide more information about clinical trials to the public, National Institutes of Health (NIH) (2016), https://www.nih.gov/news-events/news-releases/hhs-takes-steps-provide-more-information-about-clinical-trials-public (last visited Jan 6, 2017).
50. Deborah A. Zarin et al., *Trial Reporting in ClinicalTrials.gov — The Final Rule*, 375 N. Engl. J. Med. 1998–2004, 1 (2016).
51. Final Rule for Section 801 of the Food and Drug Administration Amendments Act of 2007 (42 CFR Part 11): Final Rule Webinar, (2016), https://www.nlm.nih.gov/bsd/disted/video/clinicaltrials/final ulewebinar1.html (last visited Feb 2, 2017). Even when there is no doubt that a regulation is legislative and therefore requires a notice-and-comment period prior to an agency's promulgating reinterpretation that carries the force of law, as does the Final Rule's substantive interpretation of FDAAA, an agency may sporadically comment on the regulation using interpretive modes. It thus may be difficult for egulated parties to decipher one mode from another, especially when guidance is issued in very casual formats like conference presentations.
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53. Genevra Pittman, *Study results take almost two years to be released*, Reuters Health News, March 7, 2013, http://www.reuters.com/article/us-study-results-idUSBRE9251J220130307 (last visited Jan. 6, 2017).
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55. Food and Drug Administration Amendments Act of 2007, *supra* note 52, at 801(j)(3)(E)(iii)-(vi).
56. *Id.* at 801(j)(3)(E)(i)(I)-(II).
57. "Primary completion date" indicates "the date that the final participant was examined or received an intervention for the purposes of final collection of data for the *primary outcome*, whether the clinical study concluded according to the pre-specified p otocol or was terminated" (emphasis added). "Study completion date" indicates "the date the final participant was examined or received an intervention for purposes of final collection of data for the *primary and secondary outcome measures and adverse events* (for example, last participant's last visit), whether the clinical study concluded according to the pre-specified p otocol or was terminated" (emphasis added). *See* ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies (2017), https://prsinfo.clinicaltrials.gov/definitions.html (last visited Jan. 30, 2017).
58. Meinert, *supra* note 48.
59. One of critics' concerns is that the reporting timeline for clinical trials involves the potential for discrepancies between results reported to ClinicalTrials.gov and those discussed in later subsequent publications. Meinert, *"The US Requirement to Deposit Trial Data within a Year Is Unworkable."* To fix this potential problem, Meinert argues, FDAAA should be revised to allow for publication as an acceptable deposit on ClinicalTrials.gov, and to broaden the timeline from one year to three years. Such changes would allow adequate time for publication or, alternatively, the deposit of trial results even if they have not yet been published. *Id.* However, Ross refutes this timeline concern, noting, "publication is not the same as results reporting: it takes longer." Joseph Ross, *The Importance of FDAAA Section 801: Clinical Trial Results Reporting*, JAMA Internal Medicine Blog (2013), https://internalmedicineblog.jamainternalmed.com/2013/11/13/the-importance-of-fdaaa-section-801-clinical-trial-results-reporting/ (last visited Jan 6, 2017). Having summary results available at one year, Ross maintains, furthers the goals of informed decision-making by physicians and their patients and of improved scientific research. Moreover, researchers understand that publication of results may diverge, in certain ways, from summary results owing to journal requirements, or to inclusion of additional data following the final completion of the trial
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75. ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies, *supra* note 57.
76. E-CFR, *supra* note 67, at 11.44(b)(1) and (c)(1).
77. *Id.* at 11.44(c)(2).
78. The only exception to this two-year limitation is with respect to the submission of partial results information. *Id.* at 11.44(d).
79. *Id.* at 11.44(e).
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Fair Warning: Is the Justice Center Statute Unconstitutionally Vague?

By Caitlin J. Monjeau

I. Introduction

Lawmakers and rulewriters often find themselves responding to emerging threats, sometimes by writing laws or rules that they intend to capture novel or especially troublesome behavior—like vagrancy, gang activity, or the abuse of vulnerable people. Yet sometimes these policymakers overreach by writing definitions that a e vague or ambiguous. Laws or rules like these can ensnare people who have engaged in only innocent behavior or, at least, behavior that is not blameworthy. These kinds of rules and laws are troublesome not simply because they are overbroad, but because they delegate too much discretion to law enforcers to decide just whose behavior fits within a vague definition.

The New York State Justice Center for the Protection of People with Special Needs, commonly known as the Justice Center, has at its disposal a set of definitions that are so vague that they might be construed as unconstitutional as applied in certain circumstances under state and federal doctrines. This observation is not offered to undermine the need to investigate allegations that caregivers have harmed people with disabilities in their care—a need that is obvious given the numbers of individuals with disabilities who receive care in New York each year. The Justice Center, along with provider agencies that are both state-run and privately maintained, has a duty to investigate allegations of mistreatment. Nonetheless, neither investigators nor law enforcement should be given broad definitions that they may wield with only their own discretion as a safeguard. These definitions a e so broad, in fact, that read literally they protect vulnerable people from far more than physical or sexual abuse, for instance—they seem to forbid even the possibility of mental annoyance. The people who might become targets of Justice Center investigations have a right to know which conduct might imperil their future employment, as Justice Center findings might.

II. What Is the Justice Center?

A. Purpose

Governor Andrew Cuomo signed a bill creating the Justice Center on December 17, 2012. The enabling legislation, the Protection of People with Special Needs Act ("the Act"), stated as its purpose the need to "strengthen and standardize the safety net for vulnerable persons, adults and children alike, who are receiving care from New York's human service agencies and programs."[1] New Yorkers with special needs receive care in many different settings, including both day and residential programs, and under the authority of six state agencies that operate, license, or certify those programs: the Office of Mental Health (OMH), the Office o Alcohol and Substance Abuse Services (OASAS), the Office for Peopl with Developmental Disabilities (OPWDD), the Office fo Children and Family Services (OCFS), the Department of Health (DOH), and the State Education Department (SED).[2] Hundreds of thousands of people are served by providers governed by the health-oriented agencies alone. According to OPWDD, more than 128,000 individuals with developmental disabilities receive services under that agency's auspices.[3] OMH-regulated providers care for more than 700,000 individuals.[4] OASAS providers served an average of nearly 97,000 people each day in 2015.[5]

Given this fragmented system, the Act's stated purpose was to create uniform safeguards, policed by the Justice Center, to allow the state to effectively respond to allegations of abuse and neglect.[6] To this end, the Act created a register of individuals "found responsible for egregious or repeated acts of abuse or neglect"; placement on the register was intended to prevent a person from working with vulnerable people.[7] The legislation charged the Justice Center with developing a code of conduct for those who work with vulnerable people and staffing a hotline for reporting abuse, neglect, and "significant incidents" involving vulnerable people.[8] The Act also empowered the Justice Center to investigate alleged abuse and neglect, hold wrongdoers accountable, and require providers to take corrective action to prevent recurring malfeasance.[9] Responding somewhat to criticism that one state agency was not the best choice to police other state agencies, the statute also required an independent agency to provide federally mandated oversight of the state's care of individuals with disabilities.[10]

B. Powers and Organization

An executive director, appointed by the governor, leads the Justice Center. Within the agency, a special pros-

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ecutor is charged with investigating and prosecuting crimes involving abuse and neglect of vulnerable persons and cooperating with district attorneys and local law enforcement with concurrent jurisdiction over such investigations and prosecutions.[11]

Practically, if the Justice Center receives a report of abuse or neglect through several channels—including a hotline, a web-based form, and provider self-reports—its investigators may consider the allegations and issue a Report of Substantiated Finding (RSF). An individual, perhaps an aide, named in a report like this will read that the Justice Center concluded, by a preponderance of evidence, that the aide abused or neglected an individual. The aide will also learn the category of the substantiated abuse or neglect, which ranges from category 1 for the most serious to category 3 for the least serious.[12]

"The Act created a register of individuals 'found responsible for egregious or repeated acts of abuse or neglect'; placement on the register was intended to prevent a person from working with vulnerable people."

The categorization for the substantiated allegation is a nontrivial matter for an individual; a category 1 allegation includes serious physical abuse, sexual abuse or, "other serious conduct"; a category 1 finding will mean that the individual is placed on a list known as the Staff Exclusion List (SEL), and may never again be employed by an agency subject to the Justice Center. This is a professional death sentence. Category 2 and 3 findings a e for less-serious offenses, and may be sealed after five years, except that a second category 2 finding within two years of a similar category 2 finding will be elevated to category 1. Individuals with category 2 (but not category 3) findings a e not placed on the SEL, but provider agencies will know that the affected individual has had the finding, and may consider the finding in its employmen decisions.

Individuals have 30 days to challenge an RSF with a request for amendment to the Justice Center, which it may refuse. Thereafter, an individual must challenge an RSF in a hearing before an administrative law judge. However, direct-care employees are not likely to take these reports to hearing, as many direct-care employees are minimum wage workers and are not likely to be able to afford counsel to challenge an RSF.

III. Significant Incident, Neglect, and the Limits of Punishable cCnduct

Conduct that falls into any one of nine categories must be reported to the Justice Center, including any conduct that meets the definitions for "neglect" or a "si - nificant incident." Both definitions e sweeping and, potentially, problematic.

A. Neglect

Neglect includes

> any action, inaction or lack of attention that breaches a custodian's duty and that results in or is likely to result in physical injury or serious or protracted impairment of the physical, mental or emotional condition of a service recipient.[13]

This definition captu es a wide range of actions—or failures to act—and includes not just actual injury, but likely injury, and at that not just physical injuries, but mental or emotional harm as well. Neglect might include obvious wrongful actions, like withholding food or water from a person who cannot feed herself, but it might also include actions that seem significantly less culpable. Co - sider, for instance, an aide who arrives to work in a bad mood one day. Perhaps he arrives at a group home and is curt or snappish when speaking with clients, preoccupied with bad news in his personal life. In turn, one of the clients in this group home becomes so upset that she is inconsolable and cannot participate in normal programming because she is so distraught. Is this neglect? Does the outcome change if the aide uses coarse language, or has a verbal altercation with another aide? In any of these cases, a custodian or mandated reporter might read the definition of neglect and conclude that a eport must be made to the Justice Center. Thereafter, the aide who had a bad day might find himself the subject of a eport of substantiated finding of neglect.

B. Significant Incidents

The definition of a "significant incident" also capt es behavior that does not actually cause harm to a service recipient:

> "Significant incident" shall mean an i - cident, other than an incident of abuse or neglect, that because of its severity or the sensitivity of the situation may result in, or has the reasonably foreseeable potential to result in, harm to the health,

> safety or welfare of a person receiving services[.][14]

This definition hinges on the concepts of "severity" and "sensitivity," which are not defined in statute, and surely capture a wide variety of actions or inactions that merely "may" or have the "reasonably foreseeable potential" to harm "health, safety or welfare." Consider again the group home aide, but this time perhaps he works at a substance use disorder facility. He arrives at work one day as usual. One of the new clients living in his home was once severely beaten and abused by someone who happened to resemble the aide; she becomes deeply upset by the resemblance. She shuts herself in her room, despondent, and threatens to harm herself as the painful memories return. Is this a significant incident? Again, a mandated reporter might reasonably conclude that it is, and contact the Justice Center. Nothing but investigatory or prosecutorial discretion stops the Justice Center from issuing a report of substantiated finding in this situation, particularly because this definition includes no intent provision at all. If the aide knew that this client was tormented by her past trauma and went out of his way to upset her, he is surely more culpable than an aide who had no idea that he could trigger a reaction like this. A person should be able to predict (and avoid) the kind of actions that will lead to serious, possibly career-ending repercussions, even criminal prosecution. The aide who unwittingly harms a vulnerable person should not be punished for something he cannot control.

IV. Unconstitutional Vagueness: Does the Act Give Fair Notice of the Conduct It Prohibits?

Due process of law demands that statutes or regulations not be so vague "as to be really no rule or standard at all."[15] After all, "laws must provide explicit standards for those who apply them."[16] Federal courts have held vague laws unconstitutional on this point for several reasons. First, laws must give fair warning: the law must be specific enough that a person has a easonable chance to understand what actions are prohibited and avoid them accordingly.[17] Second, vague laws delegate too much authority to law enforcement officials, courts, and egulators, which opens the legal system to arbitrary or discriminatory applications.[18] When challenged, statutes or regulations that do not touch constitutionally protected conduct, like speech or assembly, are evaluated for constitutionality as applied.[19]

In New York courts, this reasoning has evolved into a two-part test applied to discern whether the statute is unconstitutionally vague: first, the statute must be suf ciently definite that a person of o dinary intelligence has fair notice that conduct is prohibited. Second, the statute must give implementing officials clear standa ds for enforcement.[20] This requirement applies to both civil and penal statutes.[21]

Policymakers have wrestled with this issue for decades. For instance, a statute in neighboring New Jersey that attempted to define a "gangster" using b oad and ambiguous terms was held unconstitutional.[22] The punishment for conviction was a fine of up to $10,000 or 2 years' imprisonment, or both.[23] The U.S. Supreme Court rejected the reasoning of New Jersey's high court, which tried to salvage the statute by appealing to dictionary definitions and elying upon the likely intentions of the drafters. Instead, the Court found the statute unconstitutional because it did not specifically condemn a pa ticular act or omission, and used language "so vague,

"Worthy policy ends will not save a statute that does not define its key terms."

indefinite and uncertain that it must be condemned a repugnant to the due process clause of the Fourteenth Amendment."[24] Worthy policy ends will not save a statute that does not define its key terms. The Justice Ce ter's enabling legislation should be scrutinized with this requirement in mind.

A. Is the "Neglect" Definition Vague?

Specificall , both the definitions of "neglect" and "significant incident" in the Justice Center statute p esent possible vagueness problems.[25] Turning first to the defi tion of neglect, a phrase-by-phrase review of its language illustrates just how much conduct the statute captures.[26]

In the case of neglect, intent appears totally irrelevant in assessing whether a custodian has violated the statute. The statute includes not only affirmative actions and "sins of omission," but also unwitting violations of statute because it includes not only "action" and "inactions," but also "lack of attention." A group home aide is plausibly liable for neglect in each of the following scenarios:

- Serving a client who cannot feed himself food but removing the meal before the client can eat.
- Deciding not to feed a client who cannot feed himself to punish the client.
- Not feeding a client out of a mistaken belief that the client has eaten already.

Perhaps each of these behaviors should be punishable by statute, but it is striking that the neglect defin -

tion takes a strict liability approach to this conduct. Any behavior—or lack thereof—that could have a range of results is swept into the statute. That a statute imposes strict liability alone may not necessarily trigger the void-for-vagueness doctrine, but because it captures so much behavior, it sets up the statute's staggering breadth.

Similarly, neglect includes conduct that may not result in any negative outcome for a client—so long as the outcome is "likely." The language includes behavior that "results or likely results in serious or protracted impairment." This is ostensibly to punish behavior that results in a "near miss," or an outcome that was not horrific for a service recipient only through chance. On its own, this provision might not be objectionable, but combined with the breadth of the action/inaction/lack of attention language discussed above, this provision apparently captures any mistake a person might make in the field. This is alarming.

Let us return to the aide who is feeding a person who can't feed himself. The aide who mistakenly believes a client has eaten already may realize hours later that the person receiving services has missed a meal. The aide who immediately procures a meal for the client, who is otherwise well-nourished and well-cared-for, has probably not caused any harm. Compare this person with a second aide, who hates his job, hates people with disabilities, and likes tormenting a physically disabled person by showing her food but not allowing her to eat for days on end.

Both individuals have apparently committed neglect under the Justice Center's definition. One person's conduct was intentional, the other's was accidental; one person's conduct caused cruel harm, while the other's a temporary delay and no lasting harm.

Moreover, in the case of neglect, the impairment (or likely impairment) to a service recipient need not be serious; it need only be "protracted." Does this mean that a lack of attention that could likely result in harm that lasts longer than usual is prohibited conduct? Neither "serious" nor "protracted" is defined in the statute. Descri - tive terms like these are often not defined, as they set broad standards as opposed to more specific ules. Yet again combining this lack of specificity ac oss the neglect definition captu es an incredible variety of behavior.

Finally, the harm that a service recipient actually suffers or may suffer is part of this equation as well. Here too one might argue that the language is so vague as to capture just about anything, as it includes not just physical harm, but harm to a person's mental or emotional condition. Just what is a likely protracted impairment to one's mental or emotional condition? Does anger count? Does annoyance? Sadness? And how would a custodian know that such an outcome is *likely*?

Under the New York version of the void-for-vagueness test, one must ask whether this definition gives a person of ordinary intelligence fair notice of prohibited conduct, and whether implementing officials have clear standards for enforcement. While the statute includes a non-exhaustive laundry list of behavior that constitutes neglect,[27] this key definition does not warn a person of much, if anything. The neglect definition can su ely ensnare truly harmful, blameworthy behavior that deserves punishment. Then again, it can also sweep in behavior that causes only potential harm without any bad intent. That these two disparate kinds of behavior fall within the same definition suggests vagueness indeed. By imposing strict liability on conduct that need only possibly cause harm to a vulnerable person, this definition advises pe - ple of very little.

As to guidance for the regulator, the Justice Center, this definition manifestly leaves enfo cement to that entity's discretion. One might protest that the Justice Center's staff knows better than to punish mistakes that caused no harm, and that they focus their energy on true threats to the safety and welfare of people who cannot speak for themselves. Maybe so. Yet this is no protection for people who might receive a RSF if the agency decides to adopt a zero-tolerance approach to enforcement. The category classification that applies to substantiated findings—c - egory one is reserved only for "serious conduct," while categories two and three are for less culpable behavior—does not meaningfully restrict the Justice Center's direction. Here too the Justice Center may decide which conduct is "serious" and which conduct is not. Consequently, neither the regulator nor its regulatory target can predict with much certainty what punishment might attach to neglect in this context.

B. Is the "Significant Incident" Definition Vague?

The definition of "significant incident" is subject t the same difficulties that face "neglect": many of the key terms implicit in the definition a e undefined, and quite broad.

Significant incidents include any incidents that a e "severe or sensitive" enough to warrant a report, even though they do not fit other definitions of eportable incidents. This is essentially a catch-all provision that appears intended to catch bad behavior that the drafters could not anticipate. Neither "severity" nor "sensitivity" is defined. Imagine that an adult with substance use disorder living in an OASAS facility goes for a walk on a snowy day. He slips on ice covered by snow just outside the facility's front door and breaks his leg. A direct care employee of the facility was nearby having a cigarette, and saw the

man fall. The employee had walked on the sidewalk himself and knew it was icy, and does not immediately understand that the man is really hurt, chuckles at the dramatic fall and waits for him to get up on his own. After a few moments, the employee realizes what has happened and rushes inside the facility to call for help. The man is later rushed to a hospital, and struggles with the fact that he needs pain medication to handle this injury.

Is this a severe or sensitive incident? Perhaps—an individual who struggles with controlled substances has an injury that compels him to take them, and he was injured on facility property while an employee looked on. Hypothetical scenarios aside, the "severity and sensitivity" language is broad enough to capture freak accidents, like this one.

Just as was true in the definition of neglect, the inc - dent need not actually result in harm—significant inc - dents "may result in, or ha[ve] the reasonably foreseeable potential to result in" harm to the health, safety, or welfare of a vulnerable person. What if the man who slipped on the ice did not break his leg, but had only a bruise? Is an employee who knew about an icy walkway and did not warn or immediately help a person who falls culpable for behavior like this—even if there is no harm done? So much depends upon the Justice Center in a scenario like this. A reasonable facility or employee could probably report something like this in an abundance of caution and would have to simply hope that the investigator or attorney reviewing the file decides in the facility's or employee's favor.[28]

V. Conclusion

Vague laws and rules are pernicious—they only poorly deter behavior because they do not clearly warn people about what not to do, and they can lead to inconsistent enforcement because they shift so much discretion to regulators. The definitions at the heart of the Justice Center's incident monitoring mission are problematic for these reasons as well. Neither the definition of "neglect" nor the definition of "significant incident" fairly warns facility or its employees about the kind of behavior they must avoid. Both take a strict liability approach to behavior that causes perhaps only theoretical harm, and both therefore provide relatively poor guidance to the ordinary person who must interpret the law. For the same reason, these definitions task the Justice Center with d - ciding which behavior is problematic, and which is not.

Moreover, the fact that the absurd hypothetical scenarios above are plausible applications of these definitions shows that these standa ds are manifestly unreasonable. No reasonable person would expect that vulnerable people are entitled to a life free from even the slightest mental annoyance, which is how this statute reads. People with disabilities, mental health issues, or substance use disorder will experience frustration and inconvenience in their lives. This statute was passed to protect them from physical, sexual, and emotional abuse to which they are uniquely vulnerable, not shield them from slight annoyances.

Without specificity about the kind of conduct that is forbidden and punishable, the Justice Center invites direct service workers and agencies alike to report incidents that may be no more than accidents or mistakes. With hundreds of thousands of individuals receiving care from facilities subject to the Justice Center, the effect of vague definitions like these may be counte -productive—facilities and their employees have incentives to over-report, as failing to report can itself be punishable behavior. This leaves an agency with limited resources to sift through thousands of reports of relatively innocent behavior.

More to the point, this vagueness invites litigation concerning the constitutionality of the statute itself. When (and if) challenged on appeal, it is possible that New York State courts might interpret these statutory definitions in a way that saves them from an unconstitutional interpretation. Then again, doing so would seem to conflict with the plain meaning of the text. All of this invites a court to strike these definitions as void for vagueness—which would, in turn, leave the Justice Center without any statutory basis to address neglectful behavior or truly serious behavior that defies categorization. This unsavory ou - come might be avoided if the Legislature revises these definitions befo e a challenge comes to pass.

Endnotes

1. Act, Part A, Section 1.
2. Act, Part A, Section 1; Section 550(4) (defining "state oversight agency" to include these entities).
3. https://opwdd.ny.gov/opwdd_about/overview_of_agency
4. https://www.omh.ny.gov/omhweb/about/
5. https://www.oasas.ny.gov/ODR/CD/ADE2015.cfm
6. Act, Part A, Section 1.
7. *Id*.
8. *Id*.
9. *Id*.
10. *Id*.
11. Section 3, re: Article 20, Section 552 (2)(a). A recent Supreme Court decision clouds this issue somewhat. *See People v. Viviani*, No. 6-7976 (Albany Sup. Ct.) (Breslin, J.) (requiring a district attorney to retain the ultimate prosecutorial responsibility for any Justice Center criminal case).
12. A category 4 exists but is applied only to agencies, rather than individuals.
13. Social Services Law § 488(1)(h).
14. Social Services Law § 488(1)(i)

15. *Champlin Refining Co. v. Corp. Comm'n of Ok.*, 286 U.S. 210, 286 (1932).
16. *Grayned v. City of Rockford*, 408 U.S. 104, 109-10 (1972).
17. *Id.*
18. *Id.*
19. *United States v. Nat'l Dairy Prods. Corp.*, 372 U.S. 29, 36 (1963).
20. *People v. Stuart*, 100 N.Y.2d 412, 420 (2003); *In re CRP Sanitation, Inc. v. Solid Waste Comm'n of Cnty. of Westchester*, 927 N.Y.S.2d 384, 386 (2d Dep't 2011).
21. *Montgomery v. Daniels*, 378 N.Y.S2d 1, 15 (1975).
22. The statute reads: "any person not engaged in any lawful occupation, known to be a member of any gang consisting of two or more persons, who has been convicted at least three times of being a disorderly person, or who has been convicted of any crime in this or any other State, is declared to be a gangster[.]"
23. *Lanzetta v. New Jersey*, 306 U.S. 451, 451 (1939)
24. *Id.* at 458.
25. While the agencies that regulate entities subject to the Justice Center have promulgated regulations that sometimes define other conduct that is reportable, this article focuses only on the statutory definitions p esent in Section 488 of the New York Social Services Law.
26. *See* Social Services Law § 488(1)(h), (i).
27. Social Services Law § 488(1)(h)(i)-(iii).
28. As the Justice Center has been the continual target of criticism from certain activists and media outlets, one wonders whether investigators might be more likely to cite facilities or employees for conduct given this scrutiny. *See, e.g.*, Michael Virtanen, *NY Agency Has No Record of Required Referrals of Abuse Cases*, Associated Press, Oct. 12, 2016, https://apnews.com/cf079224f7db499d8fe1bd28fade2b0c/ny-agency-has-no-record-required-referrals-abuse-cases.

Land of the Free, Home of the Brave? Limits on Autonomy and Risk-Taking in Modern American Sport

By Amanda Zink, JD, MA

"Land of the free…home of the brave." Our national anthem enshrines these core American values, and yet, "freedom" and "bravery" have been subject to a wide variety of legal and moral checks throughout our country's history. While this celebrated lyric precedes virtually every major sporting event in the U.S., athletes are no exception to the caveat between the lines: just not *too* free, or *too* brave. Athletes must consent to myriad constraints on their on- and off-field behaviors that go well beyond wha most other employees must endure. In addition to requiring regular invasive tests for performance-enhancing and recreational drugs as well as "morals clauses" governing personal conduct, player contracts and collective bargaining agreements often ban numerous otherwise legal activities—including many *sports*—because they're too dangerous. A standard NBA contract prohibits riding mopeds and motorcycles, auto-racing, hang-gliding, and skydiving;[1] the New York Yankees once outlawed log-rolling and the Washington Nationals won't let players pilot a plane;[2] UFC—which promotes one of the most dangerous sports in existence—prohibits snowboarding, wakeboarding, bungee jumping, and horseback riding;[3] and the NFL simply disallows "any activity other than football which may involve a significant risk of personal injur ."[4]

Leagues, teams, and other sports organizing bodies clearly have a vested interest in keeping their athletes safe, in peak physical condition, and in line with "socially responsible" moral standards, and players and players' unions are perfectly free to contractually agree to such terms. But with astronomical health care costs driving an incendiary national debate, what does *society* have to say about letting people play sports and engage in recreational activities[5] that entail significant risks of injury o even death? Given typically broad state and municipal authority to regulate matters affecting public health, the surprising truth is—not very much. American law has traditionally proven more interested in who should pay for sport-related injuries than in reducing them in the firs place, and the legislature and judiciary usually default to insulating facility operators and team personnel from liability on the basis that an athlete "assumed the risks." This stems from a long-standing value judgment that sports are desirable and should be vigorously promoted—a position based in part on the many health *benefits* of athletic endeavors, but one that has remained largely impervious to the changing landscape of sports, increased risks, improved medical understanding, and shifting public perceptions. Where society does impose broad restrictions upon certain activities, a moral component is almost always present, and even these instances are rare. However, as recent legal developments in the areas of sport concussions and extreme sports suggest, society may be justifiably willing to reassess the legality and liability schemes of certain activities when the health and safety risks alone reach a sufficiently high th eshold.

I. Paternalistic v. Non-Paternalistic Regulation

An initial distinction must be made regarding society's general tolerance in allowing and even promoting dangerous sport-related behavior—this applies only to letting individuals assume risks to themselves. Conversely, constraining one person's freedom is generally permissible when necessary to protect others. This is why speed limits exist, and why cities including New York prohibit street racing and vehicular stunts. When laws exist primarily to protect people from themselves, however, they are deemed paternalistic. This is not to say such laws do not exist: mandatory seat belt laws are a classic example—they protect only the person wearing the seat belt, and no others. Paternalistic regulation is generally frowned upon, however, since it interferes with individual autonomy, and requires adequate justification. Oftentimes, the justification includes one or more asserted non-paternalistic bases, thus, the line is not always clear-cut.

For example, New York is one of 20 states that now require motorcycle riders to wear helmets. This may not seem particularly egregious given how dangerous motorcycling is: it accounts for 14% of all traffic fatalities natio - wide (~5,000 per year, with an additional ~90,000 injuries) despite motorcycles comprising less than 1% of all vehicles on the road. Surely anticipating the outcry against even this minimally intrusive, high-reward public health initiative,[6] the NYS Department of Health notes that not only were 1,829 motorcyclists saved by wearing helmets in 2008, but $14.8 billion in economic costs would have been saved if helmet laws had been in place from 1984-2002. Claiming reduced social costs is a classic method of asserting a non-paternalistic basis for paternalistic regulation.

This article seeks to examine paternalistic restrictions on sports predicated on both moral and health/safety rationales, with the caveat that it is frequently impossible to completely isolate them from non-paternalistic considerations.

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II. Moral Restrictions on Sport

As will be detailed below, the line is also frequently blurry when it comes to whether a paternalistic regulation derives from a health and safety or a moral justification Generally speaking, however, banning an activity outright must meet a lofty bar to withstand public scrutiny, and this usually involves the presence of a moral factor. This is reflective of the fact that society tends to take a mo e black-and-white approach to issues concerning moral judgments in general, but governance of health and safety issues without moral stigmas is more nuanced. An illustrative example is U.S. drug policy following the "war on drugs" like LSD, crack cocaine, and marijuana, contrasted with relatively lax restrictions on cigarettes, which invoke no moral concerns but kill exponentially more Americans at 480,000 a year.[7]

The classic example of a "sport" banned on moral grounds[8] is dwarf tossing, which was portrayed in *The Wolf of Wall Street* and describes the "attraction in which dwarfism-a fected persons wearing special padded clothing or Velcro costumes are thrown [as far as possible] into mattresses or at Velcro-coated walls."[9] A related practice involves affixing a dwarf to a skateboa d to serve as a bowling ball, and thrusting him or her into pins. Dwarf-tossing and dwarf-bowling became popular enough for Florida to outlaw them in 1989, and in 1990 New York followed suit by signing a bill forbidding the practices in bars (which was said to amount to a total ban since the sport was not practiced elsewhere—but perhaps Wall Street was an oversight).

These bans were based purely on morality and not on the physical welfare of little people. In passing the legislation, Governor Mario Cuomo stated: "Any activity which dehumanizes and humiliates these people is degrading to us all. This bill…declares these bizarre games to be debased."[10]

Dogfighting and cockfighting e also banned in the United States. Dogfighting constitutes a felonious o fense in all 50 states as does cockfighting in 40 states. Thes practices clearly invoke the safety and welfare of *animals*, but it's hard to imagine the lawmakers behind the cockfighting statute we e solely concerned with cruelty to chickens given that we consume 8 billion chickens and 50 billion eggs every year, many of which are raised through notoriously cruel factory farming practices (which are essentially exempted from animal cruelty laws). While one might more easily imagine outrage associated with forcing dogs, which we keep as beloved pets, to fight on another to bloody deaths, the reality is that the intensity of crackdowns on both types of fighting is ooted in their associations with other criminal activity, including "gangs, narcotics, illegal weapons possession, public corruption, and various violent crimes."[11] One study found that a full 70% of animal-fighting o fenders had been arrested for other felonies. New York was one of the first states to t eat animal fighting seriously: dogfighting has been a felo punishable by up to four years in prison since 1867, cockfighting has been banned since 1881, and in 20 1 Governor Cuomo signed legislation further cracking down on spectators of both sports.

III. Restrictions Based on a Blend of Health and Moral Considerations

Despite society's historical reluctance to prohibit even dangerous sports, the exponential rise in "extreme" sport participation over the past several decades has presented novel challenges for lawmakers. One such sport, mixed martial arts or "MMA," has been analogized to both "human cockfighting" and "human dogfighting," and seemed to raised New York's safety and morality hackles in equal measure.

New York was the 50th and final state to legaliz MMA, opening the door just last year for the sport's leading promotor (UFC) to host events in the Empire State. Concerns about the "no holds barred" brutality of the sport certainly contributed to resistance, but naysayers voiced opposition rooted in morality even more loudly, with some lawmakers forgoing political correctness altogether. Democratic Assemblyman Daniel J. O'Donnell asserted: "Two naked hot men rolling around on top of each other trying to dominate each other—that's gay porn with a different ending." Others have accused UFC of fostering a tolerance of rape and domestic violence, and a South Dakota state legislator analogized it to child pornography, meth, and feeding people to lions.[12]

Even many who voted in *favor* of legalizing MMA did so grudgingly. Said one backer: "It's a terrible, nasty, violent sport…[but] at least now we'll be able to regulate it."[13] Republican Assemblyman Stephen F. McLaughlin conceded that his personal feelings need not govern: "I'm not a particular fan of MMA but I believe in freedom and opportunity. There are a lot of people that enjoy this sport."

While New York overcame its blanket moral opposition to MMA, however reluctantly, it took rather extraordinary measures to address the health and safety concerns that remained. Much to the chagrin of promoters, the new legislation tacked a $1 million traumatic brain injury insurance policy onto (more moderately increased) general medical insurance requirements for each fighter in an combat sport contest. This has especially vexed the grassroots clubs that serve as development sites for promising sparrers, with one boxing promoter forced to limit the number of bouts he could host due to a six-fold increase in costs under the new rules.

Economically onerous requirements represent an additional, more indirect means of curbing a sport's proliferation. New York's imposition of the highest insurance

requirements in the country for boxing and MMA were reflective of its esidual opposition to the sport, but as will be discussed in the following section, economic *incentives*, such as through limited liability, comprise the more typical approach to ensuring the sustainability and growth of sports.

IV. Health and Safety Restrictions on Sport

Assumption of Risk

New York has one of the best-developed primary assumption of risk doctrines in the sports and recreation context and it serves broadly to limit liability of a defendant wherever a participant consents "to those injury-causing events which are known, apparent or reasonably foreseeable consequences of the participation."[14] Where these conditions are met, assumption of risk modifie traditional tort law's assessment of a defendant's duty of care to plaintiff, and "the [applicable] standard includes whether the conditions caused by the defendant's negligence 'are unique and create a condition over and above the usual dangers that are inherent in the sport.' A 'showing of some negligent act, or inaction, which may be said to constitute a substantial cause of event which produced the injury is necessary'."[15]

The doctrine also requires the plaintiffs to be aware of, have the capacity to appreciate, and voluntarily assume the risks from which their injuries arose. Assessment of these elements must include consideration of the plaintiff's skill level, experience, and age. For example, the Second Department held that assumption of risk did not bar recovery by a 13-year-old plaintiff when she slipped and injured herself on a ground level support bar at a track and field event sponso ed by a league, given "her age, her level of experience, and the league's failure to furnish [her] with adequate instructions."[16] Conversely, in *Auwarter v. Malverne Union Free District*, the court determined as a matter of law that an 11-year-old assumed the risks inherent in playing on a jungle gym at the school he had attended for three years.[17] Assumable risks also include those resulting from suboptimal conditions, e.g., a wet and muddy baseball fiel [18] and a garbage- and debris-filled county-owned sump used for snowboa ding.[19]

As the New York Court of Appeals specified in *Wolfe v. North Merrick Union Free School District*, "the doctrine of primary assumption is most persuasively justified fo its utility in facilitating 'free and vigorous participation in athletic activities…By putting the risk of participation on the participants themselves, rather than on the sponsor, the doctrine encourages sponsorship, which leads to more participation.'"[20] However, the Court in *Wolfe* did recognize a limitation and held that the primary assumption of risk doctrine was not applicable to a midnight game of "manhunt," which did not entail the "enormous social value" of sporting activities envisioned by the doctrine.[21]

Assumption of risk that is "implied" through willing participation applies only to those risks that are inherently known, apparent, or reasonably foreseeable consequences of participation, but express liability waivers often seek to insulate defendants even from negligent or intentional acts that result in injury. Courts are often hesitant to enforce these elements of waivers, and in general the applicable standard is whether such a waiver violates public policy.[22] Also, New York General Obligations Law § 5-326 categorically voids negligence components of liability waivers where the person signing the clause paid a fee to partake in the activity.

The Evolving Legal Landscape of Contact Sport Concussions

Society has long allowed athletes of all ages to "assume the risks" of playing high-impact sports like football and ice hockey, even though concerns over serious head injuries have existed for virtually as long as the sports themselves.[23] The modern-day concussion crisis stemming largely from the discovery of the degenerative brain disease chronic traumatic encephalopathy (CTE), however, has brought about a tidal wave of new regulations, rule changes, and litigation, all mired in thorny policy considerations and novel legal questions.

Last December, the Supreme Court approved an approximately $1 billion settlement in an NFL concussion class action. The crux of the suit was not merely about medical compensation for a previously unknown condition, but had significant moral overtones: it was p emised on the NFL's concealment and manipulation of the growing evidence linking pro football and CTE (though this clearly goes to players' abilities to understand and assume the health and safety risks posed by the game). The settlement terms did not concede such a link or limit payouts to those afflicted with CTE; players and their families ca also receive compensation for other neurocognitive impairments and neurodegenerative diseases known to occur in the general population, including Parkinson's disease, Alzheimer's, and ALS. Approximately 20,000 living athletes who retired prior to July 7, 2014, are expected to be eligible for payouts averaging $190,000 and up to $5 million.

The fate of current and future NFL players who suffer from these conditions remains unclear, as is how league liability may be viewed absent active suppression or manipulation of data regarding the risks. The concussion lawsuit unfolding in the NHL may be informative on this point, since its growing class of current and former ice hockey players allege more broadly that the league failed to adequately protect them against head injuries, and not that they were actively fraudulent. The most appropriate solution for both leagues may well be to restructure insurance schemes via collective bargaining to sufficientl cover players who suffer from certain conditions after

retirement, based on calculated risks derived from the best available evidence. How to set such terms given that there is currently no medically proven causal link between repetitive head injury and long-term neurodegenerative conditions like CTE (nor is the NFL eager to admit one) will be no simple feat, not to mention the fact that CTE is believed to result from many years of sub-acute and acute concussive trauma, including years played at the youth, high school, and college levels.

Outside of the pro leagues, multiple concussion-related suits against various defendants have withstood motions to dismiss. In January 2016, Pop Warner and four of its football coaches settled a lawsuit in excess of $1 million involving a 13-year-old who suffered injuries resulting in permanent quadriplegia after attempting a head-first tac - le, and subsequently died. The suit alleged that the coaches had taught and encouraged the dangerous method and, in 2015, a judge ruled that the pre-participation liability waiver did not preclude a gross negligence suit. Dozens of suits have also been filed against the NCA and other college athletic associations.

Despite dire predictions of the "end of football" or its likelihood of devolving from our "national religion" into a niche sport, it is not yet clear whether CTE and other concussion-related injuries increase health concerns sufficien to fundamentally alter the popularity of contact sports. The predominant problem now is not necessarily that they are too dangerous, but that we don't know how dangerous they are, or at what levels of play which risks attach. This fact, of course, poses serious assumption of risk problems, which are further complicated when it comes to minors with varying degrees of training, experience, and capacity to understand risks. Given these concerns, state-driven mandates to adopt interim concussion safety protocols in youth and high school sports have become commonplace.

Such laws, deemed "Lystedt Laws" after Zackery Lystedt, a teen football player from Tahoma, Washington who was permanently disabled after returning to play while concussed from a prior injury, have now been enacted in every state. While most outline three general requirements—immediate removal from play upon suspected concussion; no same-day return to play; and medical clearance to return to play—they generally lack clear enforcement mechanisms.[24] The laws are also often unclear as to which entities they cover, with a third of the laws failing to specify ages or grades covered, some laws covering both school sports and recreational leagues, others including private schools, and some not specifying at all. Nonetheless, lawsuits have begun to pop up all over the country. Plaintiffs in at least five states (Florida Texas, Montana, Kentucky, and Connecticut) have alleged failures by schools/school districts, athletic departments, coaches, and athletic trainers to enforce their state concussion policies in various sports including football, lacrosse, and cheerleading.

In 2015, the first high school sports concussion lawsui to be brought in Iowa since passage of the state's Lystedt law resulted in a near $1 million damage award where a football player suffered "second impact syndrome" resulting in brain damage after being allowed to continue playing while concussed. The case was notable in findin not only the school district and athletics personnel negligent, but also the school nurse for failing to diagnose the concussion. While no lawsuits have yet been filed alle - ing violations of New York's "concussion management and awareness act," it is likely only a matter of time, and courts have found New York high schools and affiliate athletics personnel liable for negligence in failing to provide a safe environment in various other contexts.

While the hoopla over concussion-related injury has dominated the discussion about acceptable sports injuries for a seeming eternity, lesser attention has been paid to the rapid proliferation of increasingly dangerous "extreme sports" in recent decades. Overall, society has displayed little resistance to letting people accept the well-known, serious, and often catastrophic risks associated with activities like flipping snowmobiles o f ski slopes, wing-suiting down the world's tallest mountains, and tight rope walking over the Grand Canyon. While New York has played host to many such extreme experiences, it has already demonstrated that at least one sport is too dangerous for its liking.

BASE Jumping

New York City has already indicated a willingness to limit just how extreme an extreme sport can be. In 2008, it banned BASE jumping (an acronym representing the four types of structures from which participants leap with specialized parachutes: buildings, antennae, spans (bridges), and earth) after Jeb Corliss tried to jump off the top of the Empire State Building, before being thwarted by guards and arrested.

After the trial court found that Corliss had not violated any laws since he was experienced enough to avoid "recklessly endangering" himself or others, the City passed a law banning the practice. But even when it comes to a sport as dangerous as BASE jumping—studies have shown that 1 in 2,317 jumps results in death, 1 in 254 results in injury, and 1 in 60 jumpers will die from the sport—the stated motivation behind the ban was not *purely* paternalistic. In addition to protecting the "safety of the would-be jumpers and climbers," the law sought to protect bystanders. The law also invoked a moral element in aiming to "preserve the integrity of New York's landmark structures." Notably, the courts have not been overly punitive of the practice even since the ban's enactment. Three men were convicted for leaping off the One

World Trade Center construction site in 2014, but they received minimal sentences and avoided jail time despite harsh admonitions from the judge regarding "sullying the memory of those who died on 9/11."

V. Tricky Issues on the Horizon

Many of the hardest future legal cases pertaining to autonomy and risk-taking in sports will continue to center around the core negligence and assumption of risks principles, asking, "were the risks known?", "was the participant capable of assuming them?", and "did the defendant negligently, recklessly, or intentionally increase the risk to the plaintiff?"

A more fundamental question may affect the evolving legal framework as well, though, and that is: do aspects of certain sports today render them outside the scope of activities envisioned as deserving of "vigorous promotion" and various legal protections in the first place? e now have evidence of novel and potentially catastrophic risks posed by some of our country's most popular contact sports, and they're being played by ever-faster, bigger, and stronger athletes—characteristics believed to directly increase these very same risks. In addition, millions of people have begun flocking to completely new sport deemed "extreme" by definition of how dange ous they are, potentially representing a non-temporary and "significant shift in participation choices resulting from people's search for enhanced meaning in their lives through novel outlets."[25]

In an analogous context, Professor William Drennan has argued that the maximum tax benefits cur ently available to sports organizations under the penumbra of an "educational" exemption must be reassessed in light of these exact issues (not to mention the dubious classification of sports as "educational" in the first plac particularly given concerns about their interference with traditional intellectual pursuits).[26] He noted the specifi concern that favorable legal policies provide "risky sports a halo effect and cultural cover, perhaps clouding the judgment of potential players and their parents about the advisability of participation."[27] Conversely, eliminating such incentives for excessively dangerous sports "may encourage schools and other sponsors to implement safety precautions or eliminate sports that they cannot reform."[28]

Combining some of the more difficult legal issues tha arise under assumption of risk doctrine with the novel questions posed by extreme sports is a final issue tha warrants mention: the participation of minors in these ultra-risky endeavors.

Children and Extreme Sports

In 2010, 13-year-old Jordan Romero was led by his father and three guides to the peak of Mt. Everest, becoming the youngest person ever to scale Earth's highest mountain. Fortunately, Romero completed the journey unscathed, but given that 6% of climbers who make this attempt *die*, would legal action have been warranted if he'd been injured (or worse)? Notably, Romero journeyed from the Tibetan side of Mt. Everest: Nepal only grants permits to climbers 16 and older, and guiding outfits ma set the minimum age even higher. Thus, one class of potential defendants might have been the Sherpa guides who accompanied Romero and their affiliated guiding outfi And what about Romero's father? These issues have yet to reach American courts, but as one reviewer of similar international incidents to date put it, "As it becomes ever more commonplace for ever younger children to participate in such extreme sports, it is only a matter of time before a child is killed and that the courts will be invited to weigh in on whether or not the child's parents are complicit and culpable in their child's death."[29]

Some extreme sport operators aren't waiting for the courts on these issues: In 2016, the U.S. Parachute Association increased the minimum age for skydivers to 18, noting that equipment manufacturers had already instituted this same restriction in reaction to an increasingly litigious society.

VI. Concluding Remarks

While professional and other increasingly elite-level sports bodies (e.g., NCAA, national teams) may impose stringent restraints on athlete behavior through collective and individual contractual bargaining, players remain free to "take or leave" such terms. But given our society's broad deference to sport- and recreation-related activities based on their historically accorded intrinsic social value, the fields, courts, rinks, and jungle gyms of our countr may indeed comprise some of the freest and bravest lands of all. New York, however, has proven time and again that its latitude has limits, curbing sporting activities that violate certain moral and safety sensibilities even where other jurisdictions acquiesce, and despite "nanny state" accusations from detractors.

This is perhaps unsurprising, given that New York government actors at both the state and municipal levels have long demonstrated extraordinary willingness to enact public health initiatives oft-accused of being unduly paternalistic. While the infamous "soda ban" was eventually struck down, numerous other health department measures (banning trans fats, mandating calorie labels for chain restaurant menu items, banning smoking in public places and ratcheting up cigarette taxes, rolling out hundreds of miles of new bike lanes, and replacing whole milk with low- and non-fat milk in public schools) were upheld, and they were deemed responsible for 60% of an astounding decade-long increase in life expectancy among New York City residents from 1990-2009.[30]

Woody Allen once said: "I could live to be a hundred if you take away all the things that make me want to live to be a hundred." New York may be willing to take more of those things away than most—even when it comes to our nationally treasured institutions of sport.

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The Health Care In-House Counsel: An Essential Member of the Senior Management Team

By Linda L. Vila

Introduction

The role and importance of in-house counsel to a health network, corporation or entity is evolving due to the growing complexity of both health care organizational structures and the regulatory environment. Today's in-house counsel is an integral constituent of the management team and viewed by leadership and the board as a coordinator of the organization's efforts to meet its legal and regulatory needs as well as a participant in issues affecting the operational, administrative and fiscal well being of the current and future enterprise.

Counsel serves in a significantly b oad capacity and ensures that the organization is compliant with its legal responsibilities. Knowledge and skills necessary extend far beyond being a good technician in the law. Undoubtedly, any health care lawyer must comprehend the health care regulatory landscape as well as possess a first-rate understanding of contracts, corporate, employment and antitrust law among additional subjects. To succeed in the present day health organization, however, it is vital for in-house counsel to possess competence in several managerial areas: leadership, multi-professional collaborations, business acumen, finance and budgeting, technology and data analytics, research and evidence-based practice, and organizational ethics.

This article describes some of the current roles of, and necessary competencies for, health care in-house counsel and proposes that a graduate degree in health administration, either as a stand-alone educational experience or earned through a dual degree law/health management program, can benefit cur ent and future health law practitioners.

Roles and Competencies

Leadership and Management

A profound transition in the provisions and delivery of health services is under way as the industry continues to move from inpatient-centric, sick care to outpatient, technology-centric, preventative well care. Health organizations are vying to achieve relevance in a system that seeks greater patient convenience, better outcomes and lower costs. This new model is attracting powerful competitors such as insurers, physician-driven integrated networks and retail companies. A transformative archetype of partnerships is emerging and the goal of these arrangements is to change markets by providing high-quality services at affordable prices in convenient locations using entirely new approaches to manage population health.[1] The principals of these integrated arrangements are wearing myriad hats as they plan, develop and execute their organizations' paths forward. And, they are relying on their inside legal departments to provide leadership and management, direction and input.

In-house lawyers are at the center of these transformative transactions. They serve as advisors and negotiators, and are tapped to function as strategists, communicators, delegators and entrepreneurs. Increasingly, it is commonplace for counsel to act as visionaries and planners who identify and formulate tactics for the desired role of the organization and who overcome hurdles and prevent derailment. This is because inside lawyers are in a position to understand the company's mission and goals and to engage in the type of risk assessment and preventative counseling that managers need to thrive in an increasingly complex and turbulent legal environment.[2] Counsel also act as catalysts in furthering the organization's interests while understanding the socio-political and economic constraints placed on new approaches to care delivery. Appreciating situations as they arise, avoiding rash decisions, sizing up opportunities and influencing others are even more so, than in the past, fundamental to the in-house posture. So are demonstrating professionalism, communicating effectively, exercising appropriate and measured judgment, listening and observing assiduously, demonstrating empathy when warranted, and engaging in self-awareness and reflection [3]

In-house attorneys must be swift to learn the nuances of novel situations as they encounter them. Counsel work in conjunction with members of the leadership team to assess new transactions and evaluate associated transactional components such as: the ability to deliver organizational mission, vision and purpose; growth opportunities to expand the care continuum; potential collaboratives with public health and global care models; new and enhanced core competencies that would be gained or required; clinical and physician alignment across a future network; business portfolio, facility and clinical service distribution requirements; antitrust issues; and human resources requirements.[4]

Multi-professional Collaborations

Population health, prevention and community-based care are crucial elements in health care and are drivers in the move towards multi-disciplinary, coordinated collaboration among providers and professionals to yield

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increased patient and family engagement and better health outcomes. The in-house attorney promotes this patient/family-centered care paradigm by serving as a credible intermediary between the medical domain and the business world and navigating the legal requirements and intricacies which consequently arise. Since consumers are savvier than in the past and are taking an active role in their health care, the attorney is often approached to assist the organization in managing consumer expectations.[5]

Business Acumen

In-house counsel are charged with providing legal services and rendering legal advice to the organization while demonstrating sensitivity to its business goals and strategies. Lawyers on the inside of an entity are better equipped to furnish advice because they understand the company's business and therefore know which guidance and news is relevant to the company and which is not.[6] Called upon to assist in engineering new business strategies such as creative joint venture structures, pay-for-performance approaches, and provider recruitment deals, counsel must possess a mastery of contract law because when the business strategies are set in motion, it is counsel who pen the deal. While attorneys are trained with the ability to identify, understand and advocate multiple sides of any issue, which has its advantages, it can have a downside in a business venture because this skill tends to cause counsel to focus more on reasons not to undertake a particular action than on the need to accomplish a business goal.

Counsel must clearly understand the role of conflict in health care concomitant with the need to build solid, comprehensive structures for dispute resolution as health care organizations realize the need to increase their market share while maximizing revenues, minimizing readmissions and controlling processes to meet the quality and satisfaction expectations built into value-based payment arrangements.[7, 8] They must be politically astute and unflappable given the multifaceted, sophisticated, fast-paced environment in which they work.

Finance and Budgeting

There are topics in finance that have become a part of the day-to-day practice of in-house counsel. Hence, a general working knowledge regarding the use of accounting information and the application of economic principles is essential in order to opine on decisions or respond to increasingly complex reimbursement methodologies for services. Inside lawyers address questions ranging from pricing and managed care contracting to cost finding, elative value units and bundled payments. They are called upon to partake in discussions concerning capital budgeting, capital formation, valuation and organizational configurations such as consolidations, mergers and acquisitions. They frequently work with outside counsel on the latter. Counsel should be able to comprehend a financial analysis that includes: app eciating the need for analysis, reading and implementing balance sheets and income statements; understanding the concepts of financial ratios; interp eting and conducting financial ratio analysis. Involvement with financ no longer revolves around issues of liability insurance coverages and constructing self-insurance formulations for professional liability.

Technology and Data Analytics

In-house attorneys practice in technical environments that service diverse patients. The need for knowledge related to health informatics and analytics along with telehealth modalities has grown as technology has moved closer to the bedside and chairside of practice and is used to improve patient safety, enhance patient experiences, optimize workflow and dec ease spending.[9] Thus, in-house counsel must be in a position to participate in health information technology (HIT) selection, development and optimization in order to drive the prevention or reduction of errors and system failures which implicate individual or, most likely, enterprise liability. Counsel should possess the ability to understand the management of "big data" (large outcomes, quality and cost data sets) to ensure that Legal Affairs has a seat at the table and is able to address legal and regulatory issues attendant with the organization moving forward with HIT needs and strategic goals. Familiarity with health technological modalities such as the use of robotics in surgery and 3-D printing should no longer be delegated only to a clinical specialist; as there is the potential for patient harm or a legal dispute, in-house lawyers should be informed as to their applications.

Research and Evidence-Based Practice

A subtle but no less important role of in-house counsel is the ability to interpret current evidence and apply it to a specific a ea of practice. Counsel should be guided by the latest research and evidence-based practices and use this new knowledge from the literature and field to lead changes in laws, regulations, guidelines, and policies. Knowing how to conduct research and translate evidence can ensure evidence-based decisions are being used and relied upon as opposed to decisions solely based on traditional, emotional, political or fiscal drivers. This is e - pecially applicable for health entities as they utilize data driven approaches to forge relationships such as private-public partnerships.

Organizational Ethics

Health care ethical issues run the gamut from autonomy and beneficence to fraud, waste and abuse. The inside attorney is frequently perceived as the guardian of the organization's integrity and reputation and, as a result, is tasked with steering the organization in the right direction when matters that can lead to corporate liability arise. In the existing health care environment of greater transparency, fraught with tighter standards and stricter

codes of conduct, counsel's ability to preserve independence while effecting ethical duties is crucial.[10]

Management Education for In-House Counsel

Schools of law offer limited or no teaching of health management and faculty lack the specific training to do so. Most law schools offer courses in health law but few offer health management courses that examine the role law plays in administering health services. The core curriculum misses the knowledge, skills and values of health care administration, and law students learn about certain aspects of the discipline if they go out of their way to take a seminar, if offered, or independent study, or enroll in an internship at a health organization.

Practicing lawyers learn most facets of health law practice through experience and exposure.

One consideration to address the morphing role of in-house counsel is conjunctive education for law students in the field of health management. Dual deg ee programs which offer a JD/MHA (Master of Health Administration) or JD/MPA (Master of Public Administration with a concentration in health care administration) provide students with the best of both worlds, a graduate health management education with legal training. Graduates of these programs are trained to become a new breed of professionals: lawyers with a health management perspective, poised to demand that management interests become part of the legal conversation. St. John's University School of Law in Queens, New York, and Long Island University Post in Brookville, New York, recently partnered and implemented such a jointly administered dual degree program.

Similarly, newly minted or seasoned attorneys, whether in the health field or in-house to a healt care entity, can pursue and benefit f om a MHA/MPA (MHA) degree as well. Although they would not realize a cost savings/credit savings which usually accompanies attaining the JD and MHA jointly, they would have formal training in the literacies called for, now and going forward, as a health law practitioner.

A MHA degree provides a practical education and training for law students or lawyers, ensuring they are markedly prepared to apply evidence-based practices and critical thinking skills toward the delivery, organization and operation of health and health services within culturally diverse environments. MHA programs have a competency-based curriculum which requires that students demonstrate they can integrate knowledge and skills from the central disciplines of core management constructs, including but not limited to: accounting and finance, o ganizational behavior and communication; economics; research design and statistics; health policy and knowledge of the key issues and challenges in health systems and public health; and health information management. Leadership is also taught both in a specific course and as a component of non-leadershi specific courses. Many p ograms undergo accreditation from CAHME, the Commission on Accreditation of Healthcare Management Education, which sets standards for quality in academic health care management education that are meticulously developed, rigorous, and highly relevant to the actual performance of health care managers, executives, and leaders. There are currently 97 accredited MHA programs in the United States.[11]

The MHA provides a robust environment for study. First, program students emanate from various disciplines in health care, most of whom are in service, and offer varied viewpoints and experiences. There is ample heterogeneity among MHA student composition. Second, MHA programs use progressive pedagogical methodologies which enhance student learning and retention. Use of experiential learning, case studies, refle - tive practice, simulations, group projects, symposia and IPE—interprofessional education, a growing area, where students from several professions learn about, from and with each other to enable effective collaboration and improve health outcomes[12]—are typical to this graduate degree curriculum. Third, MHA faculty are frequently local health care leaders and executives with sundry backgrounds, educations and positions. Students are exposed to leadership and management from experts in the field who also may p ovide employment opportunities for students in, and upon completion of, the program.

Lawyers with a health management degree expand their prospects for employment in the health law industry. As law schools have been wrestling with fewer applications and fewer jobs for graduates, and as a drought of legal jobs across the legal profession continues, today's dual degree graduates or lawyers with a MHA degree are likely to rely on their health management training to find employment [13, 14]

In lieu of seeking employment as a health care attorney, specifically an in-house counsel, one can pursu a position as a health care manager or administrator. A management education coupled with a legal education provides tremendous credibility to a candidate applying for a position as a clinical or hospital department manager, a faculty practice or nursing home administrator or a compliance director. According to the Bureau of Labor Statistics, employment of medical and health services managers is projected to grow 17 percent from 2014 to 2024, much faster than the average for all occupations.[15] Moreover, employment opportunities continue to rise in health services. Since May, 2016, the health services industry has added 329,000 jobs, 24,000 of them in May, 2017 which includes a 7,000 job gain in hospitals.[16] Salaries for both in-house health care attorneys as well as health services managers are impressive.

Conclusion

The expectations of in-house counsel to a health organization have expanded to no longer simply include providing legal guidance in particular areas of the law to executive leadership. They now include functioning as a valuable member of the management team and shouldering responsibilities of an administrator. To this end, a MHA education delivers meaningful complementarity to a law degree to meet these managerial challenges.

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NEWS flash

What's Happening in the Section

Upcoming Events

Health Law Section Fall Meeting

October 27, 2017
The State Bar Center
One Elk Street
Albany NY 12207

Program to be announced. Check www.nysba.org/health.

Fundamentals of Health Law

November 15, 2017—Albany
December 6, 2017—NYC

Program to be announced. Check www.nysba.org/health.

Health Law Section Annual Meeting CLE and Luncheon

January 24, 2018
New York Hilton Midtown
1335 Sixth Avenue
New York NY 10019

Program to be announced. Check www.nysba.org/health.

Recent Events

NYSBA Ad Hoc Committee on Reforming NYS Surrogate Court Procedure Act Article 17A and Surrogate Court Procedure Act Section 1750-b.

In April the Section's Committee on Ethical Issues in the Delivery of Health Care and the NYSBA Committee on Disability Rights convened representatives from several NYSBA committees to discuss SCPA Article 17-A Guardianship and the SCPA Article 1750-b Health Care Decisions Act. The participants discussed the need to reform:

- Surrogate's Court Procedure Act (SCPA) Article 17A Guardians of People with Intellectual and Developmental Disabilities, to ensure the compliance of its procedures with due process, equal protection, and the Americans with Disabilities Act; and
- SCPA Section 1750-b Health Care Decisions for Persons Who Are Intellectually Disabled, to move toward a decision making framework that applies to a broad range of patients, settings and treatments, to reduce the complexity and confusion that arises from multiple decision making statutes, and to foster consistency while protecting mentally disabled persons.

The Ad Hoc Committee, chaired by Brendan Parent of the Health Law Section, decided to organize a broader conference and consortium to discuss these issues and to advocate legislative reforms.

Recorded Programs Now Available Online

Looking for CLE opportunities online? The Health Law Section has three recordings available to purchase and view for CLE credit, any time that is convenient for you:

1. Legal Issues Surrounding Eye, Organ and Tissue Donation

CLE: *1.5 credits in professional practice, non-transitional and accredited for MCLE credit in New York State only.*

Cost: Free to Health Law Section Members.

Presented by the Health Law Section in partnership with the New York Alliance for Donation (NYAD), and co-sponsored by the Health Law Committee and Bioethical Issues Committee of the New York City Bar.

New York State is facing a health care crisis: the need for transplantable organs far exceeds the availability. While a single donor can help save the lives of up to eight people, potential donors are rare. It is crucial that all of the participants in the process, legal, clinical, administrative and governmental are knowledgeable about the law and the process surrounding organ and tissue donation.

2. Health Law Section Fall Meeting: Disrupting the System: Innovation and Collaboration in Health Care in New York

CLE: 7.0 MCLE credits, 6.5 Professional Practice, 0.5 Ethics. (*This program is for experienced attorneys only, is non-transitional, and accredited for MCLE credit in New York State only.)*

Cost: Health Law Section Members: $175

This program offers a look at innovative programs that are designed to facilitate access to comprehensive, coordinated care to improve patient satisfaction and clinical outcomes. These programs and the use of the technology necessary to support them do not come without legal barriers and challenges. A diverse panel of speakers will describe initiatives that are disrupting the health care system, and the practical ways to overcome the real and perceived barriers to sustained implementation. This program is relevant for attorneys representing all provider types, health systems, in-house counsel, insurance/payor

plans and governmental attorneys involved in health care regulation.

Topics:

- In-House General Counsel: Hot Topics
- Medical-Legal Partnerships in Health Care
- Collaborative Affiliation Among Large Systems and Physician Practices: Tales from the Trenches
- Medical-Legal Implications and Sustainability of SHIN-NY Regulations in Healthcare Delivery System
- Concierge Medicine/Telemedicine/Direct Primary Care
- Ethics of Health Information Technology Privacy

3. E-Health Clinical Records & Data Exchange II: Live and Webcast

CLE: *This program is accredited for 2.0 MCLE credits in the area of Professional Practice, and is non-transitional and accredited for MCLE credit in New York State only.*

Cost: Health Law Section Members: $50

The NYSBA's Health Law Section, in collaboration with Albany Law School and Fordham Law School, is holding the second program of a two-part series exploring the state of population health initiatives for improving the public's health and the law affecting: Electronic Health Records (EHRs) across provider types and payor systems; Health Information Exchanges (HIEs) and Regional Health Information Organizations (RHIOs), including the State Health Information Network of New York (SHIN-NY) and e-MOLST; data collection and integration; and research and ethics.

Topics:

- Expanding Public Policy Goals for EHR to Improve the Public's Health: Utilizing Integrated Medical and Social Data for Designing Care Systems and Population-Level Interventions—Issues in Law, Research and Ethics.
- E-Health Licensure Standards—Gaps in Law and Regulations at the State Level

Part I of this series is available for free, and does not offer CLE credit. Visit www.nysba.org/ehrs.

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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 Committee .

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