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Health Law Journal

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of the New York State Bar Association

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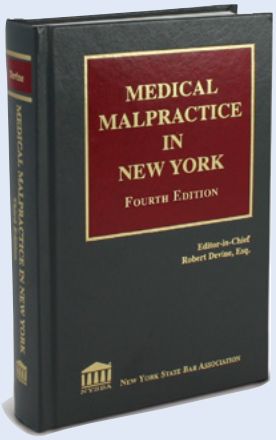

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HEALTH LAW JOURNAL

Spring 2018

Vol. 23, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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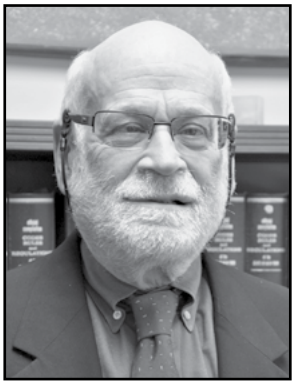
Message from the Chair



I would like to take this opportunity to review some of the activities recently undertaken by the Committees of the Section and activities planned for the coming months. The work of the Committees is a reflection of the commitment of Section members to address both the needs of the practicing health law bar and emerging issues in the provision of health care. The Section's work includes: Developing ethical standards for electronic health records; the use of technology for the "remote" delivery of health care; defining the role of in-house hospital counsel; issues surrounding medical research and biotechnology; professional discipline; and items related to Section membership and diversity. Some recent examples:

The *Committee on Medical Research and Biotechnology* recently updated committee members on legal issues such as the impact of EU General Data Protection Regulation (GDPR) on medical research in the U.S.; drafted and submitted comments on proposed rule changes to allow research findings to be communicated to physicians; studied existing policies used by academic research centers for consenting individuals who lack consent capacity, and studied and formulated tentative research approaches related to the adoption of a formal position statement about use of medical marijuana.

In the year ahead, it plans to work with *Health Law Journal* Editor Brendan Parent to produce a special edition of the *Health Law Journal*, to continue assessing existing laws/regulations in light of new biotechnologies and recommend useful changes, to sponsor or contribute to CLE events or other educational opportunities, to work on the above mentioned "best practices" policies and assist the Department of Health, where asked by the Department, on issues around the implementation of the Common Rule and the impact on enforcement of PHL Art 24-A, as well as return of research results to clinicians.

The *Health Professionals Committee* is planning to conduct a CLE in the fall entitled "Challenges Facing the Independent Physician." The CLE will address such issues as structural practice options, financial and payment challenges, and the types of litigation matters physicians are experiencing. In a time of increasing "corporatization" of the practice of medicine into large practices, this proposed CLE will be directed toward providing a service to attorneys representing independent physicians.

The *Ethical Issues in the Provision of Health Care Committee* has been involved in efforts to reform Surrogate's Court Procedure Act Article 17-A Guardianship and 1750b, Surrogate Medical Care Decision Making. This is a joint effort with the Law Revision Commission. The Committee held a day-long workshop involving representatives from other Sections of the Bar Association to discuss possible legislation, and representatives of the Committee have been working with the provider and advocacy community towards reform of the guardianship statute and the possible combining of Article 1750b of the Surrogate's Court Procedure Act, Medical Care Decision Making for Individuals with Intellectual and Developmental Disabilities, and the Family Healthcare Decisions Act.

The committee has also been investigating how to handle incidental medical findings in the course of unrelated medical care or scientific research, and working with university partners to develop related protocol. It is also working on avenues for improving organ donation rates in New York State and developing guidance for trust and estate lawyers to incorporate organ donation wishes into long-term planning. It will be working on several topics related to addressing the opioid abuse crisis in New York State and is also planning to develop a day-long CLE on end of life issues, including advanced planning, palliative care, clarifying surrogate decision making laws, and medical aid in dying.

The *Young Lawyers Committee* has recently focused on the advancement of young health lawyers in their careers by continuing to host monthly telephone conference calls which provide an open forum to discuss issues young lawyers may face as well as current issues in health law. It recently co-sponsored a CLE entitled "Health Care Cyber Security in a HIPAA Compliant World" and a special edition of the *Health Law Journal* entitled "Provocative Topics in Health Law," affording an opportunity for young lawyers to publish their work.

The *Committee on Professional Discipline* held a CLE in 2017 and is planning to issue a summary of proposed legislative changes regarding the time within which the practitioner must respond to OPMC investigative requests.

The *Legislative Committee* has primarily operated as a resource to this Section, advising the substantive committees and the Executive Committee on legislative proposals which might be of concern or interest to the Section. During the last year, for example, the Committee partici-

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pated in the evaluation of a proposal that would amend the standards for involuntary commitment and reviewed legislation relating to the prescription of biosimilars, which was ultimately enacted into law.

The *Membership Committee* has focused its efforts on increasing membership among newly admitted attorneys and young associates, establishing law school partnerships and prioritizing diversity. The committee intends to continue such efforts in the upcoming year while also enhancing member resources, such as the online community and the Industry Contact List. Specific activities will include an annual project to contact all members "at risk" of being dropped from Section membership, identifying law students who can act as liaisons to the Executive Committee, soliciting funding to expand the health law fellowship, conducting membership receptions to attract new members and encourage networking among existing members, and sponsoring panels on "careers in health law" at a variety of sites, particularly law schools around the state.

The newly formed *Payment Enforcement and Compliance Committee* intends to prepare for a future *Health Law Journal* issue on Value-Based Purchasing and possibly co-sponsoring the Value Based CLE.

The *CLE Committee* will work with the program chairs in the planning and delivery of educational programs. The committee's diverse membership is also well positioned to identify topics of interest for future events.

The *E-Health & Information Systems Committee* held a panel discussion and networking reception in New York City on the topic of "Health Care Apps, Al and Big Data: A Conversation on Legal Implications." The event was co-sponsored between NYSBA's E-Health Committee, NYSBA Young Lawyers Division, and ABA Young Lawyer Division Committees on Health Law and Science & Technology. The committee is planning a CLE event for July 2018 on the topic of "Health Care on the Blockchain" and may possibly co-sponsor an event with the Medical Research and Biotechnology Committee on the use of apps, wearable devices, and telehealth in the context of clinical research.

This is a sample of some of the activities undertaken and planned by the committees of this Section. A complete list of committees can be found toward the end of this edition of the *Journal*. I would urge members of the Section to get actively involved with committees of their choosing. The networking, outreach, and educational opportunities of such participation are unlimited.

In the New York State Courts

By Leonard M. Rosenberg

Appellate Division Upholds State Comptroller's Subpoena to Health Care Provider, Holding That Comptroller Has Broad Authority Under the Finance Law to Issue Subpoenas in Furtherance of Its Investigatory Function as a Health Oversight Agency

Matter of Plastic Surgery Group, P.C. v. Comptroller of the State of New York, 155 A.D.3d 1417, 65 N.Y.S.3d 595 (3d Dep't, 2017). The Comptroller of the State of New York appealed from a Supreme Court decision that granted a health care provider's petition to quash the Comptroller's subpoena. The subpoena sought information relating to health insurance claims paid to the provider by United Healthcare ("United") under the Empire Plan. The Empire Plan is the primary health insurance plan for the New York State Health Insurance Program. United is a private insurance company that contracts with the State to process and pay medical claims for State employees who are members of the Empire Plan.

Reversing the trial court, the Appellate Division held that the subpoena was validly issued in furtherance of the Comptroller's constitutional and statutory duties, and was not barred under the Health Insurance Portability and Accountability Act (HIPAA).

The Comptroller commenced an audit of health insurance claims paid by United to the Plastic Surgery Group, P.C. to determine if United had overpaid the provider on a number of claims submitted between 2011 and 2015. After the provider failed to respond to the Comptroller's requests to review a random sample of its records related to such claims, the Comptroller served the provider with a subpoena *duces tecum* requesting documents pertaining to patients who were members of the Empire

Plan. The provider commenced a proceeding to quash the subpoena, or in the alterative, for a protective order if disclosure were required. The Comptroller cross-moved to compel the provider's compliance. The Supreme Court held that the Comptroller lacked authority to issue the subpoena because it was not accompanied by written patient authorizations pursuant to CPLR 3122(a), and quashed the subpoena.

Relying on *Martin H. Handler, M.D., P.C. v. DiNapoli*, 23 N.Y.3d 239 (2014), the Appellate Division held that the Comptroller is constitutionally obligated to audit state payments to health insurance vendors, and was bestowed with "broad subpoena powers in furtherance of its investigatory functions" by the legislature. As the Court of Appeals made clear in *Handler*, Appellant is mandated to: (i) ensure proper billing and payments for the Empire Plan, (ii) prevent unauthorized payments and overpayments, and (iii) audit the records of participating and non-participating providers as part of its responsibility to audit payments to medical providers. Accordingly, the court held that the subpoena for the provider's records was well within the Comptroller's statutory authority and was a valid exercise of its subpoena power.

The Appellate Division held that the Supreme Court improperly relied upon CPLR 3122(a) in limiting the Comptroller's audit and subpoena authority. That statute, which requires, among other things, that a patient's written authorization accompany any subpoena *deuces tecum* issued to a medical provider, applies by its terms only to subpoenas issued by a party to a litigation seeking discovery under CPLR 3210 or 3121. Given that the Comptroller's subpoena was issued in accordance with its constitutional and statutory audit authority under Section 9 of the New York State Finance Law, and had no connection with discovery in any action or proceeding, the court held that CPLR 3122 did not apply.

The court also rejected the provider's argument that HIPAA barred disclosure of the requested records. As the court explained, HIPAA permits the disclosure of protected health information to "health oversight agencies" that are conducting oversight activities authorized by law. Finding that the Comptroller meets the definition of a health oversight agency, the court rejected the provider's argument that written patient authorizations were required by HIPAA.

Appellate Division Modifies Nondurational Court Order Authorizing State Psychiatric Center to Treat an Inmate Without His Consent

In re Radcliffe M., 155 A.D.3d 956, 65 N.Y.S.3d 227 (2d Dep't, 2017). Appellant, a state inmate sentenced to an indeterminate sentence for convic-

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

tion of, *inter alia*, attempted murder in the first degree, was admitted to a state psychiatric center, Respondent Central New York Psychiatric Center (the "Center"), in 2007, where he was diagnosed with schizophrenia and unspecified personality disorder. Approximately eight years and six months later, a court issued an order authorizing the Center to treat Appellant with medication without his consent for a one-year period. Pursuant to that court order, the Center treated Appellant with the medication haldol deconoate.

When the court order expired and Appellant refused to continue to take haldol deconoate, the Center commenced a proceeding for authorization to administer a course of medication to Appellant without his consent. The Supreme Court held a hearing in which the sole witness, the Center's expert psychiatrist, opined that Appellant suffered from schizophrenia, lacked the capacity to make decisions regarding his psychiatric care and treatment, and that continued treatment with haldol deconoate was in his best interests. The Supreme Court granted the petition, but the order that it signed did not include an expiration date for the authorization, and it included additional medications as reasonable alternatives to haldol deconoate.

The Appellate Division modified the Supreme Court's Order to strike the provisions concerning the nondurational nature of the treatment and the alternative medications. The Appellate Division explained that the State may be entitled to administer a course of treatment over a patient's objection when it establishes by clear and convincing evidence (1) that the patient lacks the capacity to make a reasoned decision with respect to the proposed medical treatment, and (2) that the proposed medical treatment is narrowly tailored to give substantive effect to the patient's liberty interest, taking into account all of the relevant circumstances, including the benefits to be gained from the treatment, the side effects associated with the treatment, and the existence of any less intrusive treatments. Pursuant to this standard, the Appellate Division held that the Center had demonstrated at the hearing that Appellant lacked the capacity to make a reasoned decision with respect to continuing his treatment of haldol deconoate, and that continuing haldol deconoate was narrowly tailored to give substantive effect to Appellant's liberty interest.

However, the court held that the Center failed to establish entitlement to a nondurational order. The court noted that a nondurational order is appropriate only where the state establishes that the proposed treatment will allow the patient to become stabilized and will restore the patient's ability to make reasoned decisions with respect to his or her mental illness; and the Center's evidence did not meet that standard.

In addition, the court held that the Center failed to establish that the additional alternative medications listed in the order were appropriate because it did not offer any testimony or evidence at the hearing with respect to the additional medications listed in the order. The Appellate Division therefore deleted the provision of the order that authorized the administration of alternative treatments without prejudice to the filing of a new petition.

State Court of Appeals Holds That a Mistaken Perception of Alcoholism Is Not a Disability Covered by the New York City Human Rights Law

Makinen v. City of New York, 30 N.Y.3d 81, 64 N.Y.S.3d 622 (NY, 2017). Plaintiffs, officers of the New York City Police Department, filed a complaint alleging that the Police Department subjected them to adverse employment actions based on an illegitimately perceived disability of alcohol abuse. Based on false allegations made by ex-partner police officers, plaintiffs were referred to the police force's internal Counseling Services Unit, a certified New York State Office of Alcoholism and Substance Abuse Services outpatient treatment center aimed toward assisting officers with substance abuse and returning them to productive service. Plaintiffs underwent treatment to avoid suspension. Plaintiffs brought suit under the Americans With Disabilities Act, the New York State Human Rights Law, and the New York City Human Rights Law.

Following a trial in the United States District Court for the Southern District of New York, the jury returned a verdict in favor of plaintiffs as to their claims under the New York City Human Rights Law (NYCHRL). The court's jury charge instructed that plaintiffs could recover under the NYCHRL without establishing that they were actually, or were perceived to be, recovering alcoholics, and free from abuse.

Defendants maintained that the trial court's instructions contradicted Sections 8-107(1)(a)and 8-102(16)(c) of the New York City Administrative Code. Section 8-107(1)(a) applies the protections of the NYCHRL only to those individuals with an actual or perceived disability, and Section 8-102(16)(c) provides that, "in the case of alcoholism . . . the term 'disability' . . . only applies to a person who is (1) recovering or has recovered and (2) currently is free of such abuse." Accordingly, defendants moved for a new trial and for judgment as a matter of law, alleging that the NYCHRL does not protect untreated alcoholics from disability discrimination. The District Court denied defendants' motion, and defendants pursued an appeal from the District Court's Order to the United States Court of Appeals for the Second Circuit. The parties agreed that plaintiffs were not alcoholics.

The Second Circuit certified, and the New York Court of Appeals accepted for review, the question of whether the Administrative Code precludes a plaintiff from bringing a disability discrimination claim based solely on the perception of untreated alcoholism. The Second Circuit retained the appeal for decision follow-

ing the Court of Appeals' determination regarding the parameters of the Administrative Code.

Holding that it was bound to give effect to the statute's plain meaning and intent, the court ruled that a mistaken perception of alcoholism is not a disability under the NYCHRL. The court explained that there is no ambiguity as to the plain language of the statute, which covers only circumstances in which employers unfairly typecast recovered or recovering alcoholics who have sought treatment and are not presently abusing alcohol, so as to ensure that such individuals are afforded a fair opportunity toward recovery.

In so holding, the court acknowledged that, following concerns that the NYCHRL was being construed too narrowly by the courts, the City Council amended the law through the Local Civil Rights Restoration Act of 2005. In particular, the Restoration Act mandates that the NYCHRL "shall be construed liberally for the accomplishment of the uniquely broad and remedial purposes thereof, regardless of whether federal or New York State civil and human rights laws, including those laws with provisions comparably worded to provisions of this title, have been so construed." The Restoration Act also states that "interpretations of New York state or federal statutes with similar wording may be used to aid in interpretation of the NYCHRL, viewing similarly worded provisions of federal and state civil rights laws as a floor below which the NYCHRL cannot fall, rather than a ceiling above which the local law cannot rise."

The court juxtaposed the NYCHRL with the ADA and New York State Human Rights Law, both of which offer protections for alcoholics, whether recovered, recovering, or presently abusing alcohol, allowing all such individuals to establish a prima facie case for discrimination. The court held, however, that despite the City Council's intention that the NYCHRL be construed as progressively as possible, and with as much breadth as the ADA and NYSHRL, if not more, the NYCHRL nevertheless must be interpreted based on its plain, unambiguous meaning. Explaining that it could not "rewrite the statute to achieve more fairness," the court identified this as a rare case in which the City Council mandated narrower coverage than provided under the statute's state and federal counterparts.

Two judges dissented on the basis that the majority's reading of the NYCHRL might encourage ill-intentioned behavior by employers and undermine the City Council's stated goals.

Third Department Upholds Dismissal of Negligence Action Concerning Patient's Combative Behavior Toward Non-Hospital Employee on Hospital Premises

Boudreaux v. Columbia Mem'l Hosp., 154 A.D.3d 1263, 62 N.Y.S.3d 633 (3d Dep't, 2017). Plaintiff commenced a negligence action against Columbia Memorial Hospital (the "Hospital") concerning a patient's combative behavior that injured plaintiff. Plaintiff alleged that the hospital failed to anticipate and take steps to protect her from the patient's conduct. After discovery, the hospital successfully moved for summary judgment. The Appellate Division affirmed.

Plaintiff worked for an entity that provided residential care to developmentally disabled adults. A resident was hospitalized and plaintiff was assigned to stay with him at the hospital. During the hospital stay the resident became combative and injured plaintiff. The resident had a history of assaultive conduct, but that information had not been provided to the hospital.

The court explained that the hospital, like all property owners, has a duty to protect persons lawfully present on its premises from the "reasonably foreseeable criminal or tortious acts of third persons." However, the hospital may establish its entitlement to judgment as a matter of law "by showing that it had no notice of any prior similar incidents or similar aggressive behavior by the patient such that it should have anticipated the alleged incident and protected the plaintiff from it."

Here, the court reasoned that even though the plaintiff and her coworkers may have had notice of the resident's combative conduct, there was no evidence that the hospital had a similar awareness. Thus, foreseeability of the dangerous behavior depended upon the resident's actions while hospitalized. The court held that the evidence showed that the resident, while uncooperative, was not a foreseeable danger. Accordingly, the hospital established that it could not have reasonably anticipated the attack as a matter of law.

Third Department Holds That Physician's Three-Year Probation and Practice Supervision for Professional Misconduct in New Jersey Warranted Reciprocal Discipline In New York

Ackerman v. New York State Dep't of Health, 155 A.D.3d 1138, 64 N.Y.S.3d 370 (3d Dep't, 2017). Petitioner, an internist and board-certified dermatologist, commenced an Article 78 proceeding, pursuant to Public Health Law (PHL) § 230-c, to review a determination of the Administrative Review Board for Professional Medical Conduct which placed petitioner on three years of probation. Petitioner's probation arose from the New Jersey Board of Medical Examiners' ("New Jersey Board") receipt of complaints regarding her mental health status and professional conduct.

Petitioner entered into a Private Letter Agreement with the New Jersey Board that permitted her to continue practicing medicine so long as she complied with the terms of the Letter Agreement. After petitioner failed to comply with the requirements of the Letter Agreement, in February 2012, the New Jersey Board issued an order of automatic suspen-

sion. Petitioner thereafter repeatedly sought to be reinstated, and in November 2015, entered into a Consent Order with the New Jersey Board reinstating her, on the condition that she continue receiving mental health treatment.

In May 2015, the Bureau of Professional Medical Conduct (BPMC) commenced a direct referral proceeding based upon petitioner having committed acts in New Jersey which, if committed in New York, would constitute professional misconduct. Following a hearing, the Hearing Committee of the State Board for Professional Medical Conduct sustained the charge and imposed a three-year stayed suspension of petitioner's license to practice medicine, placed her on probation for a period of three years and required her to provide 90 days notice should she decide to return to the practice of medicine in New York. On administrative appeal, the Administrative Review Board for Professional Medical Conduct (ARB) confirmed the Hearing Committee's determination and imposition of a three-year period of probation, but overturned petitioner's stayed suspension, finding probation and practice supervision to be sufficient.

Petitioner, thereafter, commenced this Article 78 proceeding seeking to annul the ARB's determination. Applying an arbitrary and capricious standard of review, the court found that the evidence reviewed by the ARB sufficiently demonstrated that petitioner committed professional misconduct in New Jersey that warranted reciprocal discipline in New York (i.e., that the ARB's determination had a rational basis and was factually supported by the record). In so holding, the court rejected petitioner's contention that she was denied a fair hearing because the ARB refused to consider evidence in the form of a letter from her attorney indicating that petitioner's counsel in the New Jersey disciplinary proceeding had purportedly committed legal malpractice, explaining that the administrative procedure's due process requirements are liberal and not exacting. The court also explained that such evidence would not be admissible because due process does not permit the petitioner to re-litigate the merits of out-of-state charges.

Finally, the court found that the penalty imposed by the ARB was appropriate, applying a limited standard of review, by considering whether "the penalty [was] so disproportionate to the offense that it shocks one's sense of fairness." The court explained that based on petitioner's misconduct, including her repeated failure to abide by the conditions that were imposed by the New Jersey Board, the ARB's imposition of a three-year period of probation was warranted.

Appellate Division Holds That Collateral Estoppel Does Not Bar Physician's Labor Law § 741 Claim Where Related Administrative Proceedings Did Not Determine the Basis for Termination of Her Employment

Mehulic v. New York Downtown Hosp., 153 A.D.3d 1149, 61 N.Y.S.3d 2 (1st Dep't, 2017). Plaintiff physician, a former hospital employee, appealed from the Order of the Supreme Court, New York County, granting summary judgment to defendant hospital and dismissing plaintiff's complaint.

Plaintiff alleged that during her employment, she reported inadequate medical care to her supervisors and the Department of Health, and as a result was fired in violation of Labor Law § 741, New York's health care whistleblower statute. The Supreme Court ruled that plaintiff's whistleblower claim was barred by collateral estoppel based on findings of incompetence made in a proceeding before the Office of Professional Medical Conduct (OPMC).

The Appellate Division held that the issue of whether defendant terminated plaintiff's employment because she reported inadequate medical care was not determined in the OPMC proceeding. The court noted that the issue determined in the OPMC proceeding was whether plaintiff, a then-unlicensed resident, should be granted a New York medical license and, if so, under what conditions.

The court held that while the OPMC proceeding determined that plaintiff had engaged in professional incompetence on three occasions, and that defendant had not fabricated those allegations, there was no ruling, express or implied, that defendant terminated plaintiff's employment as a result of her incompetence. Likewise, the court explained that there was no prior ruling as to whether defendant had retaliated against plaintiff for whistleblowing.

Thus the court held that although plaintiff was precluded from re-litigating her three instances of incompetence, she was entitled to pursue her Labor Law § 741 claim, having raised triable issues of fact to rebut defendant's prima facie showing that her termination was predicated upon grounds other than her exercise of rights under the statute.

Appellate Division Rules That PHL § 2801-d Does Not Apply to a Detox and Rehab Facility Regulated by OASAS

Hairston v. Liberty Behavior Management Corporation, et al., 157 A.D.3d 404 (1st Dep't, 2018). Appellants, operators of a residential substance abuse detoxification and rehabilitation facility, were treating a patient with schizophrenia and bipolar disorder for his long-term alcoholism, when the patient left the facility. He was later found dead, cause of death unknown, in the woods about a mile away from the facility.

Respondent, the administratrix of the deceased patient's estate, commenced a lawsuit against the facility, alleging negligence, wrongful death, and violation of Public Health Law (PHL) § 2801-d. Appellants moved for summary judgment dismissal, arguing they owed no duty of care to the patient, plaintiff could not show causation, and the substance abuse rehabilitation facility could not be lia-

ble under PHL § 2801-d. The Supreme Court denied Appellants' motion.

The Appellate Division modified the Supreme Court's order to dismiss Respondent's claim under PHL § 2801-d. Section 2801-d provides a private right of action to a patient of "any residential health care facility. . ." for injuries suffered as a result of deprivation of any right or benefit created, for the patient's well-being, by any contact, statute, code, rule or regulation. PHL § 2801(3) defines residential health care facility as a nursing home or a facility providing health-related service.

Citing to *Burkhart v. People, Inc.*, 129 A.D.3d 1475 (4th Dep't, 2015), the court ruled that PHL § 2801-d applies only to nursing homes or similar facilities subject to the Public Health Law and regulated by the Department of Health. Because Appellant is a detoxification and rehabilitation facility governed by the Mental Hygiene Law and regulated by the Office of Alcoholism and Substance Abuse Services, it is not subject to the private right of action available under § 2801-d.

Southern District Denies Motion to Dismiss Class Action Alleging Overcharges for Medical Records in Violation of N.Y. Public Health Law § 18

Ortiz v. CIOX Health LLC, 2018 WL 1033237 (S.D.N.Y. Feb. 22, 2018). Plaintiff is an individual who, acting through her attorney, sought copies of her medical records from defendant, the New York and Presbyterian Hospital (the "Hospital"). Defendant CIOX Health LLC (CIOX) is the successor in interest to IOD, a corporation that contracted with the Hospital to provide copies of medical records to the Hospital's patients and to bill the patients for such copies. At the time that plaintiff's attorney requested the medical records, he informed the Hospital that under N.Y. Public Health Law § 18(2)(e) its charges may not exceed $0.75 per page. Nevertheless, plaintiff's attorney received a bill from CIOX requesting $1.50 per page and paid the bill in full despite the overcharge.

Plaintiff filed suit against CIOX and the Hospital in New York state court, asserting claims for (1) violation of N.Y. Public Health Law § 18, (2) breach of the implied covenant of good faith and fair dealing, (3) fraud, and (4) unjust enrichment. Plaintiff bought her claims both individually and on behalf of a putative class of individuals who had been similarly overcharged for medical records by defendants between 2011 and 2017. Plaintiff sought both damages and injunctive relief, alleging that defendants had continued their practice of overcharging similarly situated patients for their medical records.

CIOX removed the action to the U.S. District Court, Southern District of New York, claiming federal question jurisdiction based upon the Class Action Fairness Act. Both defendants moved to dismiss plaintiff's First Amended Complaint (FAC) on numerous grounds, and CIOX also moved to strike certain allegations in support of plaintiff's fraud claim that identified the names of its managers.

The Hospital argued that plaintiff lacked standing to assert her individual claims because her attorney, and not plaintiff, paid the bill for the medical records. The court held that plaintiff had appropriately pled an agency relationship whereby the attorney paid the fee on her behalf, and that she suffered damages as a result. The court further held that plaintiff established her standing, at the pleading stage, to seek injunctive relief, as it was plausible that plaintiff would need to obtain medical records from the Hospital in the future.

The Hospital also argued that there was no live controversy between the parties because CIOX unilaterally refunded the overcharged amount to plaintiff's attorney's credit card. The court first noted that plaintiff's claims were not moot because she sought injunctive relief in addition to damages. The court further held that allowing defendants to moot plaintiff's claim for damages simply by refunding the overpayment would frustrate the purpose of a class action, as it would force individual plaintiffs with relatively low value claims to bring successive lawsuits, which could each be "picked off" prior to class certification.

The court then turned to the substance of plaintiff's claims. First, the court held that plaintiff appropriately stated a claim under Public Health Law § 18. Although defendants argued that plaintiff voluntarily paid the overcharge, the court found plaintiff had plausibly alleged that the payment was made under protest, as the FAC stated that plaintiff's attorney informed the Hospital that it could not charge more than $0.75 per page at the time he made the request for records. The court dismissed plaintiff's claim for breach of the implied covenant of good faith and fair dealing, as she did not allege that defendants deprived her of the benefit of any contract rights. The court also dismissed plaintiff's fraud claim, holding that she failed to plead that she reasonably relied on any false statement from defendants. The court also found that under New York law, plaintiff's claim for unjust enrichment was precluded by her acknowledgement that a contract existed between the parties to pay $1.50 in exchange for medical records.

The court then addressed CIOX's motion to strike. The court noted that plaintiff's naming of CIOX's managers was "gratuitous," as she did not allege that they engaged in any specific conduct underlying her fraud claim. However, the court denied the motion as moot, as plaintiff's fraud claim was dismissed for failure to state a cause of action.

Finally, the court held that N.Y. CPLR 214(2), which provides a three-year statute of limitations for claims of liability "created or imposed by statute," applied to plaintiff's one surviving claim for violation of Public Health Law § 18. The court noted that the FAC sought class relief dating back to 2011, in part because it asserted a claim for unjust enrichment,

which carries a six-year statute of limitations. Because Plaintiff's claim for unjust enrichment was dismissed, the court held that the putative class could only obtain relief for overcharges after February 24, 2014, three years before Plaintiff filed her initial complaint.

Eastern District Dismisses Action Challenging FEMA'S Redistribution of Superstorm Sandy Disaster Relief Funds From Long Beach Medical Center to South Nassau Communities Hospital

Dubow v. U.S. Fed. Emergency Mgt. Agency, 2018 WL 472816 (E.D.N.Y. Jan. 18, 2018). Plaintiffs are residents of Long Beach Barrier Island, which was previously served by Long Beach Medical Center (LBMC), a general hospital as defined under N.Y. Public Health Law § 2801. LBMC was shut down on October 29, 2012 after sustaining damage during Superstorm Sandy. Although the U.S. Federal Emergency Management Agency (FEMA) designated LBMC as the subrecipient of $154 million in disaster assistance funds intended to restore comparable medical facilities to the area, the State of New York did not permit LBMC to reopen. LBMC filed a petition for bankruptcy and, on May 22, 2014, its assets were sold to South Nassau Communities Hospital (SNCH). Thereafter, FEMA approved SNCH as the substitute sub-recipient of the disaster assistance funds originally allocated to LBMC. Under SNCH's plan, a portion of the funds would be used to construct an emergency medical facility in Long Beach, but the majority of the funds would be used to expand SNCH's facilities at its Oceanside campus.

Plaintiffs filed suit against FEMA in the U.S. District Court, Eastern District of New York, alleging that the agency deprived them of due process and equal protection of laws in violation of the Fourteenth Amendment. The Complaint also alleged that the reallocation of disaster assistance funds to SNCH violated the Stafford Act and its implementing regulations. Plaintiffs claimed that there was a need for a fully operational hospital on Long Beach Barrier Island due to the lack of sufficient access routes to neighboring communities on mainland Long Island. FEMA moved to dismiss the complaint on both substantive and procedural grounds.

The court began its analysis by observing that the Stafford Act—which provides federal assistance to state and local governments in alleviating the suffering and damage caused by major disasters—charges FEMA with the administration of allocated funds. FEMA adopted regulations governing an applicant's eligibility for such assistance, including a policy offering "guidance on allowable uses and limitations of alternate project funds when restoration of the original damaged facility is not in the best interest of the public."

The court then addressed FEMA's motion to dismiss for lack of standing. The court asserted that to establish standing, the plaintiff must demonstrate (1) that it suffered an injury-in-fact, (2) that the injury is fairly traceable to the defendant's alleged actions, and (3) that a favorable decision would likely redress the alleged injury. First, the court first held that plaintiffs did not suffer any injury-in-fact, as they had no legally protected interest in the disaster relief funds allocated to SNCH. In so holding, the court relied upon decisions by numerous courts, including the Second Circuit, asserting that a person has no property interest in government benefits where the agency charged with distributing such benefits is given discretion under the relevant statute or regulations. The court found that the Stafford Act and its implementing regulations afforded FEMA discretion in granting or denying a proposed alternate use for disaster assistance funds, as they do not guarantee funding for a project that meets certain criteria. Second, the court found that plaintiffs' alleged injury—the lack of a full service hospital on Long Beach Barrier Island—was not traceable to any action by FEMA, as plaintiffs claimed that New York State refused to permit LBMC to reopen. Third, the court found that a favorable decision would not redress plaintiffs' alleged injury, as LBMC no longer exists as an entity and FEMA cannot force New York State to reopen the hospital. Therefore, the court held that Plaintiffs lacked standing for the relief that they sought.

Next, the court turned to FEMA's motion to dismiss for lack of federal subject matter jurisdiction. The court noted that plaintiffs brought a claim pursuant to 42 U.S.C. § 1983, which permits a private right of action against persons acting under color of state law. The court found this statute inapplicable, as plaintiffs brought the claim against a federal agency and not any named person, and because FEMA was at all times acting under federal law.

The court then addressed FEMA's argument that it was entitled to sovereign immunity. The court first stated that the Stafford Act contains an "express incorporation of sovereign immunity for discretionary acts." The court then noted that there is a two-prong test to determine whether an act is discretionary and thus shielded from judicial review: (1) whether the act involved a "judgment of choice" and (2) whether shielding the act from judicial review serves to protect decisions that are grounded in social, economic, or political policy. The court held that FEMA met the first prong of this test, as there was no "prescribed course of action" in determining whether to reallocate funds designated for LBMC to SNCH. The court also held that FEMA met the second prong, as the Second Circuit had already found that the Stafford Act's discretionary acts exception serves to protect public policy determinations from judicial second-guessing. Thus, the court found that Plaintiff's claims under the statute were barred by sovereign immunity.

Finally, the court turned to FEMA's motion to dismiss Plaintiff's due process and equal protection claim under the Fourteenth Amend-

ment for failure to state a cause of action. The court noted that property rights are not granted by the Constitution, but by laws and regulations securing certain benefits. Finding once again that plaintiffs lacked any property interest in the allocated disaster assistance funds under the Stafford Act or otherwise, the court dismissed plaintiffs' claim.

Second Circuit Upholds Grant of Summary Judgment to Montefiore Medical Center in ERISA Lawsuit

Montefiore Med. Ctr. v. Local 272 Welfare Fund, 2018 WL 1081219 (2d Cir. Feb. 28, 2018). Montefiore Medical Center ("Montefiore") provided health care services to patients who were members or beneficiaries of a group health plan sponsored by Defendant Local 272 Welfare Fund (the "Fund") under the Employee Retirement Income Security Act. Although Montefiore was not a member of the Fund's provider network, the patients assigned their rights under the plan to Montefiore in exchange for the health care services. Under the Fund's Summary Plan Description (SPD), claims for out-of-network services were to be paid at a rate that is "the maximum the Plan would have paid an in-network provider for the same service."

Montefiore filed suit against the Fund and its claims administrator, Defendant Marc Goodman, in the U.S. District Court, Southern District of New York, alleging that defendants failed to provide them with appropriate reimbursement for their services under the terms of the SPD. During discovery, it was revealed that the Fund interpreted the SPD to afford it discretion to select rates for out-of-network services based upon geography and the scope of services offered by the provider. Specifically, the Fund selected an in-network hospital in a similar geographic area that provides the same or similar services as Montefiore, and paid Montefiore the maximum rate that the Fund would have provided to that hospital for the same services. As a result, Montefiore was reimbursed at a flat, per-diem rate that the Fund paid to a nearby city-owned hospital, irrespective of the specific services provided to each patient. Following discovery, the parties filed motions for summary judgment.

The District Court granted Montefiore's motion and denied the Fund's motion. The court found that the SPD unambiguously required defendants to identify the rate that the Fund paid to each of its in-network providers for the relevant service and to pay Montefiore the maximum of those amounts. Conversely, the District Court rejected the Fund's argument that it had discretion to apply rates based upon geography and similarity of services, as the plain text of the SPD did not provide them with such latitude. The District Court likewise rejected various policy arguments, holding that they did not supersede the court's obligation to interpret the SPD's text, which the Fund itself drafted.

The Second Circuit affirmed the District Court's judgment, adopting the District Court's reasoning in its entirety. Although the Second Circuit recognized that the SPD was "perhaps unartfully drafted (and against the interest of) the Fund," it held that adopting the Fund's interpretation would require it to "impermissibly overlook, and rewrite, the Plan's language." [Ed. Note: Garfunkel Wild, P.C. represented Montefiore in this case].

New York Supreme Court Grants Hospital's Motion to Dismiss a Physician's Claims for Injunctive Relief and Money Damages Arising Out of the Denial of the Physician's Application to Renew Her Medical Staff Privileges

Anyichie v. Lincoln Medical and Mental Health Center, No. 153343-CV-2017, 2018 WL 746149 (Sup. Ct. N.Y. Cty. Feb. 7, 2018)

Plaintiff Nonyelu Anyichie, M.D. was an attending physician in the Department of Obstetrics-Gynecology at Defendant Lincoln Medical and Mental Health Center ("Lincoln"). After Lincoln declined to renew her privileges, plaintiff brought an action pursuant to Public Health Law (PHL) § 2801-c seeking the reinstatement of her medical staff privileges.

Lincoln's Credentialing Committee did not recommend renewal of plaintiff's clinical privileges based on issues relating to patient care, inappropriate behavior towards colleagues, residents and students, and frequent lateness. Plaintiff filed a discrimination action alleging that Lincoln, and its parent corporation New York City Health and Hospitals Corporation (now known as Health + Hospitals Corporation, (H+HC)), amongst others, engaged in various forms of employment discrimination and retaliation including the wrongful termination of her privileges at Lincoln.

Thereafter, Lincoln commenced a hearing pursuant to its medical staff bylaws to review the non-renewal of plaintiff's privileges. The Hearing Committee upheld the non-renewal because plaintiff "failed summarily in several core professional competencies in her responsibility to be part of a larger team in the OB-GYN Department to further the mission of the institution in facilitating optimal patient care and physician teaching" and that "her professional conduct, interpersonal skills, practice based learning and system based competencies were insufficient to remain as a member of the Medical Staff." The Hearing Committee's determination was upheld by the president of H+HC.

Plaintiff then filed a formal complaint with the New York State Public Health and Health Planning Council (PHC), pursuant to PHL § 2801-b. The PHC found, in a four-sentence letter, that Lincoln "did not afford due process to the complainant" according to its own bylaws and directed Lincoln to conduct a re-review. Lincoln thereafter conducted a re-review by the president of H+HC, at which time the

president agreed with the Hearing Committee's decision that it did not deprive plaintiff of her due process rights. In the meantime, Plaintiff settled her discrimination action which included a general release that provided in exchange for $300,000, plaintiff would release the City of New York and H+HC, from "any and all claims . . . of any kind whatsoever," except preserved her right to pursue her claim before the PHC.

Plaintiff then commenced this action alleging that Lincoln violated her rights under PHL §§ 2801-b by not reinstating her and not conducting a proper review as ordered by the PHC. Lincoln moved to dismiss on the grounds that plaintiff failed to identify an improper practice under PHL § 2801-b and that plaintiff's monetary damages claims must be dismissed because PHL only permits injunctive relief (and plaintiff released all claims in the discrimination action).

In granting Lincoln's motion to dismiss the complaint in its entirety, the court found that plaintiff failed to state a cause of action for injunctive relief under PHL § 2801-c, explaining that nowhere in the complaint did she allege that Lincoln engaged in an "improper practice" under PHL § 2801-b (1), or that the stated reasons were a pretext for some impermissible, ulterior reason for terminating her privileges. The court ruled that the PHC's finding, that Lincoln did not afford process to plaintiff, was of no effect because it was "beyond the scope of the PHC's review." The court further noted that the PHC's review should have been limited to finding whether Lincoln's decision to deny privileges was related to one of the various institutional concerns set forth in § 2801-b, and made in good faith. The court also found that because the PHC's letter did not contain any findings of fact to support its conclusion, its conclusion was neither persuasive nor controlling.

Finally, the court found that plaintiff's claims for damages were barred under §§ 2801-b and c because the statue limits plaintiff's claims to injunctive relief. The court also found that any damages claims were barred by the general release signed in the discrimination action.

Federal Court Rules That Materiality Requirement of False Claims Act Need Not Be Proven at Pleading Stage

United States ex rel. Gelman v. Donovan, 2017 WL 4280543 (E.D.N.Y. Sept. 25, 2017). Judge Raymond Dearie narrowly upheld an FCA complaint in the face of a challenge under Rules 12(b)(6) and 9(b), focusing on the materiality requirement of *Universal Health Servs., Inc. v. United States Ex rel. Escobar*, 136 S. Ct. 1989, 1993, 195 L. Ed. 2d 348 (2016). That requirement, described by the Supreme Court as "rigorous" and "demanding," is only met in the health care context when the evidence establishes that the government program that paid for the health care services—here, Medicaid and Medicare—would not have paid for the services had it known certain undisclosed facts surrounding the claim that the Relator contends rendered the claim "false."

In *Gelman*, the Relator pled facts alleging that the Podiatry Residency Program at Coney Island Hospital was plagued with a laundry list of unethical and illegal practices, none of which were disclosed to the government when the hospital made reimbursement claims for services provided as part of that program. For example, Gelman alleged that unlicensed residents were providing services to patients without any supervision, and that the director of the residency program falsified medical records to cover up this conduct. Gelman also asserted that the podiatry program fraudulently obtained "approval" by the American Podiatric Medical Association to be reimbursed for providing graduate medical education through the falsification of medical records and the falsification of personnel records. Although the complaint certainly asserted improper behavior in Coney Island's Podiatric Residency Program, *Escobar* requires the Relator to connect the alleged violations to the government's decision regarding whether it would pay for the services.

The court conceded that it was unclear "how much supervision of Podiatry residents" was required by the federal health care programs, and he opined that the wrongfully obtaining approval for the residency program certainly seemed material, as a matter of common sense. The Court relied primarily on the procedural posture of the case to deny the defense motion to dismiss. At the pleading stage, it concluded, it was only necessary that the alleged misconduct be "plausibly pled as relevant to the [government's] payment decision." Judge Dearie found that the *Gelman* complaint met that threshold. He cautioned, however, that materiality is ultimately an evidentiary question, and that "the day of reckoning will come at summary judgment."

Legislative Update
The Empire State Strikes Back

By James W. Lytle

Facing a multi-billion dollar deficit and an uncertain and sometimes threatening federal policy environment, Governor Andrew Cuomo proposed a series of legislative and fiscal proposals in his 2018-19 Executive Budget that could have an important impact on health care providers, payors and consumers in New York State.

Over the past several decades, New York State budgets have incorporated an increasing volume of substantive statutory proposals that might otherwise have been introduced as separate, stand-alone legislation to be considered on their own merits. Article VII, section 3 of the New York State Constitution authorizes the Governor, when the budget is submitted, to submit "proposed legislation, if any, recommended therein." By incorporating legislative initiatives within the budget, even those that might have only a modest fiscal impact and an insignificant connection to the budget itself, the Governor is sometimes able to enact legislative priorities more successfully and expeditiously than if the legislation were to be considered separately.

While the Legislature's consideration of the Executive Budget is, as of this writing, still underway, the proposals advanced in the proposed budget signal the Administration's policy and legislative priorities during the 2018 legislative session and implement steps designed to close a more than $4 billion deficit. In addition, the proposed budget legislation seeks to insulate New York from what Governor Cuomo views as the challenges posed by the Trump Administration to New York generally, and to New York's health care system in particular. The 2018-19 Budget can be viewed, at least in part, as an embattled New York's counterattack on the policies of the current federal Administration. In case that was not otherwise apparent, the budget briefing documents assembled by the Cuomo Administration were entitled "Stand United to Fight for New York."

Among the elements of this latest round in the Federal-New York State chess match are the following:

Health Care Shortfall Fund. The Executive Budget proposed the creation of a roughly billion dollar Healthcare Shortfall Fund ("the Fund") to cushion the State from potential federal funding reductions. The budget briefing document describes the rationale of the Fund as follows:

> In 2017, New York State faced unprecedented and repeated assaults from Washington aimed at crippling the State's health care system. These attacks included attempts to repeal the Affordable Care Act, putting health care for millions of New Yorkers at risk along with billions of dollars in Federal Medicaid funding. Additionally, Federal funding for CHIP expired in September with no longterm solution in place. Further, the President took unilateral Executive action to withhold Cost Sharing Reduction (CSR) payments, threatening low-cost health insurance coverage for income eligible recipients when purchasing a Qualified Health Plan or Essential Plan coverage through the New York State of Health, New York's official health plan marketplace. The Budget assumes the continuation of these important programs and takes actions to protect the health care of New Yorkers. (FY 2019 Executive Budget Briefing Book, p. 69).

While the threats described above were clear and present when the budget was released, several of them have since been eliminated or mitigated. The eventual budget agreement by Congress to extend the authorization and funding for the Children's Health Insurance Program and to postpone DSH cuts substantially reduced the immediate federal fiscal threat to New York. And while Congress has repeatedly threatened to transform the Medicaid program and the ACA in ways that might substantially prejudice New York, Congress has been consistently unable to muster enough votes to do so—at least other than the repeal of penalties for not fulfilling the mandate to maintain insurance coverage.

Health plan conversions: A substantial portion of the revenues for the Fund would derive from the payment to the State of a share of the proceeds of the pending $3.75 billion dollar sale and conversion of a not-for-profit Public Health Law Article 44 health maintenance organization, Fidelis, to for-profit Centene. The proposal to secure those funds for state purposes is modeled on the process followed when an Insurance Law Article 43 insurer, Empire Blue Cross/Blue Shield, converted to for-profit status 15 years ago. While the funding of the fund is premised on the Empire conversion, no legislation has yet been advanced that would apply to an Article 44 conversion and the Catholic diocesan sponsors of Fidelis have made it clear

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that they will oppose the attempt by the State to undertake what they characterized as an "unprecedented confiscation." The budget projects that the State would receive receipts of $750 million per year for at least the next four years from the conversion and it proposes to use $500 million per year to support the State share of Medicaid, with the remaining $250 million per year dedicated to the proposed Fund.

Healthcare Insurance Windfall Profit Fee. As another hedge against federal Medicaid reductions and to ensure support for New York's health care system, the Executive Budget would impose a 14 percent surcharge on health insurer "windfall profits" derived from the 40 percent reduction in corporate tax rates included in the agreement on federal tax reform. $140 million will be generated by the tax that will be invested, according to the budget documents, "in vital health care services for New Yorkers." The proposal might be a seen as a doubleshot at the Trump Administration, capturing the funds from the corporate tax cut and devoting them to the beleaguered health care system.

The 14% tax would be applied to net underwriting gain—defined as premiums less claims and administrative costs—on all health insurance contracts covering a New York resident and all Medicaid-managed care contracts overseen by the New York State Department of Health. The proposed windfall tax was intended to be directed only to for-profit health insurers and health maintenance organizations, regardless of licensure (e.g., Insurance Law Article 42 or Public Health Law Article 44), exempting not-for-profit health maintenance organizations and not-for-profit health insurers that did not benefit from the federal tax cut.

ACA-related actions: A number of the budget initiatives directly seek to address the persistent assault on the Affordable Care Act by the Administration, including proposals designed to preserve the Essential Plan (EP)—authorized by the ACA's Basic Health Program provisions—that had relied on the Cost Sharing Reduction (CSR) payments discontinued by the Administration last fall. The Executive Budget would require that the Department apply the EP Medical Loss Rebate (MLR) provision in 2016, 2017, and 2018 to offset the loss in CSR payments and would reduce EP rates by 4.4%. The budget anticipates the ACA's Advance Premium Tax Credit subsidies (and other actions) will generate enough funding in future years to fully fund the EP going forward—a health insurance coverage option that has garnered approximately three-quarters of a million customers.

Perhaps of note, as well, is the absence of proposals that might affirmatively strengthen the ACA exchange in New York. While some states have advanced state-specific individual health insurance mandates to maintain participation in the insurance marketplace, neither the Governor nor members of the Legislature have advanced a proposal to establish an individual mandate in New York—nor has the Administration sought ACA-authorized insurance waivers designed to stabilize the health insurance exchange.

Child Health Plus (CHP) Provisions. Anticipating a continued Congressional stalemate over the authorization and funding of the Children's Health Insurance Program, the budget proposed granting the Department of Health and the Division of Budget with the necessary authority to recommend programmatic changes, as may be necessary, to continue CHP coverage with state-only funding and identify specific changes needed to align the program with reduced funding. As noted above, after Congress reauthorized the program and appropriated funding for it, these provisions would appear to be unnecessary.

Reserves of Not-For-Profit Medicaid Managed Care Plans. The Executive Budget would authorize the Department to make prospective adjustments to the rates of not-for-profit Medicaid Managed Care plans and MLTC plans that have an aggregate accumulated contingent reserve across all lines of business, above what is required. The proposal arguably runs counter to the recent State experience with an under-reserved ACA-participating plan, Health Republic, whose insolvency left providers and consumers at risk.

Federal tax reform response: Although not healthcare-specific, perhaps the most direct counterattack in the proposed budget consists of proposals that would seek to nullify the loss of State and Local Tax (SALT) deductions, which were severely limited in the federal tax reform law enacted at the end of 2017. Health care entities and practitioners will, like everyone else in New York, be potentially affected by the complex array of proposals advanced by the Governor in his 30-day budget amendments to blunt the near-elimination of the SALT deduction, including the following:

- *Optional Employer Compensation Expense Tax (ECET) System.* The proposal would institute an optional payroll tax by which opting-in employers would be subject to a 5 percent tax (phased in over three years, beginning in the 2019 calendar year) on all annual payroll expenses in excess of $40,000 per employee. The personal income tax system would remain in place, and the ECET would be coupled with income tax relief for employees in the form of a corresponding tax credit on their wages, resulting in an increase in take-home pay. The proposal would be revenue neutral to the State, but is projected to result in up to $4 billion in federal tax savings for New Yorkers per year.
- *Charitable contributions to support education and health care.* To address the reduction in deductibility of state and local taxes and to take advantage of increases in charitable contribution limits that were also contained in the federal tax law changes, the bill

would establish two new state-operated charitable funds to accept donations for the purposes of improving health care and education in New York. Taxpayers who contributed to these entities could claim these charitable contributions as deductions on both their federal and state tax returns and would also receive an 85 percent state tax credit on the donation amount. Local governments, including school districts, could establish similar charitable entities, to which their residents could contribute and receive a reduction of their property tax up to 95% of the donation.

- *Decoupling state tax provisions from new federal tax code.* The Governor is proposing to "decouple" a number of provisions of state tax law from the new federal provisions to avoid adverse consequences for New York taxpayers. The proposal would decouple the state and local tax deduction cap, which would otherwise result in a $441 million state tax increase—similar to legislation already passed by the State Senate. In addition, the proposal would maintain the standard deduction for single filers and would allow New Yorkers to itemize deductions for state tax purposes, even if they take advantage of the larger standard deduction on their federal return.

Whatever may be the outcome of the budget debate, the consideration of these and other proposals remind us of one of the unique strengths of our federal system: Namely, the opportunity for states to operate as "laboratories of democracy" to explore alternative and even policies directly contrary to the national government to protect the interests of their citizens.

In the New York State Agencies

By Francis J. Serbaroli

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

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 N.Y.C.R.R. to ensure coverage for essential health benefits in all individual, small group, and student accident and health policies. *See* N.Y. Register November 15, 2017.

Agency Name Change Update

Notice of Adoption. The Office for People with Developmental Disabilities amended Parts 630 and 671 of Title 14 N.Y.C.R.R. to update the agency name in Title 14 N.Y.C.R.R. Parts 630 and 671. *See* N.Y. Register November 15, 2017.

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

Notice of Adoption. The Department of Health amended § 80.84 of Title 10 N.Y.C.R.R. to allow any authorized practitioner to prescribe, administer and dispense buprenorphine for the treatment of narcotic addiction. *See* N.Y. Register November 22, 2017.

Communication Between Clinical Laboratory Physicians and Patients

Notice of Adoption. The Department of Health amended §§ 142-2.3 and 142-3.3 of Title 12 N.Y.C.R.R. to strengthen existing call-in pay protections involving employee scheduling. *See* N.Y. Register November 22, 2017.

Clarification of Assessment of Functional and Health-Related Needs

Notice of Proposed Rulemaking. The Office for People with Developmental Disabilities proposes to amend Subpart 636-1 of Title 14 N.Y.C.R.R. to clarify requirements for an Assessment of Functional and Health-Related Needs in Person Centered Planning regulations. *See* N.Y. Register November 29, 2017.

Chemical Dependence Outpatient and Opioid Treatment Programs

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 822 of Title 14 N.Y.C.R.R. to conform HIV and Hepatitis testing requirements in outpatient settings with Public Health Law. *See* N.Y. Register December 6, 2017.

Residential Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 820 of Title 14 N.Y.C.R.R. to conform HIV and Hepatitis testing requirements in residential settings with Public Health Law. *See* N.Y. Register December 6, 2017.

Food Beverages in Funeral Establishments

Notice of Proposed Rulemaking. The Department of Health proposes to amend §§ 77.5, 78.1 and 79.4 of Title 10 N.Y.C.R.R. to lift the ban of the consumption of food and beverages in funeral establishments. *See* N.Y. Register December 6, 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; addition of § 361.9 to Title 11 N.Y.C.R.R. to allow for the implementation of a market stabilization pool for the small group health insurance market. *See* N.Y. Register December 13, 2017.

Lead Testing in School Drinking Water

Notice of Emergency Rulemaking. The Department of Health amended Subpart 67-4 to Title 10 N.Y.C.R.R. to require lead testing and remediation of potable drinking water in schools. *See* N.Y. Register December 13, 2017.

Holding Companies

Notice of Adoption. The Department of Financial Services amended Subpart 80-1 (Regulation 52) of Title 11 N.Y.C.R.R. to make technical correction to and clarification of 11 N.Y.C.R.R. § 80-1.6(3). *See* N.Y. Register December 20, 2017.

Privacy of Consumer Financial and Health Information, General Provisions

Notice of Adoption. The Department of Financial Services amended Part 420 (Regulation 169) of Title 11 N.Y.C.R.R. to incorporate recent changes to federal privacy laws regarding information maintained by financial institutions. *See* N.Y. Register December 20, 2017.

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

Medical Conditions for Which an Exemption from Restrictions on Tinted Glass May Be Issued

Notice of Adoption. The Department of Health amended section 69-7.1 of Title 10 N.Y.C.R.R. to Amend the existing list of medical conditions for a NYS registered driver or habitual passenger for an exemption to tinted glass. *See* N.Y. Register December 20, 2017.

Operation of Licensed Housing Programs for Children and Adolescents with Serious Emotional Disturbances

Notice of Proposed Rulemaking. The Office of Mental Health proposes a consensus rulemaking to repeal § 594.8 and add new § 594.8 to Title 14 N.Y.C.R.R. to repeal § 594.8 of Title 14 N.Y.C.R.R. and replace it with a clarified revised version. *See* N.Y. Register December 20, 2017.

SNAP Benefit Offset

Notice of Emergency and Proposed Rulemaking. The Office for People with Developmental Disabilities amended Parts 671 and 686 of Title 14 N.Y.C.R.R. to update the SNAP benefit offset and the amount that each individual must pay to providers. *See* N.Y. Register December 20, 2017.

Site Based and Community-Based Prevocational Services

Notice of Emergency and Proposed Rulemaking. The Office for People with Developmental Disabilities amended Subpart 635-10 of Title 14 N.Y.C.R.R. to clarify site-based and community-based services and clarify reimbursement requirements. *See* N.Y. Register December 20, 2017.

Medical use of Marihuana

Notice of Adoption. The Department of Health amended Part 1004 and Subpart 55-2 of Title 10 N.Y.C.R.R. to comprehensively regulate the manufacture, sale and use of medical marihuana. *See* N.Y. Register December 27, 2017.

Residential Health Care Facility Quality Pool

Notice of Adoption. The Department of Health added § 86-2.42 to Title 10 N.Y.C.R.R. to reward NYS facilities with the highest quality outcomes as determined by methodology developed by regulation. *See* N.Y. Register January 3, 2018.

Children's Behavioral Health and Health Services

Notice of Adoption. The Department of Health added § 505.38 to Title 18 N.Y.C.R.R. to authorize Medicaid coverage of new behavioral health and health services for children under 21 years of age. *See* N.Y. Register January 3, 2018.

Hospital Policies and Procedures for Individuals with Substance Use Disorders

Notice of Proposed Rulemaking. The Department of Health proposed to amend Parts 405 and 407 of Title 10 N.Y.C.R.R. to require hospitals to establish policies and procedures to identify, assess and refer individuals with substance use disorders. *See* N.Y. Register January 10, 2018.

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

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 N.Y.C.R.R. to ensure coverage for essential health benefits in all individual, small group, and student accident and health policies. *See* N.Y. Register January 17, 2018.

Public Water Systems

Notice of Adoption. The Department of Health amended Subpart 5-1 of Title 10 N.Y.C.R.R. to incorporate federal rules and revisions to Public Health Law. *See* N.Y. Register January 17, 2018.

Repeal Part 830 (Acupuncture) and Add New Part 830 (Designated Services; Acupuncture and Telepractice) to Title 14 N.Y.C.R.R.

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 830; addition of new Part 830 to Title 14 N.Y.C.R.R. to repeal obsolete regulations and incorporate provisions into a new Part with additional provisions. *See* N.Y. Register January 24, 2018.

Children's Behavioral Health Services.

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services added Part 823 to Title 14 N.Y.C.R.R. to define and implement children's behavioral health services pursuant to the EPSDT program in New York. *See* N.Y. Register January 24, 2018.

Medical Use of Marihuana

Notice of Emergency Rulemaking. The Department of Health amended §§ 1004.3, 1004.4, 1004.22 and 1004.23 of Title 10 N.Y.C.R.R. to allow certain defined facilities to become a designated caregiver for a certified patient in NYS's Medical Marihuana Program. *See* N.Y. Register January 24, 2018.

Emergency Medical Services (EMS) Initial Certification Eligibility Requirements

Notice of Proposed Rulemaking. The Department of Health proposed to amend § 800.6 of Title 10 N.Y.C.R.R. to reduce the EMS certification eligibility minimum age from 18 to 17 years of age. *See* N.Y. Register January 24, 2018.

Erratum Office of Mental Health: extending comment period

I.D. No. OMH-51-17-00001-P, pertaining to Operation of Licensed Housing Programs for Children and Adolescents with Serious Emotional NYS Register/January 24, 2018 Rule

Making Activities Disturbances, published in the December 20, 2017 issue of the State Register, indicated that public comment would be received until 45 days after publication of the Notice. The public comment period for this Notice has been extended until February 20, 2018.

Erratum Office for People with Developmental Disabilities

I.D. Nos.: PDD-51-17-00005-EP and PDD-51-17-00006-EP, pertaining to SNAP Benefit Offset, Site-Based and Community-Based Prevocational Services, published in the December 20, 2017 issue of the State Register, indicated that public comment would be received until 45 days after publication of the Notices. The public comment periods for these Notices have been extended until February 20, 2018.

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

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 361; and addition of § 361.9 to Title 11 N.Y.C.R.R. to allow for the implementation of a market stabilization pool for the small group health insurance market. *See* N.Y. Register February 7, 2018.

Public Water Systems – Revised Total Coliform Rule

Notice of Proposed Rulemaking. The Department of Health proposed to amend Subpart 5-1 of Title 10 N.Y.C.R.R. to increase public health protection by reducing exposure to contaminants in drinking water. *See* N.Y. Register February 7, 2018.

Establishment, Incorporation and Certification of Providers of substance Use Disorder Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 810 of Title 14 N.Y.C.R.R. to clarify the obligation to recognize alcohol/substance abuse programs operated by Indian Health Services facilities. *See* N.Y. Register February 14, 2018.

Lead Testing in School Drinking Water

Notice of Emergency Rulemaking. The Department of Health added Subpart 67-4 to Title 10 N.Y.C.R.R. to require lead testing and remediation of potable drinking water in schools. *See* N.Y. Register February 14, 2018.

Medicaid Reimbursement of Nursing Facility Reserved Bed Days for Hospitalizations

Notice of Proposed Rulemaking. The department of Health proposed to amend § 505.9 of Title 18 N.Y.C.R.R.; and amendment of § 86-2.40 of Title 10 N.Y.C.R.R. to make changes relating to reserved bed payments made by Medicaid to nursing facilities. *See* N.Y. Register February 14, 2018.

Rate Rationalization—Intermediate Care Facilities for Persons with Development Disabilities

Notice of Proposed Rulemaking. The Department of health proposed to amend Subpart 86-11 of Title 10 N.Y.C.R.R. to amend rate methodology effective July 1, 2016 and include addition of an occupancy adjustment and revision to April 1, 2015 2% compensation calculation. *See* N.Y. Register February 14, 2018.

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

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

Adult Sibling Update

Notice of Proposed Rulemaking. The Office for People with Developmental Disabilities proposed a consensus rulemaking to amend Parts 624 and 633 of Title 14 N.Y.C.R.R. to add adult sibling to the list of qualified persons available, pursuant to Mental Hygiene Law § 33.16(a)(6). *See* N.Y. Register February 14, 2018.

Advocacy Organization Definition Update

Notice of Proposed Rulemaking. The Office for the Aging adopted a consensus rulemaking to amend § 676.12(ab) of Title 14 N.Y.C.R.R. to redefine the advocacy organizations listed under § 676.12(ab). *See* N.Y. Register February 14, 2018.

Administration of the Long Term Care Ombudsman Program

Notice of Adoption. The Office for the Aging repealed § 6660; and addition of new § 6660 to Title 9 N.Y.C.R.R. to bring NYSOFA's rules and regulations governing LTCOP into conformance with the Federal Statute and regulations. *See* N.Y. Register February 21, 2018.

Managed Care Organizations

Notice of Proposed Rulemaking. The Department of Health proposed amending § 98-1.11(e) of Title 10 N.Y.C.R.R. to maintain the contingent reserve requirement applied to the Medicaid Managed Care, HIV SNP and HARP programs. *See* N.Y. Register February 28, 2018.

Procedure for Treatment and Hospitalization of Certain Mentally Ill Prisoners in Jail

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending § 18.7 of Title 14 N.Y.C.R.R. to conform implementing regulations with a change in the authorizing statute. *See* N.Y. Register February 28, 2018.

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health Medicaid Decisions

Compiled by Margaret Surowka Rossi

Nothing reported in this issue.

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

Compiled by Bridget Steele, Jamie Dughi Hogenkamp, Eric Dyer, and Dena DeFazio

Brooklyn Home Health Provider Settles Allegations of False Billing for $6.4 Million—January 31, 2018—A Brooklyn-based Licensed Home Care Services Agency (LHCSA) was alleged to have violated the New York and federal False Claims Acts for billing the Medicaid program for services rendered or delivered by unqualified staff, resulting in a $6.4 million settlement. The settlement follows allegations that the provider allowed its aides to circumvent the attendance verification system, resulting in billings for services that were never delivered. In fact, aide supervisors were alleged to have modified and created entries to make it appear as though aides clocked-in for work and, in one instance, the provider billed for the services of a particular aide who was vacationing in the Caribbean. It was also alleged that the provider hired employees who used stolen identities from qualified individuals, and the provider did not adequately try to prevent this from occurring. https://ag.ny.gov/press-release/ag-schneiderman-announces-64-million-settlement-brooklyn-home-health-care-provider.

New York Files a Lawsuit Against the President for Cuts to New York's Essential Plan—January 26, 2018—A lawsuit was filed by New York and Minnesota, the only two states that operate Basic Health Programs (i.e., a state-run health insurance program for low-income residents created under the Affordable Care Act). In New York, the program is called the Essential Plan. The lawsuit alleges that the Department of Health and Human Services unlawfully cut off more than $1 billion of funding to New York's plan, violating the Administrative Procedures Act, and failed to respond and adopt the states' reasonable alternative funding proposals. According to the lawsuit, the federal government's decision impacts 700,000 New Yorkers on the Essential Plan. https://ag.ny.gov/press-release/ag-schneiderman-and-governor-cuomo-announce-1-billion-lawsuit-against-trump.

New York Reaches a Settlement Agreement with Aetna over HIV Status Privacy Breach—January 23, 2018—In July 2017, Aetna improperly disclosed the HIV status of 2,460 of its New York members. The disclosure occurred after mailings were sent in oversized envelopes with transparent address windows that revealed the member's HIV status. As a result, Aetna agreed to pay a $1.15 million civil penalty, enhance its privacy protections related to mailings, and hire an independent consultant to monitor and report on the settlement. Of particular significance, the purpose of Aetna's mailings were to notify members of a class action lawsuit related to purchasing HIV medications at pharmacy locations instead of through mail/delivery order, as the mail/delivery order policy could compromise member privacy. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-aetna-over-privacy-breach-new-york-members-hiv.

Owners of Medical Testing Company Indicted and Arrested in Relation to an $8 Million Medicaid Scheme—January 16, 2018—The two owners of a Brooklyn-based medical testing company were indicted and arrested for charges related to illegally billing Medicaid for fraudulent diagnostic testing services and money laundering

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

in relation to their "medical mill" scam. The two owners had been indicted by a federal grand jury for a similar fraud scheme one month before this indictment. The fraudulent scheme allegedly solicited Medicaid recipients with no medical concerns by offering them cash payments. The business then submitted payment requests to Medicaid and Medicaid Managed Care Organizations for services that were not delivered or were medically unnecessary. The scheme involved unlicensed providers, as well as licensed health providers that were paid by the "medical mill" for use of their medical licenses and Medicaid credentials, and subjected patients to various medical tests. The charges could result in each Defendant serving up to 25 years in prison, in addition to civil damages of $24 million. https://ag.ny.gov/press-release/ag-schneiderman-announces-indictment-and-arrests-medical-testing-company-owners-multi.

Second Indictment for Unlicensed Plastic Surgeon—January 12, 2018—A Westbury, New York-based unlicensed plastic surgeon who had already been indicted for assault, grand larceny and the unauthorized practice of medicine was indicted on additional allegations related to insurance and public benefits fraud. The unlicensed plastic surgeon, who had his license revoked in 2007 by the New York State Department of Health, Office of Professional Medical Conduct for professional misconduct, was allegedly performing illegal surgeries along with a licensed physician. The scheme went on from 2012 to 2016, with over 60 patients undergoing surgery. One such patient was permanently disfigured. The most recent indictment relates to the unlicensed plastic surgeon's alleged scheme to obtain over $360,000 in disability insurance payments by falsely certifying that he was no longer practicing medicine. In addition, the unlicensed plastic surgeon allegedly filed sworn documents with the government that he was entitled to food stamp benefits ,thereby concealing the income from the illegal medical practice, disability insurance payments, and income from a start-up skin-care company. This most recent 21-count indictment is on top of the 22-count indictment from November 16, 2017. https://ag.ny.gov/press-release/ag-schneiderman-announces-second-indictment-unlicensed-plastic-surgeon-insurance-fraud.

Methadone Clinic Reaches a Settlement for Improperly Billing Medicaid—January 12, 2018— New York State reached a $1.25 Million settlement with a Methadone Maintenance Treatment Program for the program's failure to properly document patient treatment plans. In many cases, the treatment plans were not discussed, reviewed or signed by the patients. The settlement also requires that an independent monitor be put in place to ensure the program's compliance with the Medicaid rules and regulations. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-whitney-m-young-health-center-improperly-billing.

New York Reaches a Settlement with a Business Group to Revitalize a Nursing Home and Replace Health Gaps in New York Communities—January 5, 2018— A settlement with a nursing home-related business follows the closure of two nursing homes, one on the Lower East Side and another in Brooklyn. This business purchased two nursing home facilities from non-profit nursing home operators and then closed the facilities a short time after the purchase with little notice provided to the affected communities. The settlement requires the business to pay $750,000 in penalties and costs to the State, and $1.25 million to Lower East Side health care non-profits to make improvements to one nursing home and to open a new one in Brooklyn. The settlement also adds measures to ensure the processes that led to the closures will not happen again. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-allure-group-revitalize-harlem-nursing-home-fill.

Certified Nurse Aides Arrested for Nursing Home Neglect—December 20, 2017— Two Certified Nurse Aides (CNAs) employed by a White Plains nursing home were arrested for allegedly failing to properly monitor a dementia resident. This resident left the nursing home at around 7:54 p.m., was not discovered missing until 10 p.m., and was eventually found, uninjured, at 3:00 a.m., approximately two-miles from the facility. The CNAs allegedly failed to perform their 15-minute safety checks and then falsely recorded that the checks had occurred between 8:00 p.m. and 9:30 p.m. Both CNAs face up to four years in prison for Endangering the Welfare of an Incompetent or Physically Disabled Person in the First Degree, a class E felony, and Willful Violation of Health Laws, a class A misdemeanor. One of the CNAs was also charged with Falsifying Business Records in the First Degree, a class E felony. https://ag.ny.gov/press-release/ag-schneiderman-announces-arrests-alleged-cover-white-plains-nursing-home-neglect.

N.Y. A.G. Announces $13.5 Million Multi-State Agreement with Boehringer Ingelheim Pharmaceuticals, Inc. for Deceptive Marketing Practices and Promotion of Prescription Drugs for Unapproved Uses—December 20, 2017—A settlement was reached with Boehringer Ingelheim Pharmaceuticals, Inc., resolving allegations of deceptive and misleading marketing practices based on alleged misrepresentations of drug usage, dosage, and effectiveness. All 50 states and the District of Columbia were involved in the $13.5 Million settlement, with New York to receive $490,341. The agreement also requires Boehringer to reform its marketing practices by not unlawfully promoting the four prescription drugs at issue, limiting samples of the products, providing unbiased clinical information separate from

promotional materials, refraining from offering financial incentives that may indicate unapproved uses for sales of the drugs, and referring any requests for unapproved usage information for the drugs to its Medical Division. https://ag.ny.gov/press-release/ag-schneiderman-announces-135-million-multi-state-agreement-boehringer-ingelheim.

Operation Ghost Ride: N.Y. A.G. Announces Sentencing of Owner of Albany Transportation Companies for Stealing Thousands in Medicaid Transit Scam—December 8, 2017—The owner and co-owner of two transportation companies were sentenced to two to six years in prison after a conviction for Grand Larceny in the Third Degree, a class D felony. The conviction arose from an undercover investigation by the Attorney General's office called "Operation Ghost Ride," which found that over $50,000 in fraudulent claims were submitted to Medicaid for transportation rides that never occurred. The defendant's business partner also pled guilty to similar charges and is awaiting sentencing. https://ag.ny.gov/press-release/operation-ghost-ride-ag-schneiderman-announces-sentencing-owner-albany-transportation.

N.Y. A.G. Leads 16-AG Coalition Opposing Birth Control Rollback—December 6, 2017—New York's Attorney General led a coalition of 16 Attorneys General in filing comments with the federal Department of Health and Human Services, opposing the interim final rules rolling back birth control coverage under the Affordable Care Act. The comments allege harm to the states, and violations of the Establishment Clause, Equal Protection Clause, and the Administrative Procedure Act. The Attorneys General have also filed a federal lawsuit seeking to protect access to birth control. New York's A.G. joined the Attorneys General from California, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Minnesota, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, and the District of Columbia, in the comments and suit. https://ag.ny.gov/press-release/ag-schneiderman-leads-16-ag-coalition-opposing-birth-control-rollback.

Guilty Plea and Conviction for Nurse Who Stole Over $27,000 From Medicaid—November 30, 2017—A Hamburg Licensed Practical Nurse pled guilty to Grand Larceny in the Fourth Degree, a class E felony, for submitting false claims to Medicaid for private-duty nursing services over 17 months that were never performed. The defendant faces probation or one to four years in state prison and must pay $27,186.46 in restitution to the New York State Medicaid Fraud Restitution Fund. https://ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-and-conviction-private-duty-nurse-who-stole-over.

Settlement with Brooklyn Hospital to Ensure Rape Survivors Are No Longer Illegally Billed for Forensic Rape Examinations—November 28, 2017—The Attorney General announced a settlement with the Brooklyn Hospital Medical Center, resolving allegations that the hospital illegally billed sexual assault survivors for forensic rape examinations between January 2015 and February 2017. The settlement requires the hospital to maintain a Sexual Assault Victim Policy to prevent improper billing, and to provide full restitution to improperly billed survivors. Following the investigation, the Attorney General by letter requested information on billing policies from ten other hospitals across New York State. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-brooklyn-hospital-ensure-rape-survivors-are-no.

Settlement with Oswego County to Ensure Health Insurance Coverage for Transgender Employees—November 20, 2017—The Attorney General announced a settlement with Oswego County, to ensure that transgender county employees and retirees have health coverage through employer-provided health plans. The Oswego County insurance plan contained a broad exclusion that affected medications, implants, hormone therapy, surgery, and both medical and psychiatric treatment, violating a number of laws including Title VII of the Civil Right Act, the New York State Human Rights Law, and the Mental Health Parity and Addiction Equity Act. Under the settlement, the county will eliminate the categorical exclusions of expenses related to gender transition in its health plan, offer affirmative benefits for treatments and procedures for gender transition, and ensure both training and compliance with anti-discrimination laws. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-oswego-county-ensure-health-insurance-coverage.

Pharmacy Owner, Pharmacist, and Three Pharmacies Indicted for Allegedly Defrauding Medicaid of Over $3 Million—November 17, 2017—Two individuals and three pharmacies were indicted for allegations of fraudulently billing Medicaid and Medicare for prescription refills that were not actually filled. The pharmacy owner was indicted for Grand Larceny in the First Degree (class B felony), Grand Larceny in the Second Degree (class C felony), Healthcare Fraud in the Second Degree (class C felony), Scheme to Defraud in the First Degree (class E felony), Offering a False Instrument for Filing in the First Degree (class E felony), and Medical Assistance Provider, Prohibited Practice (class E felony). The supervising pharmacist was also indicted for Grand Larceny in the Second Degree (class C felony), Grand Larceny in the Third Degree (class D felony), Scheme to Defraud in the First Degree (class E felony), and Medical Assistance Provider, Prohibited Practices

(class A misdemeanor). The three pharmacies were also charged with several similar crimes. If convicted, the pharmacy owner faces up to 25 years in state prison, the supervising pharmacist faces up to 15 years, and the pharmacies can be forced to pay substantial fines and restitution. Civil asset forfeiture and recovery actions are also pending against the parties. https://ag.ny.gov/press-release/ag-schneiderman-anounces-indictment-against-pharmacy-owner-pharmacist-and-three.

Binghamton-Area Transport Company and Owners Sentenced for Stealing from Medicaid and Failing to Secure Workers' Compensation Insurance—November 15, 2017—Two defendants and a medi-van and taxi company were sentenced after fraudulently receiving Medicaid funds and knowingly operating transportation services without workers' compensation insurance. The defendants forfeited and released $455,604 to the Attorney General's Medicaid Fraud Control Unit, which was being withheld by the New York State Department of Health, and each will pay $50,000 in restitution. Additionally, one defendant was sentenced to five years' probation, another to one year of conditional discharge, and the transport company to three years conditional discharge. The sentences stem from one defendant's guilty plea to Offering a False Instrument for Filing in the Second Degree, a New York penal law violation, and guilty pleas by the other defendant and the transportation company to Effect of Failure to Secure Compensation, a violation under the Workers' Compensation law. https://ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-binghamton-area-transport-company-and-owners.

N.Y. A.G. Files for National Injunction to Block the President's Unlawful Rollback of Birth Control Rule—November 10, 2017—Several State Attorneys General, including New York's Attorney General, filed a petition for a nationwide injunction to protect access to birth control and to halt the Presidential Administration's rules seeking to roll back the Affordable Care Act's contraceptive coverage mandate. The Trump Administration's rules would allow employers to opt out of the contraceptive coverage mandate. New York has regulations in place to protect contraceptive access, but these regulations do not apply to self-funded insurance plans governed under federal law. The injunction was sought following a federal lawsuit filed by the same Attorneys General earlier in November 2017. https://ag.ny.gov/press-release/attorney-general-schneiderman-files-national-injunction-block-trump-administrations.

Rochester Man Sentenced for Stealing From and Defrauding Medicaid—November 9, 2017—A Rochester man pled guilty to Falsifying Business Records in the First Degree, a class E felony, after submitting false timesheets claiming that he provided home care services to a disabled Medicaid recipient when he never made such home visits, resulting in over $6,000 in payments improperly billed to Medicaid. The Attorney General's investigation, conducted by the Medicaid Fraud Control Unit (MFCU), revealed that the man submitted false timesheets for at least three months indicating he had provided daily personal care services to the Medicaid recipient in Geneva, New York; in fact, he had been 40 miles away in Rochester, New York when the services were supposedly rendered. He was adjudicated as a second felony offender due to two prior felony convictions, and was sentenced to 1½ to 3 years in state prison. https://ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-rochester-man-stealing-and-defrauding-medicaid.

Registered Nurse Convicted of Stealing Over $390,000 From Medicaid Sentenced—November 2, 2017—A private duty Registered Nurse pled guilty to Grand Larceny in the Third Degree, a class D Felony, for submitting false claims for private duty nursing services he never provided to Medicaid recipients over a nearly five-year period. The nurse submitted claims for payment to Medicaid between August 2010 and January 2015, resulting in over $390,000 in improper Medicaid payments. Claims were submitted to Medicaid when recipients were in the hospital, when another nurse provided the care, when the registered nurse was in Europe or providing care to another recipient, and for periods of time when an unlicensed person provided care. https://ag.ny.gov/press-release/ag-schneiderman-announces-jail-sentence-registered-nurse-convicted-stealing-over.

Former Nursing Home Resident Who Sexually Abused Disabled Resident at Same Facility Pleads Guilty—November 1, 2017—A former nursing home resident and patient at a nursing home in Cooperstown, New York, pled guilty to Sexual Abuse in the First Degree, a class D felony, for sexually abusing a disabled resident at the same nursing home facility. While the 79-year-old patient was at the nursing home, he subjected another elderly disabled resident to unwanted sexual contact. The former resident was sentenced to two years in state prison, three years' post-release supervision and will have to register as a sex offender. https://ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-former-nursing-home-resident-who-sexually-abused.

Settlement with Molina Health Care to Address Language And Communication Access Deficiencies—October 31, 2017—Central New York health insurer, Molina Health Care of New York ("Molina"), formerly Total Care of New York ("Total Care"), reached a settlement with New York's Attorney General following claims that the insurer failed to provide legally required information and notices to Limited English Proficiency (LEP) enrollees. Under federal and state law, health plans are required to provide enrollment

notices and information in an easily understandable manner, translate materials depending on the language needs of enrollees, and provide free interpretation services. As a result of the settlement, Molina will need to remove language and communication barriers and pay a $25,000 civil penalty to New York State. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-molina-health-care-address-language-and.

Guilty Pleas and Convictions for Owners of Albany Transportation Companies for Stealing Thousands in a Medicaid Transit Scam—October 31, 2017—Two owners of Albany transportation companies pled guilty to grand larceny for defrauding Medicaid by transporting Medicaid recipients to fictitious medical appointments. The Attorney General's undercover investigation of the companies revealed over $50,000 in improper Medicaid payments for fraudulent claims for transportation services that were never provided. https://ag.ny.gov/press-release/operation-ghost-ride-ag-schneiderman-announces-guilty-pleas-and-convictions-owners.

Nurse Arrested for Failing to Give Critical Medications to Nursing Home Residents—October 26, 2017—A Brewster, New York Licensed Practical Nurse was arrested for failing to administer prescribed medications to three disabled residents. The nurse allegedly failed to administer critical medications to these three patients but made entries into their medical records indicating the medications were administered. The nurse pled not guilty to three counts of Endangering the Welfare of an Incompetent or Physically Disabled Person in the First Degree, a class E Felony, three counts of Falsifying Business Records in the First Degree, a class E Felony, and three counts of Willful Violation of Health Laws, a misdemeanor. https://ag.ny.gov/press-release/ag-schneiderman-announces-nurse-arrest-failing-give-critical-medications-nursing-home.

Rochester Man Arrested for Misusing Medicaid To Sell Opioid Prescriptions—October 25, 2017—A Rochester man was arrested for allegedly using Medicaid benefits to illegally fill Oxycodone prescriptions. The pills were allegedly sold to drug dealers in the Rochester area. The man faces up to nine years in prison for charges of Criminal Possession and Sale of a Controlled Substance in the Third Degree, both B felonies, and Grand Larceny in the Third Degree, a class D felony. The Attorney General launched its investigation after the Drug Enforcement Agency (DEA) received an anonymous tip. The man allegedly purchased 25 prescriptions for Oxycodone, adding up to 12,500 pills, and costing Medicaid $12,437.62. https://ag.ny.gov/press-release/ag-schneiderman-announces-arrest-rochester-man-misusing-medicaid-sell-opioid.

New York A.G., Coalition of AGs Seek Emergency Injunction Over Health Care Subsidies—October 18, 2017—Several Attorneys General, including New York's Attorney General, filed a motion to compel the President's Administration to pay health care subsidies after the Administration refused to make October cost-sharing reduction payments required under the Affordable Care Act. These payments reduce co-payments, deductibles, and other out-of-pocket expenses. New York insurance plans face a loss of millions of dollars budgeted to come from these subsidies destabilizing the health care market. New York's Attorney General called the Administration's decision to cut these subsidies "reckless, dangerous, —and illegal[.]" https://ag.ny.gov/press-release/attorney-general-schneiderman-coalition-ags-seek-emergency-injunction-over-health-care.

New York State Office of the Medicaid Inspector General Update

Compiled by Eric Dyer

OMIG Plays Critical Role in Multi-Agency Takedown of Massive $146M Health Care Fraud Scheme—December 8, 2017—https://www.omig.ny.gov/latest-news/1080-omig-plays-critical-role-in-multi-agency-takedown-of-massive-146m-health-care-fraud-scheme.

OMIG Posts Webinar for 2017 Mandatory Compliance Programs & Deficit Reduction Act of 2005 Certification Process—November 27, 2017—https://omig.ny.gov/latest-news/1077-omig-posts-webinar-for-2017-mandatory-compliance-programs-deficit-reduction-act-of-2005-certification-process.

OMIG Posts 2017 Managed Care Annual Program Integrity Report Information and Submission Instructions—November 27, 2017—https://omig.ny.gov/latest-news/1078-omig-posts-2017-managed-care-annual-program-integrity-report-information-and-submission-instructions.

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Edited by Cassandra Rivais

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For Your Information

By Claudia O. Torrey

Just a thought—I am sure by now you are aware that Amazon, Berkshire Hathaway, and JPMorgan Chase announced in January 2018 that they are working together to address rising health care costs for their employees by attempting to take the "profit motive" out of health care. When the initial announcement was made, the thinking was that the sheer size of the companies would introduce the resources and scaling needed to tackle the issue via an independent company free from constraints and profit-making incentives. Thus, one of the initial goals will be to utilize technological solutions (probably yet to be developed) to help lower health care costs and "de-commercialize" the health insurance system. Such partnerships could be a "new dawn" in other areas of the healthcare arena; for example, Amazon has been selling items such as thermometers and Tylenol for some time on its website.

Berkshire Hathaway Chairman Warren Buffett calls healthcare costs "a hungry tapeworm on the American economy." Although an excellent observation, the Amazon, Berkshire Hathaway, JPMorgan Chase employee collective will only benefit about 1.1 million people (maybe 1 percent of the total American population).[1] Thus, another reason why our nation's politicians should be looking at universal health care (which I stated in a column a few months ago) or a "Medicare for all" approach!

In February 2018, the Trump administration released a proposed rule that would expand the availability of short-term, limited-duration health insurance plans.[2] These policies tend *not* to have the Affordable Care Act (ACA) protections, including such things as non-coverage of pre-existing conditions and denial of coverage based upon medical history. This type of "undercut" without a meaningful replacement potentially undermines the health of many people, as well as potentially destabilizing the health insurance market.

The short-term "massacre" comes on the heels of similar changes to association health insurance plans;[3] together, these proposed rules would tend to take healthy consumers from ACA plans and leave behind a sicker, potentially older population for a costlier health care market. Quoting Jamie Dimon, Chairman and CEO of JPMorgan Chase, "[o]ur people want transparency, knowledge and control when it comes to managing their healthcare,…our goal is to create solutions that benefit our U.S. employees, their families and, potentially, all Americans."

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Ethical Implications of Right to Try Legislation

By Lisa Kearns

Introduction

For decades terminally and seriously ill patients have been able to use investigational drugs before they have received FDA approval through the agency's expanded access program. In 2014, a libertarian organization launched the "right to try" movement in an effort to speed up this process. As part of that effort it has painted the FDA as an unnecessary bureaucratic impediment that interferes with patients' autonomy to decide whether to try an experimental drug. The group promoted model state legislation that purports to remove the federal roadblock from the expanded access process. Since the effort began, 38 states have enacted right to try laws. Ten more states have bills pending, and federal legislation is currently under consideration.

The constitutionality of the state laws has been called into question, as they may violate federal regulations governing the use and shipment of investigational drugs. A bill that would remedy this is currently pending in the Senate. Yet while a federal law might solve conflicts between state law and federal policy, it would do nothing to address unethical provisions in state laws. These include provisions that would allow access to agents with insufficient safety and efficacy data or ones that would permit insurers to deny coverage for certain services—or deny coverage altogether—to patients who avail themselves of drugs under right to try.

Right to try is in flux, as the future of the Senate bill is unclear. I discuss the current landscape and its history, and raise practical and ethical concerns along the way. I conclude with some best guesses about what the future of right to try might be.

History of Right to Try

The U.S. Food and Drug Administration's (FDA) expanded access program allows patients, in certain circumstances, to use investigational drugs, devices, and biologics before they have been approved by the agency. They must have serious or life-threatening diseases or conditions and be unable to participate in a clinical trial for the drug being sought; there must be no satisfactory alternative to the drug, and its use must not interfere with its clinical development; and the FDA must have determined both that the drug does not pose a greater risk to the patient than does the disease or condition and that there is satisfactory evidence that it is safe and effective for patients to use. The program allows individual (single) patients, intermediate size groups (more than one person but a maximum number is not defined), and larger cohorts ("widespread" use) access to investigational drugs, when permitted by the products' developers.[1]

Very generally, this is the process for single patient expanded access, also known as compassionate use: A patient's physician requests an investigational drug from its manufacturer. If the manufacturer agrees to provide the drug, the physician submits the request to the FDA. After the FDA has signed off, an institutional review board (IRB) must approve the application (with exceptions for emergency requests). Of note, the FDA allows 99% of requests to proceed, and does so in a median of four days, or in less than a day for emergencies.[2]

The right to try movement was launched in 2014 by the libertarian Goldwater Institute to speed up this process by eliminating FDA's role in it. Goldwater and right to try proponents frame the pre-approval access issue as one of personal autonomy. Despite the fact that a drug's manufacturer must agree to provide the drug being sought, and ignoring the FDA's proven track record of approving nearly all requests, they consistently portray the agency as infringing on dying patients' liberty to access potentially lifesaving drugs. Eliminating FDA oversight, they argue, would reduce the amount of time between a patient requesting and receiving a drug.

Right to try began as a state legislative movement. Goldwater drafted a model bill,[3] under which terminally ill patients, through their doctors, could request access to investigational products from pharmaceutical companies without having to then secure FDA approval, and promoted it to state legislators. The first right to try law was enacted in May 2014 in Colorado. Currently 38 states have laws,[4] 10 states have bills pending (New York among them), and federal legislation is under consideration in Congress. All hew closely to the Goldwater model.

Right to Try Legislation: Cons

All state laws and bills contain provisions that are ethically troubling because of their potential to cause harm to patients. One such provision stipulates that insurers are not required to pay for drugs obtained through right to try. And although manufacturers are limited by federal regulation in what they may charge for these drugs,[5] no state law includes a mechanism to provide

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funding for costs attendant to using an investigational drug, such as hospital, office, or physicians' fees, the cost to administer the drug, transportation and lodging to procure/receive the agent, loss of work, and the like. Thus, a right to try law may either be useless to patients or could lead to considerable debt.

A second provision of all laws and bills allows patients to access drugs after they have passed only Phase 1 of clinical testing. At this point in drug development, very little safety, much less efficacy, data is known.[6] Opponents of right to try point to this provision to support arguments that obtaining true informed consent is difficult, if not impossible, under right to try legislation. Sec. 1.(2)(d)(iv) of the model bill stipulates that informed consent must include "a description of the potentially best and worst outcomes of using the investigational drug… and a realistic description of the most likely outcome.… The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition." Because of the scant amount of data available after Phase 1, a realistic description of outcomes is impossible. For the same reason, a physician's knowledge at this point would be quite limited, particularly clinical insight about how an early phase investigational agent would work in a very ill patient, who may be taking other medications or whose immune system may be weakened from treatments such as chemotherapy. Consider, too, that information about a company's drugs in development is largely considered proprietary. Any physician who was not part of a drug's clinical trials would likely not know enough about it to have adequate knowledge of its effects.

Right to try critics note that FDA staff, given their involvement in the clinical trials process, often have access to exclusive information about investigational drugs that physicians and patients do not, putting them in a unique position to better evaluate the risks and benefits of using such a drug. As neutral third parties, their only role in the review process is to safeguard the interests of patients. A survey published last year found that in more than 10% of expanded access protocols submitted to the FDA for approval, the agency recommended adjustments—to dose, dosing schedule, or safety monitoring—to the protocol. By eliminating this expertise from the expanded access process, right to try removes an important patient protection.

Even more troubling is the fact that no right to try law or bill requires manufacturers to provide the investigational drug being requested. There are many reasons why companies, especially smaller ones, may be reluctant to do so, including insufficient supply, insufficient personnel or resources to manage requests, fear of diverting drugs from trials, and the like. This lack of a mandate is why critics deem right to try "hollow" legislation that lures dying patients with "false hope" of access to experimental drugs.[7]

All 38 state right to try laws and the pending bills mirror provisions in the model bill described above. Some states and bills echo additional ethically concerning provisions. Current bills in the New York State legislature illustrate some of the more egregious provisions.

New York State Right to Try Bills

Right to try bills were introduced in New York in 2015. Assembly Bill 6889 was introduced on April 8,[8] and Senate Bill 4716 was introduced two days later.[9] Each was referred to its respective Health committee, from which neither advanced. Both ultimately died when the legislative session ended at the end of 2016. New bills were reintroduced in January 2017: S2044 in the Senate,[10] A3932 in the Assembly.[11] The Senate bill's text is identical to its earlier version's, as is the Assembly's. They both are currently in their respective Health committees.

New York's Senate bill contains three provisions that right to try opponents consider to be especially harmful to patients: one allows insurers to deny coverage for hospice care for patients using drugs obtained under right to try; a second allows denial of coverage for in-home health care; and the third allows denial of insurance coverage altogether while a patient undergoes treatment with an investigational product and for up to six months after treatment ends. (A3932 does not contain the in-home health care provision.)

Nineteen state laws join New York in allowing insurers to deny coverage for hospice care to patients using drugs under right to try. As critics of the legislation have noted, the FDA's expanded access program was created so that "terminal patients can legally seek access to investigational products outside of clinical trials (indeed, the entire point of right to try is to make this quest faster and easier), so there is no basis for subjecting these patients to harsh consequences for their choice to try to live longer."[12] Goldwater representatives have responded to this criticism by shifting blame for the provision to Medicaid and other insurance regulations that require patients entering hospice care to forgo all therapeutic treatment.[13] In response, critics have noted that there's a difference between the scenarios for hospice, in which terminally ill patients voluntarily forgo further curative treatment, and right to try, under which patients are actively trying to save their lives.

Seven states share New York's S2044 provision that would allow loss of coverage for in-home health care. Oddly, as patients battle the life-threatening diseases or conditions that make them eligible for access to drugs under right to try, these states would permit insurers to deny coverage for a service that may give them a better chance of success with those drugs. That the agents may have completed only Phase 1 testing, when potential side effects may be unknown, makes patients more at risk for adverse events that could require medical assistance at home.

The provision that allows denial of insurance coverage altogether is perhaps the most patient-hostile provision in all right to try law and bills. Four states and three bills, including S2044, have this provision, which could leave patients treated under such a law liable for costs of doctor visits for flu or sprained ankles, common surgeries, or diagnostic procedures.

Right-to-Try Legislation: Pros

All right to try legislation requires a fairly extensive written informed consent form to be signed by patients (or a guardian or surrogate). Which provisions must be included differs by state, although most consent requirements, including those in both of New York's bills, echo the Goldwater model. As previously noted, using drugs that have completed just Phase 1 testing poses challenges to informed consent. Other concerns about the validity of consent in this context include whether any patient facing death can adequately weigh risks and benefits of a treatment, and whether therapeutic misconception, or misestimation, is possible to overcome in terminal patients.[14] Setting aside those concerns, a provision in many laws and bills that consent forms must state that "new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment" is straightforward and appropriate.

Oregon's law has several patient-centric provisions, including one requiring physicians to refer any patient who they suspect might be suffering from mental impairment to an appropriate mental health expert. It also stipulates that witnesses to informed consent must not be eligible for a share of the patient's estate. Oregon also requires that certain information about patients accessing drugs through right to try be reported to the state health authority. (Calls and emails to determine whether such reports had been filed were not returned.)

Perhaps the most beneficial, albeit unintended, consequence of right to try legislation is the awareness it has raised about the FDA's expanded access program—that it has informed patients that drugs can be obtained from developers before they have received FDA approval. Critics maintain that no patients have obtained drugs under right to try that they could not have obtained via the FDA program;[15] those who claim to have done so in fact may have accessed them through existing expanded access channels and mistakenly considered it to be right to try. Opponents of right to try who instead favor improving the FDA program frequently recommend establishing better education and outreach about the program.

Federal Right to Try Legislation

All state laws share what may be considered a fatal flaw: they are subject to preemption by federal, in this case FDA, regulation. Under Article VI of the Constitution, "the Laws of the United States…shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[16] Federal preemption could be one explanation for why no one has accessed investigational products via the state laws in the nearly four years since the first one was enacted. (The lack of a requirement that companies provide the drugs being sought is an obvious, and more likely, second explanation.)

Since early July 2015, pro-right-to-try legislators have attempted to neutralize the preemption threat by making right to try the law of the land, not just of individual states. Bills were introduced in both houses, although none advanced very far. Then, in 2017, federal right to try legislation finally gained traction. Wisconsin Republican Ron Johnson introduced S204[17] in January that year; it was referred to the Committee on Health, Education, Labor, and Pensions, where it sat until summer. In August, Johnson threatened to hold up a vote on a crucial FDA funding reauthorization bill unless his right to try bill received a unanimous consent vote, a legislative maneuver through which no debate on a bill is allowed and a single nay vote blocks it from advancing.[18] His gambit succeeded, and S204 advanced out of the Senate on August 3 and was referred to the House Energy and Commerce Committee, where it is now. Of note, S204 had been amended since first introduced to allow for, among other things, adverse event reporting requirements in some instances and FDA use of this information under certain conditions.

Proponents of right to try got a forceful new ally in January 2018, when President Trump endorsed the federal legislation in his first State of the Union address. In February he was pressuring Energy and Commerce Chair Greg Walden to advance S204, according to news reports.[19] Critics did not keep silent: A group of health and ethics academics sent a letter with more than 300 signatures to Walden and Energy and Commerce ranking member Frank Pallone, expressing their ethical concerns with S204.[20] The following day 38 patient advocacy groups sent a letter expressing opposition to the bill to House leadership.[21]

The House was reported to be working on a compromise version of S204 when, just before midnight on March 9, 2018, it instead issued HR5247.[22] It is similar to S204 but includes a narrower definition of "eligible patient" and stronger adverse event reporting requirements, among other provisions. Speaker Paul Ryan brought HR5247 to a full floor fast-track "suspension of the rules" vote four days later. Suspension of the rules votes, which are usually reserved for non-controversial measures, require a two-thirds majority to pass. The bill failed. On March 21, it was brought to another vote in the House, this time under "regular order," by which it would require a simple majority to pass;[23] it passed, 267-149, and, with House approval, right to try legislation was once again before the Senate. During this all, critics and supporters continued to passionately defend their positions. Finally, in the early

morning of March 23, Johnson tried to pass the bill via unanimous consent once again. This time the manuever failed, and HR5247 has been put on the Senate legislative calendar.

Conclusion: Current Right-to-Try Landscape

What will happen next is unclear. It is unknown if or when the Senate will take up the House bill or to which committee it might be referred for further deliberation. The Senate could also decide to pass S204, the original Senate bill, as is, and send it to the president to sign. It is also possible that nothing further will happen with right to try in this legislative session, as both chambers turn their attention to the midterm elections in November.

Critics of right to try remain concerned that a federal law could mean that patients who use investigational drugs would be subject to the harmful provisions in their respective state laws. Others take comfort in the belief that a federal law, for all the political posturing, would have little effect on the expanded access landscape, since the FDA already approves the vast majority of such requests.[24] Still others fear that, because right to try would coexist alongside the FDA program,[25] confusion over how patients should access investigational products and under which program a company should provide them would result. Such confusion could lead companies to decline to provide them altogether, even under the FDA program. Meanwhile, advocates are optimistic that a federal law will be enacted. At the same time they worry that, after the extensive revisions it has been undergoing, it would resemble too closely the existing FDA program.

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115TH CONGRESS
2D SESSION

H. R. 5247

AN ACT

To authorize the use of eligible investigational drugs by eligible patients who have been diagnosed with a stage of a disease or condition in which there is reasonable likelihood that death will occur within a matter of months, or with another eligible illness, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018".

SEC. 2. USE OF UNAPPROVED INVESTIGATIONAL DRUGS BY PATIENTS DIAGNOSED WITH A TERMINAL ILLNESS.

(a) IN GENERAL.—Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by inserting after section 561A (21 U.S.C. 360bbb–0) the following:

"SEC. 561B. INVESTIGATIONAL DRUGS FOR USE BY ELIGIBLE PATIENTS.

"(a) DEFINITIONS.—For purposes of this section:

"(1) The term 'eligible patient' means a patient—

"(A) who has been diagnosed with an eligible illness;

"(B) who has exhausted approved treatment options and is not eligible to participate in (for a reason such as the patient not meeting inclusion criteria) a clinical trial designed to evaluate an investigational drug for the treat-

ment of such eligible illness with which the patient has been diagnosed, including one involving the eligible investigational drug, or for whom participation in such a clinical trial is not feasible (for a reason such as a lack of geographic proximity to the clinical trial), as certified by a physician, who—

"(i) is in good standing with the physician's licensing organization or board; and

"(ii) will not be compensated for so certifying; and

"(C) who has provided to the treating physician written informed consent, as described in part 50 of title 21, Code of Federal Regulations (or any successor regulations), regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent.

"(2) The term 'eligible investigational drug' means an investigational drug (as such term is used in section 561)—

"(A) for which a phase 1 clinical trial has been completed;

"(B) that has not been approved or licensed for any use under section 505 of this Act or section 351 of the Public Health Service Act;

"(C)(i) for which an application has been filed under section 505(b) of this Act or section 351(a) of the Public Health Service Act, as applicable, that is active; or

"(ii) that is under investigation in a clinical trial that—

"(I) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under section 505 of this Act or section 351 of the Public Health Service Act; and

"(II) is the subject of an active investigational new drug application under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, as applicable; and

"(D) the active development or production of which—

"(i) is ongoing;

"(ii) has not been discontinued by the manufacturer; and

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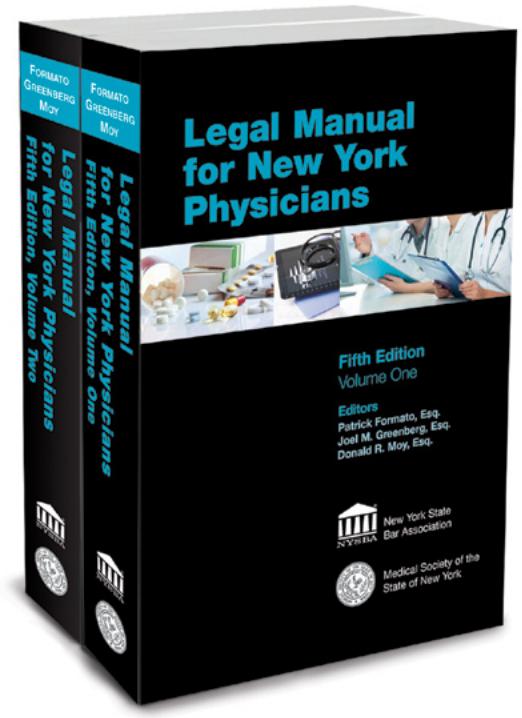

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"(iii) is not the subject of a clinical hold under the regulations implementing section 505(i) or section 351(a)(3) of the Public Health Service Act, as applicable.

"(3) The term 'phase 1 trial' means a phase 1 clinical investigation of a drug as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

"(4) The term 'eligible illness' means—

"(A) a stage of a disease or condition in which there is reasonable likelihood that death will occur within a matter of months; or

"(B) a disease or condition that would result in significant irreversible morbidity that is likely to lead to severely premature death.

"(b) ALTERNATIVE PATHWAY FOR ELIGIBLE PATIENTS WITH A TERMINAL ILLNESS.—

"(1) IN GENERAL.—Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 502(f), 503(b)(4), and subsections (a) and (i) of section 505 of this Act, and section 351(a) of the Public Health Service Act so long as the conditions specified in paragraphs (2), (3), and (4) are met with respect to the provision of such investigational drugs.

"(2) COMPLIANCE WITH CERTAIN REGULATIONS.—The conditions specified in this paragraph, with respect to an eligible investigational drug referred to in paragraph (1), are that—

"(A) the eligible investigational drug is labeled in accordance with section 312.6 of title 21, Code of Federal Regulations (or any successor regulations); and

"(B) the provision of such eligible investigational drug occurs in compliance with the applicable requirements set forth in sections 312.7 and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs, subject to paragraph (5).

"(3) NOTIFICATION.—The condition specified in this paragraph, with respect to an eligible investigational drug referred to in paragraph (1), is that the sponsor of such eligible investigational drug notifies the Secretary of the provision of such eligible investigational drug for use by an eligible patient pursuant to this section. Such notification shall be submitted within 7 business days of the provision of such eligible investigational drug as correspondence

to the investigational new drug application described in subsection (a)(2).

"(4) ADVERSE EVENT REPORTING.—The condition specified in this paragraph, with respect to an eligible investigational drug referred to in paragraph (1), is that the sponsor or manufacturer of such eligible investigational drug has required, as a condition of providing the drug to a physician for use by an eligible patient pursuant to this section, that such physician will immediately report to such sponsor or manufacturer any serious adverse events, as such term is defined in section 312.32 of title 21, Code of Federal Regulations (or any successor regulations), associated with the use of the eligible investigational drug by the eligible patient.

"(5) APPLICATION. For purposes of this section, the requirements set forth in sections 312.7 and 312.8(d)(1) of title 21 of the Code of Federal Regulations (or any successor regulations) are deemed to apply to any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section.

"(e) USE OF CLINICAL OUTCOMES.—

"(1) IN GENERAL.—Notwithstanding any other provision of this Act, the Public Health Service Act, or any other provision of Federal law, the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug pursuant to this section to delay or adversely affect the review or approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act unless—

"(A) the Secretary makes a determination, in accordance with paragraph (2), that use of such clinical outcome is critical to determining the safety of the eligible investigational drug; or

"(B) the sponsor requests use of such outcomes.

"(2) LIMITATION.—If the Secretary makes a determination under paragraph (1)(A), the Secretary shall provide written notice of such determination to the sponsor, including a public health justification for such determination, and such notice shall be made part of the administrative record. Such determination shall not be delegated below the director of the agency center that is charged with the premarket review of the eligible investigational drug.

"(d) REPORTING.—The manufacturer or sponsor of an eligible investigational drug that provides an eligible investigational drug pursuant to this section shall post on the same publicly available internet website used by the manufacturer for purposes of section 561A(b) an annual summary of any provision by the manufacturer or sponsor of an eligible investigational drug under this section. The summary shall include the number of requests received, the number of requests granted, the number of patients treated, the therapeutic area of the drug made available, and any known or suspected serious adverse events, as such term is defined in section 312.32 of title 21, Code of Federal Regulations (or any successor regulations), associated with the use of the eligible investigational drug.

"(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as limiting the authority of the Secretary to require manufacturers or sponsors of investigational drugs to review and report information relevant to the safety of such investigational drug obtained or otherwise received by the sponsor pursuant to part 312 of title 21, Code of Federal Regulations (or successor regulations).".

(b) NO LIABILITY.—Section 561B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), is amended by adding at the end the following:

"(f) LIABILITY.—

"(1) ALLEGED ACTS OR OMISSIONS.—

"(A) MANUFACTURER OR SPONSOR.—No manufacturer or sponsor (or their agent or representative) of an investigational drug shall be liable for any alleged act or omission related to the provision of such drug to a single patient or small group of patients for treatment use in accordance with subsection (b) or (c) of section 561 or the provision of an eligible investigational drug to an eligible patient in accordance with this section, including, with respect to the provision of an investigational drug under section 561 or an eligible investigational drug under this section, the reporting of safety information, from clinical trials or any other source, as required by section 312.32 of title 21, Code of Federal Regulations (or any successor regulations).

"(B) PHYSICIAN, CLINICAL INVESTIGATOR, OR HOSPITAL.—

"(i) No licensed physician, clinical investigator, or hospital shall be liable for any alleged act or omission related to the provision of an investigational drug to a

single patient or small group of patients for treatment use in accordance with subsection (b) or (c) of section 561, as described in clause (ii), or the provision of an eligible investigational drug to an eligible patient in accordance with this section, unless such act or omission constitutes on the part of such physician, clinical investigator, or hospital with respect to such investigational drug or eligible investigational drug—

"(I) willful or criminal misconduct;

"(II) reckless misconduct;

"(III) gross negligence relative to the applicable standard of care and practice with respect to the administration or dispensing of such investigational drug; or

"(IV) an intentional tort under applicable State law.

"(ii) The requirements described in this clause are the requirements under subsection (b) or (c) of section 561, including—

"(I) the reporting of safety information, from clinical trials or any other source, as required by section 312.32 of title 21, Code of Federal Regulations (or any successor regulations);

"(II) ensuring that the informed consent requirements of part 50 of title 21, Code of the Federal Regulations (or any successor regulations) are met; and

"(III) ensuring that review by an institutional review board is obtained in a manner consistent with the requirements of part 56 of title 21, Code of the Federal Regulations (or any successor regulations).

"(2) DETERMINATION NOT TO PROVIDE DRUG.—No manufacturer, sponsor, licensed physician, clinical investigator, or hospital shall be liable for determining not to provide access to an investigational drug under this section or for discontinuing any such access that it initially determined to provide.

"(3) LIMITATION.—

Demonstrating the Need for Updated Gender Affirmation Medical Care Policies for Insurers

By Kelly McBride Folkers

Abstract

Section 1557 of the Affordable Care Act prohibits discrimination for health insurance coverage on the basis of sex. In December of 2016, a federal injunction was placed on this part of the law, ordering the U.S. Department of Health and Human Services to temporarily stop enforcing these protections. The Trump administration plans to continue to roll back protections for transgender and gender nonconforming (TGNC) individuals. As such, state anti-discrimination laws and insurance policies will become more important in order to protect access to gender affirmation care and to prevent TGNC individuals from being denied health insurance coverage on the basis of their gender expression. New York is one of 16 states plus the District of Columbia that prevents exclusions for medically necessary care for the treatment of gender dysphoria in both private insurance and Medicaid. However, many TGNC individuals report that they are denied coverage for gender affirming services and non-transition related care despite the existence of these policies. This review describes federal and New York state law on coverage for gender affirmation care and illustrates the need for clear updated guidance for insurers so that these policies can be strengthened in practice.

Introduction

According to an estimate from Williams Institute at the UCLA School of Law, there are approximately 1.4 million transgender adults living in the United States, comprising 0.58% of the population. Approximately 0.7% of youth, or 150,000 individuals aged 13 to 17, identify as transgender. The largest populations of transgender people live in California, Texas, New York, and Florida.[1] Of these states, New York and California have adopted formal policies banning insurance coverage exclusions for gender affirming health care and other anti-transgender insurance discrimination.[2] The Williams Institute estimates that the number of adults identifying as transgender has doubled from its previous figure in 2011, which may be the result of greater public acceptance of transgender and gender non-conforming (TGNC) individuals in American society.[3] Transgender individuals in the 18 to 24 age bracket were more likely than older adults to publicly identify as such, which may be in part attributed to an acceptance among young adults that gender is not a binary concept. These estimates give weight to the TGNC community's call for equity in many policy areas, including access to affordable healthcare that meets their distinct needs and refrains from discriminating against this population on the basis of gender expression.

New York is one of 16 states and the District of Columbia that prohibits exclusions for medically necessary care for the treatment of gender dysphoria in both private insurance and Medicaid. However, TGNC individuals report anecdotally that they are often denied coverage for gender affirming services and non-transition related care despite the existence of these policies.[4] According to an open letter drafted by the Sylvia Rivera Law Project, "… hundreds of transgender individuals in New York State have sought gender affirming healthcare and services and have been wrongfully denied coverage by their health insurance plans. Denials are coming from commercial and Medicaid managed care plans."[5] Social determinants of health, like poverty, homelessness, and lack of education, can present additional hurdles for TGNC individuals who seek gender affirmation care and prevent them from being able to access and afford health insurance.[6]

This review describes recent changes in federal and New York state law on coverage for gender affirmation care. Despite the existence of these regulatory changes, there is a need for clear, updated guidance for insurers so that these policies can be strengthened in practice. As the Trump administration continues to roll back protections for LGBTQ+ people, the role of state law in protecting equitable access to health insurance coverage for gender affirming care may be more crucial going forward.

Gender Dysphoria Diagnosis and Treatment

In the past decade, healthcare for TGNC people has received increased attention as the medical community seeks to establish evidence-based standards of care for this population. The current edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) regards "gender dysphoria" as a mental health diagnosis, which is defined as the distress or discomfort that one experiences as the result of incongruence between experienced and assigned gender.[7] Gender affirmation care may include mental health evaluation and treatment, hormone therapy, and surgical interventions; each of these treatments is individualized to a specific patient's needs. Medical and psychosocial interventions that aim to positively affirm an individual's experienced gender identity have been demonstrated to mitigate the negative psychological effects of gender dysphoria.[8] Without access to care, many TGNC people are at

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risk of self-harm and suicide.[9] The field of gender affirmation care, however, is hampered by a lack of long-term outcomes data, on which insurers rely to make decisions regarding which treatments they will cover.

Federal Policy Landscape

Section 1557 of the Patient Protection and Affordable Care Act (ACA) prohibits health insurance coverage discrimination on the basis of sex by any health program receiving federal financial assistance.[10] Section 1557 was designed to prevent insurers from charging customers higher premiums and from denying health insurance coverage altogether to women or TGNC individuals, though it did not create any anti-discrimination policies that have not previously been asserted in court decisions.[11] Under Section 1557, the following practices are illegal: 1) excluding gender affirming or transition related care from coverage, 2) refusing to enroll an individual, cancelling coverage, or charging higher rates because an individual identifies as transgender, and 3) denying coverage to a TGNC individual that is typically associated with one gender (i.e., prostate exams for transgender women or gynecological exams for transgender men). In December of 2016, a federal injunction was placed on this part of the law that ordered the U.S. Department of Health and Human Services (DHHS) to temporarily stop enforcing these protections, concluding that Section 1557 violates the Administrative Procedure Act and likely violates the Religious Freedom Restoration Act.[12],[13] TGNC people who experience discrimination are still able to sue insurance companies or healthcare providers or file a complaint with DHHS if they face discrimination, but the federal government is prohibited from enforcing Section 1557. At this time, it is unclear how insurers will respond to the injunction on Section 1557.

The Trump administration plans to continue to roll back protections for TGNC individuals, though these policies are thinly veiled as protecting conscientious objection rights for health care providers. For example, in January of this year acting DHHS secretary Eric Hargan announced the proposed creation of the department's new Conscience and Religious Freedom Office in the agency's Civil Rights Division, which would reverse Obama-era rules that prohibited health care providers from refusing to treat transgender people or perform abortions.[14] Multiple conscientious objection protections for healthcare providers have existed since the 1970s, and collectively, they protect providers from legal repercussions if they object to participating in any procedure that conflicts with their religious or moral beliefs.[15] The creation of this new office would serve to strengthen the enforcement of these protections. According to a response from the Human Rights Campaign, the creation of this office would protect providers at the expense of providing healthcare to LGBTQ+ individuals and encourage discrimination against them, thus creating an additional barrier to appropriate and affordable gender affirmation care for TGNC people.[16] Conscientious objection protections are meant to protect providers or entities who object to participating in or performing certain medical services for an individual patient that conflict with their moral or religious beliefs.[17] The creation of the Conscience and Religious Freedom Office would protect conscientious objectors under an even broader religious refusal policy, allowing them to object to treating a group of patients on the basis of a moral or religious belief. DHHS's Civil Rights Division has focused on enforcing federal civil rights protections and health privacy laws, but the creation of the new office would shift the Division's resources toward reviewing, responding to, and punishing organizations accused of prohibiting health care providers from expressing their religious or moral convictions.[18] Broad conscientious objection protections from the federal government open the door for health care professionals to deny gender affirmation or other medical care to individuals on the basis of their gender expression. TGNC people, however, have few options for legal recourse if they are unfairly discriminated against in the healthcare setting.

These changes to federal policy come at a time when there are increasingly more individuals in the United States publicly identifying as TGNC, so demand for gender affirmation care is rising. In the current political and social climate, state anti-discrimination laws and insurance coverage policies may become more important in order to protect access to gender affirmation care and to prevent TGNC individuals from being denied health insurance coverage on the basis of their gender expression. However, there is considerable variation in these state policies, which may be a source of confusion for TGNC individuals seeking gender affirmation care and for insurers and providers who want to help. For example, New York's Medicaid policy allows for the payment of hormone therapy, including puberty suppression and gender affirming (commonly known as "cross-sex") hormones, for patients over the age of 16 with parental informed consent. But, coverage for youth over the age of 16 and under the age of 18 must be based on a "determination of medical necessity by a qualified medical professional."[19] Colorado's policy dictates that coverage for services for any patient under the age of 21 will be determined on a case-by-case basis, depending on the medical necessity of the treatment.[20] Both of these states prohibit transgender exclusions in Medicaid and private insurance, yet there is considerable room for individual interpretation in each policy as the definition of "medical necessity" varies state-by-state.[21] One insurer could conceivably cover gender affirming treatment if its deemed necessary to prevent mental illness in a TGNC youth, while another could deny coverage if the treatment plan is not fully in line with accepted standard of care practices. Additionally, puberty suppression treatment can be indicated for children as young as 9, depending on the age at which a patient enters puberty.[22] Depending on the severity of the child's gender dysphoria, it may be beneficial to begin

puberty suppression treatment at the earliest sign of puberty to prevent the development of secondary sex characteristics that may cause the child to experience mental distress. State Medicaid policies, then, may not reflect clinical guidelines for the standard of care for gender affirmation.

New York State Policy Landscape

Currently, New York state law prohibits transgender exclusions in both private insurance and Medicaid and is one of 16 states, plus the District of Columbia, with both of these policies enacted.[23] These changes to New York state policy have occurred in a series of incremental steps over the past four years. In 2014, Medicaid and Medicare policies previously denying transition-related care were lifted. The change to Medicaid policy prohibited the exclusion of some, but not all, gender affirmation care services. In December 2014, the office of Governor Andrew Cuomo issued guidance regarding health insurance coverage for the treatment of gender dysphoria, with the goal of ensuring that transgender New Yorkers have equitable access to health insurance coverage. The Department of Financial Services sent a letter to all private insurers in New York state asserting that they could not "…deny medically necessary treatment otherwise covered by a health insurance policy solely on the basis that the treatment is for gender dysphoria."[24]

The letter argued that issuers of policies that include mental health coverage cannot exclude medically necessary treatments for gender dysphoria, as the condition is explicitly described in the DSM-5 as a mental disorder. Despite this policy's step forward for equity for health insurance coverage for TGNC people, its characterization of "gender dysphoria" was open to misinterpretation. It states, "The current, fifth edition of the DSM-5 recognizes a diagnosis of gender dysphoria for people whose gender at birth is contrary to the one with which they identify." While gender dysphoria is indeed a recognized condition in the current edition of the DSM, the drafters of the DSM-5 intended for the diagnosis to emphasize the distress that a person experiences when natal gender and experienced gender do not align.[25] The definition of gender dysphoria in this letter, by contrast, could be interpreted as classifying the experience of being transgender to be a disorder in and of itself. While the intent of this policy is to provide medical services to TGNC people, this classification has been used in the past to deny medical treatment to this group.

Further changes have been made that explicitly lay out which gender affirmation medical procedures and services Medicaid will and will not cover; these changes were enacted in December of 2016 and amended Section 505.2 of New York Codes, Rules and Regulations Title 18. First, the current law makes payment available for medically necessary hormone therapy and/or gender affirmation surgery (referred to as "gender reassignment surgery") for the treatment of gender dysphoria for adults over the age of 18. Hormone therapy can include treatment with GrNH agonists for puberty suppression and treatment with estrogen or testosterone (among others) for gender affirmation, under a set of necessary conditions: 1) the patient must meet the diagnosis for gender dysphoria; 2) the patient has at minimum experienced an early stage of puberty that has resulted in an increase in gender dysphoric feelings; 3) the patient does not suffer a psychiatric co-morbidity that interferes with the diagnosis of gender dysphoria; 4) the patient has adequate social support while receiving transition-related services; and 5) the patient has the capacity to give informed consent. Hormone treatment for patients above the age of 16 can be covered by Medicaid upon a determination of medical necessity by a health care provider when the above conditions are met.

Surgical interventions are covered for individuals 18 or older under several conditions. First, the patient must provide two letters from licensed medical professionals in New York state who have independently assessed the individual, and one of these letters must be from a provider with which the patient has an established and ongoing relationship. The letter must describe the following: 1) the patient's persistent gender dysphoria; 2) the patient's treatment with hormone therapy appropriate to the patient's gender expression goals; 3) that the patient has lived for 12 months or longer in a gender role congruent with the patient's gender identity and has received mental health counseling; 4) that the patient has no other significant medical or mental health conditions that would be a contraindication for surgery; and 5) that the patient has the capacity to give informed consent. Breast augmentation is only covered for individuals who have completed a minimum of 24 months of hormone therapy during which breast growth has been negligible, or for patients for which hormone therapy is contraindicated.

Similar to the regulations for payment of hormone treatment, insurers may pay for patients under the age of 18 but above the age of 16 in specific cases where medical necessity is demonstrated. The regulatory impact statement explaining these policy changes justifies the lack of clear guidance on paying for hormone therapy for minors by appealing to the lack of quality, longitudinal data on outcomes associated with use of cross-sex hormones on adolescents. The U.S. Food & Drug Administration has not yet approved the use of these hormones in patients under the age of 18, nor have they been indicated for acceptable off-label usage.

In general, the policy states that payment is not offered for the following services: fertility preservation, reversal of surgery, reversal of any procedure resulting in sterilization, and procedures solely aimed at improving an individual's appearance, unless there is justification that such a procedure is medically necessary.

Demonstrating the Need For Updated Guidance

Though the existence of these policies is markedly better than not having them at all, there are several ways in which they could be improved and revised to further increase equity in healthcare for TGNC people.

1. Update guidance to ensure that TGNC patients are guaranteed equitable access to procedures and services typically associated with one gender.

Electronic medical record coding for screening procedures typically associated with one gender, like Pap smears or prostate exams, often require that the provider designate the patient as "male" or "female" without additional options. Depending on an individual's private insurance provider's policies, insurance claims for preventive screening may be denied if the patient's gender is not in accordance with the sex-specific nature of the procedure.[26] Though empirical data on these insurance claims denials does not exist, anecdotal reports of such denials should be taken seriously by policymakers concerned with equity and with allowing all individuals access to potentially life-saving screening procedures. The New York State Cancer Services Program provides breast, cervical, and colorectal cancer screenings and diagnostic services at no cost; however, its website does not specify whether TGNC people are able to receive these screenings under the program.[27] TGNC people in New York have expressed hesitance about interacting with the medical system, specifically regarding access to mental and sexual health services.[28]

It is not unreasonable to expect that this hesitance will persist, even with the existence of anti-discrimination legislation. Publicly available information regarding preventive screening services should be updated to address the needs of TGNC people in New York and should ensure that they are able to receive free screenings. These updates might allay the worries of TGNC people that they will experience discrimination in a healthcare setting.

2. Update guidance to define treatment that is considered "medically necessary" and "for the purpose of improving an individual's appearance (cosmetic procedures)."

Many procedures and services that TGNC people desire are considered "cosmetic" or only serve the purpose of improving an individual's appearance. These include facial feminization surgery, some reconstructive surgeries, voice therapy, and hair electrolysis. While these procedures may indeed be cosmetic for cisgender people, they are crucial for TGNC people who want to change the appearance of secondary sex characteristics that do not match their experienced gender. Voice therapy, for example, teaches TGNC people how to speak in a manner consistent with their gender identity. The tone and sound of one's voice is a vital part of one's identity, so voice therapy may significantly improve quality of life for a patient that experiences mental or emotional distress when speaking with other people in day-to-day activities. Thus, these services are not merely to improve appearance; they are to affirm one's gender identity. Providers and policymakers ought to consider how these procedures may positively impact the mental health of TGNC people.

Cost is, of course, an issue. Some reconstructive surgeries have been deemed too expensive to be covered by insurance. However, research shows that the cost in relation to quality adjusted life years of providing gender affirming and reconstructive surgeries to TGNC people is favorable, as compared to the costs of not treating this population.[29] Federal law also guarantees that insurers cover reconstructive surgery to cisgender women who have had a mastectomy to treat breast cancer, ensuring that every step of the reconstruction is covered.[30] The law states that surgery and reconstruction must be covered so that breast appearance is symmetrical, which means that there could be additional surgical procedures necessary to ensure that a cisgender woman is satisfied with her appearance. If such procedures are covered for cisgender women who have a medically necessitated reason for reconstructive surgery, transgender women should also receive the same coverage. Breast reconstruction surgery for cisgender women is not life-saving, but the procedures can prevent depression associated with body image and restore a critical sense of identity, confidence, and productivity. The same is true for transgender women who experience similar body image distress. Furthermore, the medical need for surgery must be documented by health care provider who deems the procedure medically necessary for both populations, ensuring that treatment is not superfluous or merely cosmetic based on the patient's individual medical history.

3. The New York State Assembly should pass SB3148A, which would require health insurance providers to provide coverage for in-vitro fertilization (IVF) and other fertility preservation treatments for all New Yorkers, regardless of gender expression.

Fertility preservation and IVF are not typically covered by insurance providers. This bill would require that insurers cover fertility preservation treatments, with a clause that specifically requires coverage for any individual that suffers from an "…impairment of fertility by surgery, radiation, chemotherapy or other medical treatment affecting reproductive organs or processes."[31] It also includes a clause that prevents insurers from discriminating against individuals on the basis of sexual orientation or gender identity, meaning that TGNC people are explicitly recognized and covered by this bill. The New York State Assembly should pass this legislation and send it to the governor's desk. Complications arise, however, in the fact that surrogacy agreements and payments are illegal under New York state law at this time. Thus, transgender parents who cannot carry a child biologically must seek out surrogacy agreements out of state.[32] Despite this hurdle, such a law would be a major step forward in reproductive rights for TGNC individuals as the law leaves

little ambiguity as to whether they should be included in the interpretation of this bill.

4. Commission an expert group to analyze and to address causes of insurance claims denials.

Despite New York's prohibitions on transgender exclusions, the Sylvia Rivera Law Project reports that TGNC individuals have faced "…plans denying medically necessary procedures because of administrative errors and non-medical policies that violate patients' dignity and rights [and] plans developing and using criteria to determine a patient's eligibility for gender affirming care based on outdated standards of care [that are] not aligned with commonly accepted standards of care…"[33]

Indeed, some of the regulations codified in Title 18 are not in line with the World Professional Association for Transgender Health's (WPATH) standards of care. For example, puberty suppression treatment can be indicated for children as young as nine, if they have progressed to a stage of puberty in which secondary sex characteristics have begun to develop.[34] The New York state guidelines specify 16 as a minimum age for coverage for any hormone treatment, with an exception for younger individuals who demonstrate the need for hormones based on medical necessity. These guidelines should be updated using progression into puberty combined with persistent distress about the development of secondary sex characteristics, as assessed by a qualified physician, as suppression. Additionally, WPATH guidelines address voice and communication therapy and suggest that they "…may help to alleviate gender dysphoria and be a positive and motivating step towards achieving one's goals for gender expression."[35] New York's policy explicitly does not cover voice therapy or voice lessons.

An expert group, consisting of physicians, TGNC advocates, health economists, and policymakers, should be convened to analyze whether coverage exclusions for specific procedures are unnecessarily restrictive and prevent TGNC people from accessing treatments that may be necessary for wellbeing. Bringing all relevant stakeholders to the conversation can resolve some of these inconsistencies.

Conclusion

Former Vice President Joe Biden has characterized transgender discrimination as "the civil rights issue of our time."[36] While New York is ahead of the majority of states in ensuring that TGNC people can access healthcare to meet their needs, state policymakers should not be complacent with the status quo when there are improvements that could be made. New York has an opportunity to lead the charge in this important civil rights issue. With the multitude of excellent hospitals and clinical research enterprises in New York City alone, the state government should devote available scientific funding to research on outcomes for gender affirmation care, which are currently lacking. Funding clinical research on TGNC populations will justify to insurance companies the importance of covering costs of related procedures, as well as convince legislatures of the value of healthcare protections for TGNC people.

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The Need to Foster and Protect Physician Group Practice Malpractice Prevention Programs

By Robert N. Swidler

Larger physician group practices may be able meet the same rigorous malpractice prevention program standards that hospitals must meet.[1] Those that do so should be afforded the same malpractice prevention program confidentiality and immunity protections that are afforded to hospitals.[2] If the legislature were to implement that simple principle, physician group practices across the state would enhance their malpractice prevention efforts, and thereby improve the quality and safety of patient care.

Hospital Malpractice Prevention Programs

Every general hospital in New York is required "to maintain a coordinated program for the identification and prevention of medical, dental and podiatric malpractice."[3] Such "Malpractice Prevention Program" must include at least these elements:[4]

(a) A quality assurance committee.

(b) A medical staff[5] privileges sanction procedure to check credentials, capacity and competence periodically and when warranted.

(c) A procedure to check credentials, capacity and competence in delivering health care of other persons employed or associated with the hospital.

(d) A procedure for the prompt resolution of grievances by patients;

(e) The collection of information concerning negative health care outcomes and incidents injurious to patients and other data.

(f) The maintenance of information gathered above concerning individual practitioners;

(g) Education programs dealing with patient safety, injury prevention, and other matters;

(h) Continuing medical education programs; and

(i) Policies to ensure compliance with the obligation to report professional misconduct.

In other provisions, hospitals are required to conduct investigations prior to the granting or renewal of privileges[6] and to report adverse events to the Department of Health.[7]

The law requires hospitals to maintain the confidentiality of the information collected pursuant to PHL § 2805-j and other provisions, "except as to the department."[8] It then goes on to protect from disclosure in litigation records and information gathered pursuant to the Malpractice Prevention Program, with a focus on protecting information discussed at quality assurance committee meetings (which would include "peer review committees" set up to review specific incidents):

> 2. Notwithstanding any other provisions of law, none of the records, documentation or committee actions or records required pursuant to sections §2805-j[9] and 2805-k of this article, the reports required pursuant to section 2805-l of this article nor any incident reporting requirements imposed upon diagnostic and treatment centers pursuant to the provisions of this chapter shall be subject to disclosure under article six of the public officers law or article 31 of the civil practice law and rules, except as hereinafter provided or as provided by any other provision of law. No person in attendance at a meeting of any such committee shall be required to testify as to what transpired thereat. The prohibition relating to discovery of testimony shall not apply to the statements made by any person in attendance at such a meeting who is a party to an action or proceeding the subject matter of which was reviewed at such meeting.[10]

In addition, the law protects individuals who participate on a quality assurance committee from liability on account of the communication of information in the possession of such person or entity, or on account of any recommendation or evaluation, regarding the qualifications, fitness, or professional conduct or practices of a physician.[11]

These twin protections—the protection of QA information from disclosure, and the protection of participants in the QA process from liability, are not a reward or political trade-off to hospitals. Rather they are essential components of an effective quality assurance program. More generally they are a necessary part the public policy to promote quality of care. As the Court of Appeals stated in *Logue v. Velez*:

> ...The purpose of the discovery exclusion is to "enhance the objectivity of the re-

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> view process", and to assure that medical review committees "may and objectively analyze the quality of health services rendered" by hospitals....[12]

Education Law § 6527.3 offers protections similar to those in PHL § 2805-m but, as discussed further below, it is not clear whether the provision protects the confidentiality of medical group practice quality assurance and peer review activities unrelated to a hospital.

In 2011, the Legislature granted accountable care organizations similar authority by deeming them to be a "hospital" solely for purposes of malpractice prevention programs under PHL § 2805-m and Education Law § 6527.3.[13]

Physician Group Practices in New York

For decades, health care services have been moving from inpatient settings to ambulatory settings including physician practices. In a related development, physician practices have grown exponentially in size and sophistication. For example, Beckers Hospital Review reports that Northwell Health Physician Partners in Syosett, N.Y. has 2,700 physicians; Physician Affiliate Group of New York (PAGNY) has 1,511 physicians.[14] Many other physician groups have hundreds of physicians.

Some of these groups are associated with hospitals, others are not. In either case, large group practices can dwarf independent community hospitals in size, revenue, infrastructure, sophistication. Many could implement malpractice prevention program activities on par with those implemented by hospitals. Patient safety and quality of care would benefit if they did so.

The Inapplicability of PHL § 2805-m Protections to Events Outside the Hospital

The twin protections in PHL § 2805-m—the protection of QA information from disclosure, and the protection of participants in the QA process from liability—are afforded only to general hospitals, not to physician practices. To be sure, physicians in group practices fall under the protections of PHL § 2805-m when there is a review of an event that occurred in a hospital, including a hospital-operated extension clinic. And they have immunity under PHL § 2805-m when they sit on or testify before a hospital peer review committee. But they do not have PHL § 2805-m protection for events that have no connection with a hospital.

Consider these two scenarios: A radiologist fails to diagnose a tumor, causing a delay in treatment that results in a patient death.

If the imaging was performed in a hospital or a hospital operated extension clinic, the hospital would conduct a root cause analysis and/or convene a peer review committee.[15] The goal is to determine what happened, and to identify steps that should be taken to avoid a recurrence, and to review physician performance. Due in part to the confidentiality protection for these activities, physicians and staff are willing to engage in a full and frank discussion of the case. The result is that the hospital might take corrective actions with regard to the radiologist, or implement changes in processes in the department to improve patient safety.

If the same error occurred by a physician in a 1,000-person physician group practice, the practice certainly has the "bandwidth" to convene a peer review committee, determine what occurred, take corrective steps if warranted with respect to the physician, and take steps to prevent a recurrence. But the effort would be impeded by the lack of confidence in confidentiality and immunity protections. Physicians and staff—including investigators, witnesses and peer reviewers—would be less willing, or unwilling, to participate, and the discussion would be less frank and full.

"These twin protections—the protection of QA information from disclosure, and the protection of participants in the QA process from liability, are not a reward or political trade-off to hospitals. Rather they are essential components of an effective quality assurance program."

It is hard to identify a policy rationale for affording such protections to the hospital quality assurance process, but not to an equivalent physician practice process.

Notably, in both instances, a malpractice plaintiff would retain full access to evidence necessary to make his or her case: i.e., the medical record, the pre-trial and testimony of fact witnesses, expert testimony, policies, etc. But the plaintiff would not have access to the records of activities that were conducted specifically to improve quality.

N.Y. Education Law § 6527

N.Y. Education Law § 6527.3 offers liability immunity to individuals who engage in certain quality assurance activities, and protects from disclosure in litigation information about certain medical and quality assurance review activities.

The immunity protection is limited to individuals who serve on specified types of committees, including hospital quality assurance committees, hospital utilization review committees, medical review committees of professional societies, professional standards review organizations, other hospital malpractice prevention program related committees. It does not specify or apply to physician group practice quality or peer review committees.

The reach of the § 6527.3's confidentiality provision is more debatable.[16] It states in relevant part:

> Neither the proceedings nor the records relating to performance of a medical or a quality assurance review function or participation in a medical and dental malpractice prevention program nor any report required by the department of health pursuant to PHL § 2805-l of the described herein, including the investigation of an incident reported pursuant to MHL § 29.29, shall be subject to disclosure under CPLR Article 31 except as hereinafter provided or as provided by any other provision of law.

On one hand, the opening clause plainly appears to protect physician practice quality assurance and peer review activities:

> Neither the proceedings nor the records relating to performance of a medical or a quality assurance review . . . shall be subject to disclosure under CPLR Article 31 except as hereinafter provided or as provided by any other provision of law.

Accordingly, physician practices can and should point to the clause above to protect their quality assurance activities. But on the other hand it is unsettling that:

- The clause does not define the phrase "medical or quality assurance function," and the preceding clause, relating to immunity, uses these terms in the context of hospital or professional organization functions;
- Arguably the phrase is linked to "... required by the department of health pursuant to PHL §2805-l;"
- Westlaw shows 193 decisions construing EL § 6527 as of April 19, 2018. It appears that none of those reported court decisions apply EL § 6527.3 to a physician group practice quality assurance or peer review activity; and
- Numerous court decisions describe the purpose of EL § 6527, as stated by the NYS Court of Appeals in *Logue v. Velez*, "to assure that medical review committees 'may objectively analyze the quality of health services rendered' *by hospitals.*"[17]

In these circumstances, physician practices are deterred from instituting quality assurance programs and conducting peer review activities.

A Legislative Proposal

In 2017, Senator Kemp Hannon and Assemblymember Richard Gottfried, the respective chairs of the Senate and Assembly health committees, introduced identical bills to address this issue.[18] The bills provide that a medical, dental or podiatric group practice that operates a malpractice prevention program that meets largely the same standards of a hospital malpractice prevention program (a "qualified group practice") will have the same confidentiality and immunity protections as a hospital.

The bill is short, and is reproduced below:

> Section 1. The public health law is amended by adding a new section 2998-f to read as follows:
>
> § 2998-f. Qualified group practice. 1. For the purposes of this section, "qualified group practice" means a medical, dental or podiatric group practice or other lawful combination of such health care practitioners, licensed or certified pursuant to title eight of the education law, that meets the standards set forth in paragraphs (a) through (h) of subdivision one of section twenty-eight hundred five-j of this chapter, other than the governing board requirements of such paragraph (a).
>
> 2. A qualified group practice may operate a malpractice prevention program independently, or through an otherwise lawful collaborative arrangement with a hospital or accountable care organization program operated pursuant to section twenty-eight hundred five-j or twenty-nine hundred ninety-nine-r of this chapter, in which case the qualified group practice and the hospital or accountable care organization may share, confidential information with each other for purposes of such practice without waiving confidentiality with respect to others.
>
> 3. A qualified group practice shall be deemed a hospital, and its malpractice prevention program shall be deemed a medical, dental and podiatric malpractice prevention program, for the purposes of subdivision two of section twenty-eight hundred five-j, subdivision four of section twenty-eight hundred five-k and section twenty-eight hundred five-m of this chapter, and subdivision three of section sixty-five hundred twenty-seven of the education law. Such provisions of law shall apply to

its information, records, documentation and committee actions, and to participants in committee proceedings.

§ 2. This act shall take effect immediately.

The bill has these notable features:

- To be a "qualified group practice" the group, like a hospital, would need (a) a quality assurance committee;[19] (b) sanction procedures for medical staff members; (c) review of credentials and competence for all; (d) prompt resolution of patient grievances; (e) collection of information about negative outcomes, premiums, settlements, awards, etc.; (e) procedural recordkeeping; (g) education programs on patient safety, injury prevention, etc.
- The qualified group would not be subject to the hospital-specific requirement to report adverse events to the Department of Health.
- The qualified group would be subject to the same limitations in confidentiality protections that apply to hospitals, i.e.:
  - the Department of Health would have access to the materials, as they do with hospital QA materials;
  - the protection from discovery would not apply to" the statements made by any person in attendance at such a meeting who is a party to an action or proceeding the subject matter of which was reviewed at such meeting."[20]

Importantly, the bill is an option for group practices, not a mandate. A group could opt to continue as is, without implementing the elements of a malpractice prevention program, and forgoing the protections described above. Or it could choose to become a qualified group practice and avail itself of those protections. This option is necessary because not all physician groups will have the ability to "measure up" to these standards.

New York would not be inventing a protection for quality assurance activities by physician groups. Indeed, about half the states have some form of protection for physician group quality activities.[21] But with this bill, New York would be imposing perhaps the most detailed and rigorous standards for groups that wish to earn confidentiality and immunity protection for their QA activities.

As a result, the qualified group practice bill, if enacted in New York, will prompt larger group practices to adopt malpractice prevention program standards, and thereby enhance quality of care by physician practices and greatly benefit patients and the public.

Endnotes

1. NY Public Health Law (PHL) § 2805-j.
2. PHL § 2805-m.
3. PHL § 2805-j.
4. PHL § 2805-j. The statute sets forth more detailed requirements for each item.
5. All references in this article to "medical staff" should be considered to include dental and podiatric staff.
6. PHL § 2805-k.
7. PHL § 2805-l.
8. PHL § 2805-m.1.
9. The statute spells these section numbers out. Numbers are used here for readability.
10. PHL § 2805-m.2.
11. PHL § 2805-m.3. The federal Health Care Quality Improvement Act of 1986 (42 USC §§ 11101 et seq.) also protects peer review participants from liability when its standards are met. It does not address confidentiality.
12. 92 N.Y.2d 13 (1998).
13. PHL § 2999-r.
14. *SKA&A: 20 medical groups with the most physicians — The Permanente Groups top the list,* Beckers Hospital Review, January 5, 2017.
15. A "root cause analysis" is a quality assurance investigation focused on improving systems and processes. "Peer review" is a review of a practitioner's performance in one or more cases, conducted by other qualified practitioners.
16. For readability, cross-referenced statute sections are expressed in numerals. In Section 6527.3, these cross references are spelled out.
17. *See* n. 12. Emphasis added.
18. Senate Bill 3662 (2017)(Hannon), Assembly Bill (A.8556) (2017).
19. Hospitals are required to have a member of their governing board on their quality assurance committee. PHL § 2805-j.1. The "Qualified Group Practice" proposal would omit that requirement.
20. PHL § 2805-m.2. An unrelated bill would repeal this exception. Senate Bill 3661 (2017)(Hannon); Assembly Bill 2460 (2017) (Gottfried).
21. E.g., Florida, Fla. Stat § 766.101; Idaho, Idaho Code § 39.1392; Michigan, MCLS. § 331.531; Oregon, Oregon Ann. 2305.25.

Reflections on "Aid in Dying" and the Paradox of "Achieving Death": Avoiding the Confluence of Language and Ideology at Life's End

By Joseph J. Fins and Mary Beth Morrissey

I. Introduction

The subject of aid in dying has been front and center in New York for several years in the context of legalization debates that have been spearheaded principally by two advocacy organizations, End of Life Choices New York and Compassion & Choices. These debates have intensified in light of activity in other states and high-profile media attention to individual cases, such as that of Brittany Maynard. New York has seen the introduction of an aid in dying bill,[1] as well as litigation in the case of *Myers v. Schneiderman*.[2] The New York Court of Appeals handed down its decision in the case in September 2017, ruling that there is no fundamental constitutional right to aid in dying in New York as defined by the plaintiffs. A recent article in this New York State Bar Association *Health Law Journal* reviewed in detail legislative efforts in New York to establish medical aid in dying as a right.[3]

The focus of our particular commentary is to address in a non-ideological manner bioethical, clinical, and public policy issues about aid in dying that have not received sufficient attention in public forums to date, or have perhaps been given an ideological and libertarian slant. Drawing on interdisciplinary perspectives, the authors seek to reframe the debate about a complicated problem not amenable to technical or simplistic fixes that will not meet the need of most patients and families.

II. From Ideology to Understanding

Proponents of aid in dying have framed the goals of the movement as an extension of patient self-determination that would encompass a right to aid in dying, also known as physician-assisted suicide (PAS).[4] In this article, we address ethical issues related to the practice known as physician or medical aid in dying. Under either term, this practice involves physician-prescribed lethal medication to a terminally ill, competent patient for the purposes of such patient's self-administration of such medication to end his or her own life as he or she chooses. (Other practices that would involve intentional acts by a third party to bring a physically or mentally ill person's life to an end through administration of lethal medication or injection, such as euthanasia, are legally permitted in some countries, but are not legal or under active consideration in the United States at this time and will not be discussed here.)[5]

Often motivated by libertarianism or neoliberal ideology,[6] [7] [8] which may be less progressive than it seems, this expansion of patient autonomy represents an illusory desire to control the timing and manner of death. But it is a hollow quest. Physician aid in dying will neither negate the dread of death nor its sad aftermath. As the bioethicist Daniel Callahan has wisely written, no matter the desire for control, we cannot escape our mortality.[9] It is simply out of our hands.

Moreover, death is not an atomistic event affecting only the patient taking her/his own life. Most of us are embedded in families and larger social and cultural contexts, and there can be consequences for complicated bereavement when aid in dying occurs and there is unresolved conflict over the action.

All this complexity is obscured by the language of those who favor aid in dying. At a conference held at the Sandra Day O'Connor Law School focusing on dementia, brain injury and disorders of consciousness, a national proponent of aid in dying spoke rather eloquently and convincingly not about dying, but rather what was described as "achieving death."[10] It was not clear what this meant, and whether the speaker intended to frame death and dying as a type of accomplishment.

Efforts to reduce aid in dying to an individual achievement or "good death" fail to account for the complexity in experience of suffering and death, dying, and bereavement. Dying is not a usual sort of achievement, but a passage with consequences. Changing the language leads to conflations that obscure differences with serious implications both for professional practice and for patients. For example, PAS is represented as aid in dying, seeking to conflate the multiple ways in which doctors help patients die, such as withdrawal or withholding of life-sustaining therapies (LST) and DNR orders. Indeed, language in the New York State Bill on "Medical Aid in Dying" suggests that PAS is no different from other ways that patients receive care at life's end. This obscures important differences that we need to explicate.

Previously, each one of us has argued that there is a valid distinction between PAS and decisions to withhold or withdraw life-sustaining therapies.[11, 12] While this itself warrants an essay-length explication and is not the subject of our article here, suffice it to say that the argument hinges on causality and intent. Consider the example of two patients on a ventilator. The first has Acute Respiratory Distress Syndrome (ARDS) and respiratory failure. The second had general anesthesia for an operative procedure. If the ventilator is removed from both patients, once the second patient has recovered from anesthesia, death will occur in the first but not the second case. In this case, the mere removal of a ventilator is necessary for the first pa-

tient to die but insufficient in the second. In the first patient, extubation removes an impediment to death, allowing a natural process (ARDS) to proceed to its biological conclusion. The same action in the second patient leads to the recovery room because there was no longer a need for ventilation once the patient's level of arousal returned to normal. Thus, a withdrawal of LST only leads to death in patients who continue to need LST. A similar argument can be made for decisions to withhold LST. Only patients who are having a cardiac arrest need resuscitation.

Contrast these actions, whose outcomes are predicated upon specific biological realities (ARDS and cardiac arrest), with assisted suicide. When a patient is given a lethal dose of medication to self-administer, the medication, versus an underlying disease process, is the proximate cause of death. While one could argue that medication is only provided to patients who have a terminal illness, this stipulation does not address the causality question, which is further compounded by the challenge of accurate prognostication at the end of life as carefully explicated by Nicholas Christakis.[13]

Another key distinction is that of intention. In the context of intending to treat pain with escalating doses of medication necessary to achieve analgesia versus a fixed dosage that is known to cause death, the former action may have a double effect, a foreseeable but not intended consequence of death, but the latter is meant to unambiguously cause death. In sum, both causality and intentionality distinguish PAS from decisions to withhold or withdraw LST and the provision of high doses of pain medication to alleviate significant patient distress.

There also is an attempt here to say that the public needs aid in dying because we have no other remedy to "achieve death," as many proponents would assert. Indeed, the New York State Bill suggests that medical aid in dying is an *alternative* to palliative care. This seems to undermine the importance of palliative care and its known efficacy. Such conflations only breed fear, and prompt people to support desperate measures because they worry that they will be abandoned and die in pain.

We can mitigate these fears with good palliative care by teaching it well in New York State[14,15] and not undermining its legitimacy as the New York State Bill seems to do by casting PAS as an equal alternative. Medicine is not powerless. We can control the pain and symptom burden that may occur at life's end. We can temper the use of aggressive, but disproportionate, medical technology. We can talk with patients and families about forgoing resuscitation and opting for comfort measures.

We can even withdraw LST when it no longer serves a patient-centered purpose. And, if the pain is too great, we can sedate patients with strong medications to ease their passage. These palliative care interventions are distinct from deliberately ending one's life and consistent with long-established medical and ethical norms. In a moral universe where *intent and intentionality matter,* these decisions must be distinguished from physician-assisted death.

III. *Vacco v. Quill* and *Washington v. Glucksberg*

This concern about intent was notable in the 1997 U.S. Supreme Court assisted suicide cases, *Vacco v. Quill*[16] and *Washington v. Glucksberg*.[17] In rejecting a constitutional right to assisted suicide, the Court—Chief Justice Rehnquist himself—affirmed a right to palliative care, including pain medications, which might secondarily hasten death. Notably, it was asserted that pain management efforts were not intended to cause respiratory cessation, but that because this outcome was secondary to the goal of pain management, it was morally acceptable. This became known as the doctrine of "double effect," which clarifies that such instances are not assisted suicide but appropriate palliative care. The late Robert Burt, then Sterling Professor of Yale Law School, made this point in a *New England Journal of Medicine* at the time.[18]

Quill v. Vacco[19] was also important because the litigants sought to conflate withholding and withdrawing LST (which law and ethical consensus support) with PAS. Invoking the Equal Protection Clause of the Fourteenth Amendment, litigants in the Second Circuit *Quill v. Vacco*[20] case asserted that if there were a right to withhold or withdraw LST, there should also be a right to PAS. The Second Circuit agreed and SCOTUS reversed, rightly noting that the Equal Protection Clause only guaranteed equal protection to folks who were *similarly situated*.[21] As noted, patients on a ventilator that might be withdrawn, or those who are in imminent need of LST that might be withheld, are in quite a different position than those who need an affirmative action to end a life with PAS.

There is another potential consequence to conflating PAS with LST. Should the political tides change, one could see the rejection of PAS extending in a retrograde fashion to decisions to withdraw or withhold LST. Here the false invocation of the Equal Protection Clause would have a regressive effect. It would paradoxically erode liberties by bringing additional scrutiny to decisions at life's end that are now more routinely approached.

An expansion of rights to include assisted suicide could also undermine well worn rights at the end of life by forcing a more critical examination of motivations for acts that might either be construed as falling under "double effect" or a proper withdrawal of LST or as assisted suicide. This concern is more than hypothetical if we consider arguments made by Supreme Court Justice Neil Gorsuch in his volume, *The Future of Assisted Suicide and Euthanasia*.[22] In the book's final chapter, arguments are made that might either be construed as falling under double effect or as relitigating well-established rights of surrogate decision makers at the end of life. While Gorsuch accepts the right to refuse LST, he does so with the provision that these refusals are only acceptable when

death is not the goal, that is, when it is not sought. He argues that any decision or action that would involve the intentional taking of human life would contravene what he describes as "the inviolability-of-life principle." Those who seek to expand rights to include assisted suicide should be careful not to engender regressive responses that would undermine the liberties that have been hard won at life's end.[23]

The risk of constricting rather than expanding rights in the current environment is further complicated by the tragedy of the current opioid epidemic. We already see how access to opioid pain relief for people with chronic pain and at the end of life has been adversely affected by the national epidemic of opioid abuse and how this has been politicized. Those who live by the proverbial ideological sword can also have their arguments undercut when the same logic is applied in reverse. Hannah Arendt called this the error of logicality, in which acceptance of a first false premise can lead to logical conclusions that are wrong because of the initial predicate being erroneous.[24] Here the false conflation of PAS with other end-of-life choices leads to the potential error of logicality.

The best remedy to avoid such errors is to be sure that the application of these principles fits the evidentiary predicate in the first place. Patients receiving or in need of LST are different from patients who are fearful of future distress and want to invoke a negative right to be alone. Those who would forgo treatment in order to die are in a fundamentally different position than those who want, and request, an affirmative action so as to die.

IV. The Language of Good Intentions

The ideological manipulation of language at life's end to achieve political goals has important clinical repercussions because it recasts how doctors think about their obligations. It will become easier to jump to unexamined conclusions about patient wants and needs, sometimes distorting the very autonomy that "death with dignity" seeks to protect. While this is speculation, this is an arena for potential abuse.

Consider the case of a patient with endocarditis secondary to intravenous drug abuse who was hospitalized in the intensive care unit with a spinal cord abscess involving cervical spine level c3-c5.[25] He had septic emboli to his brain and lungs, compromising both his level of arousal and his respiration. Because of cervical cord compression at the origin of the phrenic nerve, the patient needed to be ventilated.

Unconscious and in critical condition, the patient's mother consented to a DNR order. A few weeks later the patient regained consciousness. Essentially locked in because of his spinal cord lesion, he began to communicate with his eyes. His doctors called for an ethics consult because he had indicated that he wanted to die and have his endotracheal tube removed. They asked for an ethics consultation to validate this request so that they could honor his wishes and allow a "dignified death."

When the consultant met the patient, he was alert and clearly able to signal *yes* and *no* with his eyes. After some preliminary questions to ensure that he could follow instructions and answer consistently by blinking his response, and after some additional neutral queries, he was asked if he wanted to die as had been indicated by the clinical team.

He answered, *No*.

The consultant sought to confirm that this was his answer and continued to ask about his endotracheal tube. *Do you want the tube out?*

Yes, he responded with his eyes.

You would like the tube out?

Yes, again with his eyes.

You know that if I take the tube out you could die?

Yes, he said looking directly at the consultant.

So you still want it out?

Yes.

So you want to die?

No, he responded.

The consultant repeated the sequence several times and in different ways and came to the conclusion that the patient wanted the tube out, understood that taking it out would cause him to die, and that he did *not* want to die.

There was an inconsistency and the consultant felt obliged to offer an explanation. After all, all the patient could do was to respond to his questions. He could neither generate his own questions nor explain himself. He was voiceless and at the mercy of others.

So, let me summarize. You don't want to die, but you want the tube out? Correct?

Yes.

And then the consultant's hypothesis, *Does the tube hurt you?*

The question was met with a massive swooshing of downward gaze of his eyes and even something of a grimace, which would be fair to translate as an emphatic, *Yes*.

So, the consultant suggested, *You want the tube out because it hurts?*

Another expressive, *Yes*.

Adopting a more prudential stance, the consultant suggested that if he wanted to live, then the tube would

be kept in place until it was safe to take it out or place a more comfortable tracheostomy tube. That option was not currently possible because he was on a significant amount of pressure support so the procedure could not be done safely.

The patient and consultant agreed to a number of things now that his goals were clear. First, the DNR order would be rescinded as he wanted to live. Second, he would be put under general anesthesia for a week to see if his lungs would heal thereby making tracheostomy placement possible. If that became an eventuality, he would be awakened to obtain his consent for that procedure. On the other hand, if his condition worsened and he were unable to come off the tracheostomy tube he asked that the DNR order be reinstated and that a terminal extubation be performed.

For comfort relief, the patient was placed under general anesthesia and continued to receive antibiotic treatment for his systemic endocarditis. He emerged a week later as a candidate for tracheostomy placement. This was done and he eventually went to rehabilitation.

A fortuitous outcome, but whatever had occurred it is important to return to how the case was too easily framed as a right to die case and how this changed. Over the course of 40 minutes of "discussion" with this patient, a "routine" withdrawal of care—presented by the patient's medical team with much self-satisfaction—had become something quite different. Through a deeper exploration of the patient's narrative, the consultant was able to clarify that the patient *never* wanted a withdrawal of life support and did *not* desire death. His request to have his tube removed, too easily interpreted as a euphemism, "like pulling the plug," was actually a call for pain relief in a patient who had become voiceless due to his paralysis and intubation.

The desire to provide this patient a "dignified death" also suffered from a lack of credible evidentiary information about the patient's prognosis. His fate was presumed by the treating team to be far worse than his actual prognosis. After additional consultation, it was estimated that he had a 50% chance of independent respiration after the abscess was drained and treated with antibiotics. Why the "treating" team so quickly saw the patient's situation as terminal can only be surmised. We might speculate that it may be related to prejudicial views towards his substance abuse and the "self-inflicted" nature of illness or be a cognitive bias stemming from a framing about paralysis and disability. Whatever the explication, unexplored attitudinal biases were working upon this case in a manner that distorted decision making to the point of almost sacrificing a patient's life.

We view these possibilities as antithetical to the origins of palliative care as means of providing comfort and relief, an evolving tradition dating back to the Irish Sisters of Charity who opened Our Lady's Hospice in Dublin in 1879.[26]

According to an account by Dame Cicely Saunders, herself the founder of the modern palliative care movement, the Sisters' sole focus was on the care of the dying.[27] Describing their hospice, it has been said that the Sisters observed, "It is not a hospital, for no one comes here expecting to be cured. Nor is it a home for incurables, as the patients do not look forward to spending years in the place. It is simply a 'hospice' where those who are received have very soon to die, and who know not where to lay their weary heads."[28] Here the Sisters capture the distinction between the balance of cure and care, the epitome of hospice and palliative care as contrasted with hospital acute care.

That phrase, "lay their weary heads," lingers in the heart and mind, embodying that empathy, that compassionate care that had so informed the palliative care movement as it marched through the 1990s fighting for legitimacy in clinical circles and fighting off those who more narrowly sought to use the movement as an ideological means to advance the case for PAS.

As practiced by its most thoughtful proponents, palliative care originated from a patient/family-centered stance that focused on relief of distress and closure, as well as an appreciation that patients and families came to their decisions in their own way and in their own time. Each patient's trajectory would be unique, and the key to formulating a smooth glide path to a peaceful death was to help articulate goals of care. Decisions to withhold or withdraw care were never goals in that framework. They were the means, meant to be derivative of a prior articulation of goals, desires and aspirations, some of which could be satisfied in other ways.

In the intervening decade, much has changed. In too many cases, the clinician's angst of an impending death and sense of causality, or even responsibility, for a patient's demise has been replaced by the consolation that those who withhold or withdraw LST are acting in a progressive fashion, invariably in the right, acceding to patient or family wishes. And if such consolation is wanting, then the default is clinical decision-making based on the superior judgment on such matters that is expected to come with medical practice. There is a certainty to these decisions replacing the ambiguity of clinical intentions and the moral angst that used to be felt. In short, this ideological belief becomes a prescriptive way to die that has taken some of the gravitas out of dying, and not in a manner that either benefits or consoles patients and families.

No longer is it just about securing a right to die. Practices and beliefs have morphed so that a timely death has become proper and prescriptive. When patients don't die as expected, or on time, one hears house staff using the phrase, "failure to die"—an echo of the earlier geriatrician's, "failure to thrive"—to describe terminally ill

patients who lingered and refused to die. A failure to die … *we used to call that survival*. Now that is being seen as a failure, a strange twist since Wanzer wrote of death as a medical failure back in 1989.[29] That classic essay will celebrate its jubilee in 2019, but so much has changed. From death as medical failure to a failure to die: *Everyone is in such a hurry*. The risk of rushing to judgment at life's end could be further accelerated by having a PAS option.

V. Fears of Abuse: Oregon

Some will counter and say that the New York State Task Force's unanimous reservations about the legalization of assisted suicide articulated in its 1994 *When Death Is Sought*[30] have not been realized. The evidence in states where it has been legal has not shown tremendous abuse.

There is much to say here, but let us focus on one clinical and epidemiological issue. First is the question of how we would determine that a patient has the capacity to make a voluntary decision about PAS. This hinges on the dual questions of capacity and voluntariness. In Oregon, capacity is not the threshold—instead they use a vaguer term about being capable. The statute reads:

> (3) "Capable" means that in the opinion of a court or in the opinion of the patient's attending physician or consulting physician, psychiatrist or psychologist, a patient has the ability to make and communicate health care decisions to health care providers, including communication through persons familiar with the patient's manner of communicating if those persons are available.[31]

There is the need for a concurring physician. Also, there is no mandate for a psych referral unless a psych disorder is suspected. "Capable" is the threshold and not formal decision-making capacity, which is usually the predicate for competence to make medical decisions. A decision to willfully end one's life would seem to require legal competence, not mere capability, which seems to be a term of art. This is a rather low threshold.

How applicable would this be to our highly regulated context in New York State? This was a point recently made by the Bar Association of the City of New York in its examination of the proposed legislation.[32] Tellingly, New York State regulates surrogate decision-making *more* rigorously than Oregon regulates PAS.

All kinds of questions arise about the regulation of PAS. We presume the law would continue to be limited to adult competent patients. But beyond that are several important questions: What illnesses would qualify? Who would evaluate patients for their ability to make decisions and determine their medical eligibility? What sort of training would these practitioners require? Would they need to be certified or credentialed? Could a hospitalist just meeting a patient make this judgment? Would these assessments require that a patient have an ongoing doctor-patient relationship? Would that limit this service to those without access to primary care? Speaking of the poor, would this further limit their equitable access to care or make them more vulnerable?

Let us return to what exactly can be inferred from Oregon's experience and examine the epidemiological evidence. There has not been a high incidence of cases in Oregon. No matter how normative proponents of PAS want to make the act out to be, it is still but a small fraction of cases. From 1998-2017, only 1,967 patients obtained a prescription for lethal medication under Oregon's Death with Dignity Law. This is against the backdrop of 30-35,000 adult deaths per year in Oregon over this 20-year span.[33] That would equal approximately 0.28 to 0.32% of all adult deaths in the state. These data suggest that assisted suicide remains an exceptional action, chosen by a very small minority of dying patients, with an even smaller number bringing their decision to completion. And of the 1,967 who obtained a prescription since 1997, only 1,275 patients died from a legal ingestion, just under two thirds of patients who obtained medication.

This experience suggests that the needs of most dying patients cannot be addressed by pharmacology alone. Legalization of PAS is not a remedy for the vast majority of patients who will never consider, much less avail themselves of, this option. In Oregon, 99.7% of patients did not take advantage of the law. These data suggest that the focus on PAS is misplaced and constitutes a distraction from more compelling clinical need. Good end-of-life care is more complicated than having a stash of pills in the medicine cabinet. Patients need comprehensive palliative care, including psychological support to address their suffering and fears.

Whatever one thinks of PAS, it is *not* a population-based public health remedy for the vast majority of patients. Nonetheless, it consumes a disproportionate amount of our attention, at the expense of more productive conversation. This begs the question, why?

VI. Brittany Maynard and the Need for Better Palliative Care

If we think of the Brittany Maynard case, we can begin to understand assisted suicide's appeal.[34] The images are heart-wrenching: A young woman, newly married, in her prime, dying of a *glioblastoma multiforme*. She decided not to seek treatment for her tumor, convinced it would be burdensome, if not futile. Moving to Oregon where physician-assisted suicide is decriminalized and regulated, she bravely expressed her desire to die. She wanted to end her life on her own terms before the tumor made a free choice impossible. But at the end she wavered, taken over by ambivalence. It is hard not to admire Ms. Maynard's courage and to mourn this tragic loss.

Yes, we feel for Ms. Maynard, but does that make her choice a good one? Does her compelling narrative make for good public policy?

The great jurist Oliver Wendell Holmes, Jr. once said that, "hard cases make bad law." He worried about the misinterpretation of facts and the miscarriage of judicial reasoning, "… because of some accident of immediate overwhelming interest which appeals to the feelings and distorts the judgment."[35] Such is true in the Maynard case. Her youth, the tragedy of her circumstances, and yes, the media appeal of her story, can distort judgment and lead us to conclude that what seems right for her is good for others.

But it is not so simple. The care of the dying is a challenge that American medicine has yet to fully embrace. In 2014, the Institute of Medicine (IOM) of the National Academies of Sciences issued a report, *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life,*[36] which outlined the clinical, financial and cultural barriers to good palliative care and made constructive recommendations for reform. An endorsement of physician-assisted suicide was not one of them.

In the 19 years since the last IOM report,[37] progress at the end of life has been spotty. Although medical education has improved and palliative medicine became a nascent medical specialty, we have a long way to go to ensure that all Americans die well, or as well as can be expected. We remain wedded to ever-more medical technology, often in the face of futility.[38] Intensive care has become more *intense* fueled by a medical arms race, unthinkable even a decade ago.

We still have inadequate access to hospice and palliative care. Referrals are difficult and length of stay an issue.[39] Families may be insensitively asked about discharge plans upon arrival to in-patient hospice even when death is imminent.[40] Such callousness is prompted by CMS regulation of in-patient hospice length of stay with fiscal claw-backs.[41] These policies make hospice hard to access substantively and in a timely fashion. This becomes more complicated as most hospice care is provided at home, and that requires a home and an unpaid caregiver. So what happens if you're dying and single, or homeless, how do you get hospice care?

It shouldn't be that way, and as long as it remains so difficult to get competent and accessible palliative care, people will be susceptible to easy answers like assisted suicide, which now sounds so much more appealing when dressed up with polished phrases like "achieving death." It is also cheaper, creating a perverse conflict of interest in times of scarcity.

V. Conclusion

In the aggregate, these tensions illustrate the true complexity of end-of-life care, a complexity not subsumed by a solitary position on PAS. More fundamentally, America remains deeply divided. We remain a country that denies death.[42,43] Instead of planning for end-of-life care with sensible interventions such as advance care planning and goals of care discussions, we become enmeshed in ideological debates about so-called (and fictional) "death panels." The force of denial is also part of the appeal of assisted suicide. By pursuing this agenda, we gain psychological reassurance that somehow we can avoid life's final chapter.[44] It will provide the illusion of solace, but if the Oregon demographics are dispositive about utilization, this change in law will do little more for the vast majority of New Yorkers, and as noted potentially will have unintended consequences for decisions at the end of life.

Dr. Joseph J. Fins presented remarks on aid in dying to the New York City Bar Association Bioethical Issues Committee on December 5, 2016. The City Bar issued a commentary on aid in dying in June 2017, citing Dr. Fins' remarks before the Bioethical Issues Committee. This article draws on Dr. Fins' presentation to the Bioethical Issues Committee. Both Dr. Fins and Dr. Morrissey gratefully acknowledge the comments of members of the Bioethical Issues Committee for their fruitful dialogue.

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Sexual Harassment in the Health Care Workplace

By Francis J. Serbaroli

In recent months, many prominent persons have had career-ending allegations of sexual harassment brought against them. Those accused in these high-profile cases have come from media and entertainment, sports, government, finance, the arts, and other areas. The organizations with whom they were affiliated are scrambling to investigate these allegations, to do damage control, and to implement new policies and processes to demonstrate their zero-tolerance for such harassment. Questions are being raised as to whether the leadership of these organizations and their governing boards knew about the harassment, and if so, why appropriate action was not taken to stop it and prevent its recurrence.

Sexual harassment has had a long and unfortunate history in the health care sector. Many female physicians, nurses, technicians, supervisors and other employees of medical schools, hospitals, nursing homes, clinical laboratories, pharmacies, and other health care institutions have been victims of harassment and abuse for decades. That has included being pressured to engage in sexual relations, rude remarks about their physical features and personal lives, abusive language and behavior, even throwing scalpels and other items in the operating room, and derogatory remarks about women in general. In a study published in the Journal of the American Medical Association (315 JAMA No. 19, May 17, 2016) a team of researchers headed up by Dr. Reshma Jagsi, deputy chair of radiation oncology at the University of Michigan Medical School, conducted a survey of clinician researchers in which 30 percent of the female responders reported having experienced overt sexual harassment compared with 4 percent of the male respondents.

In a Nov. 20, 2017 post entitled "Not Just the Rich and Famous," Jocelyn Frye, a senior fellow at the Center for American Progress, analyzed sexual harassment charges filed with the EEOC from 2005 to 2015 and found that the Health Care and Social Assistance category had the fourth highest instance of complaints—11.48 percent—following Accommodation and Food Services (14.23 percent), Retail Trade (13.44 percent) and Manufacturing (11.72 percent).

Sexual harassment in any workplace is both illegal and intolerable. It is intolerable in institutions caring for patients where harassment can disturb and distract care givers and threaten patient and employee safety. The problem is not limited to male abuse of females. There have been many cases of same-sex harassment and abuse, as well as some instances of female abuse of males. And abuse has occurred in the spectrum of health care, from small physician offices, to hospitals and clinics, to the hallowed halls of some of our most prestigious medical schools.

Nor are the perpetrators of sexual harassment limited to those working together in the same organization. It can also come from patients, family members or friends of patients, third party vendors and service providers, and others who have dealings with the organization but are not employees.

Laws

Title VII of the Civil Rights Law of 1964 prohibits, inter alia, discrimination on the basis of sex, and sexual harassment is regarded as a form of sexual discrimination. Title VII applies to all employers with 15 or more employees. The federal Equal Employment Opportunity Commission (EEOC), which enforces the provisions of Title VII, explains that harassment can include:

> . . . "sexual harassment" or unwelcome sexual advances, requests for sexual favors, and other verbal or physical harassment of a sexual nature. Harassment does not have to be of a sexual nature, however, and can include offensive remarks about a person's sex.
>
> . . . Both victim and the harasser can be either a woman or a man, and the victim can be the same sex.
>
> . . . (H)arassment is illegal when it is so frequent or severe that it creates a hostile or offensive work environment or when it results in an adverse employment decision (such as the victim being fired or demoted).

The EEOC's position is that illegal harassment is not limited to other employees:

> The harasser can be the victim's supervisor, a supervisor in another area, a co-worker, or someone who is not an employer of the employee, such as a client or customer.

New York State's Human Rights Law (NY Exec. Law Article 15), which applies to all employers, similarly out-

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laws sexual harassment and includes harassment based on gender identity and transgender status. Various municipalities, including New York City (New York City Admin. Code Ch. 1, § 8-107), have their own staturoy prohibitions on sexual harassment; indeed, the legal standard for establishing harassment under the New York City Human Rights Law is lower than that under the federal or state laws.

These laws also have strict prohibitions on any kind of retaliation against individuals who notify their employers that they have been the victims of, or participated in investigations of, sexual harassment. Yet despite so many legal protections, many instances continue to go undetected because of the hierarchical nature of many health care institutions, and the victims' fear that their allegations will not be given credence, or may in fact result in their losing their jobs or hurting their careers.

- Employers may be strictly liable for harassment by a lower-level manager, or by a supervisor if that supervisor has a sufficient degree of control over the working conditions of the victim. This means that the employer may be legally responsible for such harassment, even if no owner or manager knew about it.
- Employers may be liable for the harassment of an employee coworker, if the employer knew or should have known about the harassment and failed to take action. This means the employer will be liable if the employer was negligent about preventing or stopping harassment.
- If an employee complains of harassment to any supervisor or manager, the knowledge of the supervisor or manager will be considered to be the knowledge of the employer.

"A health care organization that does not take the problem seriously may end up experiencing highly public downfalls of prominent physicians or health care executives, incurring potentially large damage awards and government enforcement actions, and damaging its reputation among patients, donors, regulators, and the community it serves."

Moreover, cases of sexual harassment have either been the subject of a cover-up, or they have been quietly settled with some amount of compensation paid to the victim in return for a confidentiality agreement, and the re-assignment or resignation of the victim. But in these situations the underlying problem remains, and the perpetrator of the abuse not only may go unpunished, but is enabled to continue his predations.

It is a sad fact that, in the past, some hospitals would take extraordinary steps to protect a sexually abusive physician because he brought in a high volume of patient admissions, or was in a senior management position, or was responsible for obtaining substantial research grants, philanthropic gifts, or other significant income. Times are changing, however, and more people are not only more aware of their rights but also prepared to assert them.

Liability

The New York State Division of Human Rights, in its "Guidance on Sexual Harassment for All Employers in New York State," summarizes the liabilities of an employer for sexual harassment in the workplace:

Sexual harassment may result in a lawsuit or class action by the victim(s), a lengthy, costly, reputation-harming exercise for which the losing employer may not only be liable for a significant financial verdict or settlement, but also potentially for the plaintiff's legal costs. It can also trigger an enforcement action by the EEOC, the New York State Division of Human Rights or the State Attorney General, or other agencies. Of course, any kind of physical assault or coerced sexual relations can also be a crime.

Damages

In 2012, a jury awarded a female cardiac surgery physician assistant nearly $168 million in a case in which she alleged that she had been sexually harassed and physically abused by cardiac surgeons at Mercy General Hospital in Sacramento, California, and had lost her job after repeatedly complaining to the hospital about the harassment. The hospital countered that she had been fired for not showing up for an on-call shift, and for allegedly sleeping on the job.

The trial judge later reduced the award to approximately $82 million, and then vacated the award in its entirety when the parties entered into a confidential settlement. *Chopourian v. Catholic West et. al*, Case No. 2:09-cv-02972-KJM-KJN (E.D. Calif.).

In 2003, the former Lutheran Medical Center in Brooklyn agreed to pay $5.425 million to settle an enforcement action commenced by the EEOC after a physician was accused of sexually harassing at least eight female

employees in the course of employment-related physical examinations. According to the EEOC complaint, the harassment included invasive touching and intrusive questions about the female employees' sexual practices.

Last month, the Second Circuit Court of Appeals, in *MacCluskey v. University of Connecticut Health*, Case No. 17-0807-cv. (2d Cir. Dec. 19, 2017), upheld a district court verdict that found the University of Connecticut Health System liable for sexual harassment of a dental assistant, who alleged that she had been repeatedly harassed and physically touched by a dentist over a period of months. The dentist had a past record of harassing at least one other dental assistant, and had been disciplined and threatened with termination after the prior incident. The appeals court also upheld the $125,000 in damages awarded to the dental assistant.

Policies

An employer protects itself and its employees first and foremost by having a comprehensive set of policies and procedures defining and prohibiting sexual harassment, and setting forth the process for an employee to lodge a complaint, and how the complaint is to be handled internally. It also involves educating (and periodically re-educating) every person in the organization—including board members and senior management—about sexual harassment policies and procedures. It involves timely and thorough investigation of an employee's complaint, and enforcement and remediation as needed and as appropriate. Education and enforcement of a health care organization's sexual harassment policies are important compliance functions.

Conclusion

It is hard to know whether and to what extent the recent spate of high-profile downfalls will have a salutary effect on sexual harassment in health care workplaces. The problem has been widespread, and has gone on for so long, that it seems that only a major change in the underlying culture will mitigate the problem. A health care organization that does not take the problem seriously may end up experiencing highly public downfalls of prominent physicians or health care executives, incurring potentially large damage awards and government enforcement actions, and damaging its reputation among patients, donors, regulators, and the community it serves.

Unlike some unfortunate medical complication in a patient's care that could not have been foreseen, sexual harassment can and should be detected and addressed. Everyone from board members to executives, to physicians, to supervisors has a stake in maintaining a safe and professional workplace for all employees.

Consumer Pre-Dispute Arbitration Clauses: The Manifestation of Mutual Assent?

By Joan D. Hogarth and Marcia Adelson

What constitutes an "agreement" in the context of consumer agreements that contain a pre-dispute arbitration clause?

This issue is being litigated in court, including the U.S. Supreme Court, because pre-dispute arbitration clauses are routinely included in standard-form contracts for goods and services and, for health care, in nursing home admissions agreements. After purchasing a cell phone, the consumer may be unpleasantly surprised to learn that she has agreed to resolve disputes in arbitration. In 2015, the *New York Times* ran a series of articles[1] expounding weaknesses in using arbitration as a means to resolve consumer disputes. The articles characterized arbitration clauses as being buried in contracts, thereby depriving Americans of their constitutional right to "a day in court." The matter remains unsettled despite the U.S. Supreme Court's clear holdings on the status of arbitration agreements. The resultant debate among consumer advocates and arbitration proponents have led to some regulatory agencies, e.g., the Consumer Financial Protection Bureau (CFPB) and the Centers for Medicare and Medicaid Services (CMS), proposing and promulgating regulations limiting the use of pre-dispute arbitration clauses.

However, in December, 2016, the CMS rules were suspended and in November 2017 the CFPB rules were voided. Recently, the Second Circuit Court of Appeals clarified the conditions for a binding arbitration agreement in website and online transactions when in *Meyer v. Uber Technologies, Inc.*,[2] it reversed the lower court and held that (1) the Uber App provided reasonably conspicuous notice of its Terms of Service, and (2) "Although Meyer's assent was not express, we are convinced it was unambiguous in light of the objectively reasonable notice of the terms." In classic contract law terminology, the issue is whether there is a manifestation of mutual assent to pre-dispute arbitration and thus the formation of a contract.

Arbitration Agreements Are Contracts

"[A]rbitration is simply a matter of contract between the parties; it is a way to resolve those disputes—but only those disputes—that the parties have agreed to submit to arbitration."[3] The U.S. Supreme Court has repeatedly held that arbitration contracts are to be interpreted and enforced according to the same standards of contract law, no more, no less. It has held that the Federal Arbitration Act of 1925 (FAA)[4] preempts state statutory schemes that aim at prohibiting arbitration or imposing limits on arbitration clauses; rather, arbitration agreements must be placed on equal footing to that of all other contracts.[5] For example, the Supreme Court held that a state-law contract rule that singles out arbitration by requiring a power of attorney to expressly refer to arbitration agreements before the attorney in-fact can bind her principal to an arbitration agreement is not valid and is preempted by the FAA.[6] As another example, in *AT&T Mobility*[7] the Court overruled the California Supreme Court, which had held that class waivers and mandatory arbitration in consumer agreements were generally unconscionable and unenforceable because, the Court stated, they stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[8] The U.S. Supreme Court consistently favors arbitration and despite the best efforts of state courts sympathetic to consumers, parties opposing any type of arbitration, including those of consumer contracts, will find it improbable that arbitration agreements will be afforded a lesser treatment than other contracts. Even consumer contracts are enforceable under the FAA, save where contract defenses are available.

The Question of Assent

The question of assent directly addresses the very existence of a contract. In the commercial environment, the decision as to the terms and conditions, including arbitration clauses, is a natural part of the negotiations. In the consumer environment, there is minimal or no negotiations of the terms and conditions, including that of arbitration clauses. The arbitration clause is not negotiated but is stated as a condition of doing business when being admitted to a nursing home, when purchasing a cellphone, when first using an internet application, or when opening a bank account. Unlike negotiated agreements in the commercial environment, agreements in the consumer environment generally lack negotiations and when conflict arises, debate ensues regarding whether the consumer assented to arbitration.

Contracts such as the admissions agreement for a nursing home, or the "in the box" warranty for the purchase of a cell phone, or the standard agreement in obtain-

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ing a credit card, require assent, which means parties approve of and agree to the terms. The arbitration clauses within those agreements, like all the other clauses within the contract, are subject to the requirement of manifestation of assent. In *Specht v. Netscape*[9] the issue being argued was whether the plaintiff before downloading and using software had reasonable notice of and manifested assent to the license agreement which contained the arbitration clause. The Second Circuit Court of Appeals found that the plaintiffs neither received reasonable notice of the terms of the license nor did they manifest "unambiguous assent" to such terms.

"This principle of knowing consent applies with particular force to provisions for arbitration."[10] Citing other cases, the court pointed out that clarity and conspicuousness of arbitration terms are important in securing informed assent. "If a party wishes to bind in writing another to an agreement to arbitrate future disputes, such purpose should be accomplished in a way that each party to the arrangement will fully and clearly comprehend that the agreement to arbitrate exists and binds the parties thereto."[11] While the court cited California law, it could have been citing classic contract law. The meaning of assent is clear—it is an objective standard that evaluates the totality of the contract negotiation—what the offeror and the offeree said, wrote and did.[12]

Similarly, the New Jersey Supreme Court held that "[a]n arbitration provision—like any comparable contractual provision that provides for the surrendering of a constitutional right must be sufficiently clear to a reasonable consumer." The opinion added that mutual assent requires that the parties have an understanding of the terms to which they have agreed. And, the party must agree clearly and unambiguously.[13] To distinguish the holding in this case from the U.S. Supreme Court's holdings[14] that reject state law schemes aimed at protecting consumers from being bound by mandatory arbitration clauses, the New Jersey Supreme Court cited other instances where New Jersey disallows the waiver of constitutional or bargained-for rights without knowing consent.[15]

The Question of Assent in Nursing Home Admissions

In nursing home admissions, often there are disputes surrounding "meeting of the minds" and whether the patient, otherwise known as a nursing home resident, gave assent to the terms and conditions of the admission agreement. The admission to a nursing home is invariably a time of stress for the patient and for those assisting in the decision-making process. The person being admitted often lacks capacity and accompanying friends or family members may not have the proper authority to act on the patient's behalf. Capacity is necessary for assent to a contract. In the case of the patient, that person is often entering the nursing home from a hospital stay or from home after an emergency. The person is in need of skilled medical services or has physically or mentally declined to the point of requiring substantial assistance. The person may be suffering from dementia or another form of cognitive decline. The nursing home admissions process is a lengthy and complex one requiring both an understanding of and signatures on multiple forms. These forms may include a medical history, a list of drugs, treating physicians, financial and banking forms, health care proxy forms and do-not-resuscitate forms. Nursing homes require and are permitted to have third party facilitators sign on behalf of the incapacitated patient to ensure there is some accountability for the patient. However, these "designated representatives" cannot bind the patient, and therefore cannot assent to contractual provisions without further authorization that is provided through such instruments as are available at law, e.g. a power of attorney or a health care proxy, or through affirmative patient designation.

In a recent case involving nursing home admissions, the New York Supreme Court heard from experts on both sides and held that the patient was cognitively impaired and was not competent to sign the arbitration agreement that was included as part of the admissions agreement. As such, there could be no assent to the admissions agreement let alone the arbitration clause.[16] This was a matter of a lack of capacity. However, in *Friedman v. Hebrew Home for the Aged*,[17] another New York case, the lower court refused to enforce the arbitration contract holding that it was unconscionable and against public policy in light of Public Health Law §2801-d that declares any waiver of the right to a trial by jury, prior to an action, as being null and void. The lower court stated that the mandatory admissions agreement was unconscionable where the patient was effectively deprived of his ability to assent to the agreement because the patient either could sign the agreement, which included the arbitration clause, or not be admitted to the nursing home. There was an imbalance of bargaining power between the parties such that the patient could not have assented to terms of the agreement. In keeping with the U.S. Supreme Court holdings, the Appellate Division reversed the lower court, finding that the agreement was not unconscionable either on procedural or substantive grounds because the signatory, the patient's son, was an attorney. Attorneys are more sophisticated than the average consumer and was at no disadvantage in the bargaining. As for PHL § 2801-d, the court found that the nursing home was engaged in interstate commerce and as such was subject to the FAA that preempts state law affecting arbitration clauses. The New York Supreme Court upheld the arbitration agreement.

In *Bair v. Manor Care of Elizabethtown*,[18] the Pennsylvania Superior Court affirmed the lower court's order, ruling that the arbitration agreement was unenforceable because there was no meeting of the minds. In 2009, the same parties had entered into an agreement to admit the patient to the nursing home. The 2009 admission agree-

ment was completed for all the essential terms and signed by all the parties. In the instant case, the court found that the admissions agreement was incomplete as to its essential terms; i.e., the names of the contracting parties and the dates were missing. Moreover, the agreement referred to a brochure that explained arbitration, yet that brochure was never attached to the agreement. Finally, while the patient's representative had signed the admissions agreement, the nursing home's representative had not. The court noted that there was no meeting of the minds where these essential details were absent. It noted that the "absence of signatures is not fatal unless required by law or by the intent of the parties…." The parties intended that signatures should be affixed to acknowledge the statement in caps (right above the signature line) that both parties were aware that the required arbitration would mean they had waived their right to a jury trial.

The assent to arbitration was held against the nursing home. The court wrote that a contract must be intentional and sufficiently definite in its terms and that no offer will be found to exist where its essential terms are unclear.

Where a patient is accompanied by a third party, the issue becomes whether that person has been granted the power to assent on behalf of the patient. In *Extendicare v. Whisman*,[19] a consolidation of three nursing home cases, the Supreme Court of Kentucky refused to enforce the parties' arbitration agreements because it held that the attorneys-in-fact who signed those agreements lacked authority to enter into the agreements, despite broad powers of attorney, including the power to make "contracts." The Kentucky court concluded that because those agreements waive a "divine God-given right" to a jury trial, only an express mention of arbitration agreements in the power of attorney permits an attorney-in-fact to bind the principal to an arbitration agreement. In fact, Kentucky law does not require such an express mention of any other types of contracts.

On February 22, 2017, the United States Supreme Court heard this case and the question presented was "Whether the FAA preempts a state-law contract rule that singles out arbitration by requiring a power of attorney to expressly refer to arbitration agreements before the attorney in-fact can bind her principal to an arbitration agreement."[20] On May 5, 2017, the Supreme Court held that "the Kentucky Supreme Court specifically impeded the ability of attorney-in-fact to enter arbitration agreements." Arbitration agreements are like any other contracts and by singling them out, the Kentucky Supreme Court had failed to place arbitration agreements on equal footing with other contracts and had discriminated against them. The U.S. Supreme Court reversed the Kentucky Supreme Court and held that the standard is to be found in the specific powers granted to the attorney-in-fact. If it should be a broad general power that permits the attorney-in-fact to enter into contracts, then the attorney-in-fact can enter into any contract including, arbitration agreements.

State law regulates the validity of contracts through generally applicable contract defenses such as the lack of assent, the lack of capacity or unconscionability. Kentucky attempted to protect the right to a trial for what it saw as its "vulnerable citizens." However, this ran afoul of the Supreme Court's holding that the FAA pre-empts states from singling out arbitration agreements and requiring more stringent or different requirements for arbitration contract formation.

The Issue of Assent in Other Consumer Arbitration Agreements

To be an enforceable contract, whether the agreement is provided in person, in a box or over the internet, the rules of contract formation still apply. Thus, as the Second Circuit stated in *Meyer,*[21] there must be both "reasonably conspicuous notice of the existence of contract terms and unambiguous manifestation of assent to those terms to find that a contract has been formed." In *Meyer*, the Second Circuit found that Terms of Service which contained the arbitration agreement were reasonably conspicuous since the "entire screen was visible at once and although the sentence is in a small font, the dark print contrasts with the white background, and the hyperlinks are underlined." The court distinguished the screen in *Meyer* with the screen in *Nicosia v. Amazon*[22] in which the court found that the privacy notice and conditions of use were on the left side of the screen and the user placed an order by clicking on a button on a different part of the page. Meyer unambiguously manifested his assent to the Terms of Service by clicking on the register button. By doing this, not only was an account created but the Terms of Service were accepted. Meyer was allowed to review the Terms of Service prior to creating an account and the text on the payment screen not only included a hyperlink to the Terms of Service but warned the user that by creating the account, the user agreed to be bound by the linked terms.

The outcome of this case was unfavorable for Meyer. Yet, the requirement to read the terms and conditions of a contract has not changed because it is an online contract. It is the placement of the notice on an otherwise busy page that was in question here. The court wanted to ensure those terms were visible and accessible to the user. It found that they were, even if Meyer did not unambiguously assent to them. Many consumers are like Meyer and where there are "boiler plate" terms and conditions, may not take the time to ensure to what they are agreeing, including agreeing to arbitrate a dispute.

In *Specht v. Netscape Communications,*[23] the court held that "reasonably conspicuous notice of the existence of contract terms and unambiguous manifestation of assent to those terms by consumers are essential if electronic bargaining is to have integrity and credibility. We hold that a

reasonably prudent offeree in plaintiffs' position would not have known or learned, prior to acting on the invitation to download, of the reference to SmartDownload's license terms hidden below the Download button on the next screen." The *Specht* court is noting that contract formation requires assent and that it would not be possible for the consumer to assent to terms of which they were not aware. In these online agreements where the consumer has no role in the negotiation of the terms, there has to be a way of bringing those essential terms front and center; in other words, they must be conspicuously placed to give the consumer the opportunity to access them. For Meyer, that notice was conspicuously placed and his assent, though not unambiguous, was given the moment he clicked on the "terms" button. On the other hand, Specht had no opportunity to give assent where placement of the terms was so inconspicuous that he never had an opportunity to access them, never mind giving assent to them.

In *Guadagno v. E*TRADE,*[24] the arbitration agreement was enforceable. Here the Court found that "a highlighted underlined link to the Agreement was directly above the acknowledgment box, along with notice that "[t]he following contain important information about your account(s)." The court stated that a reasonably prudent offeree would have noticed the link and felt compelled to review the terms to be found in this section before acknowledging. In addition to the aforementioned statement, the introduction of the agreement had in all caps "YOUR ATTENTION IS DRAWN TO THE ARBITRATION PROVISION OF THIS AGREEMENT." And at the start of the arbitration clause it had in bold caps **IT IS IMPORTANT THAT YOU READ THIS ARBITRATION CLAUSE.** The court therefore concluded that the terms of this arbitration clause were clear, reasonably conspicuous, and because the consumer accepted the terms of the agreement, she essentially assented to the arbitration clause.

By contrast *Noble v. Samsung,*[25] where the arbitration agreement was only in the shrink-wrap, the court found that it was not reasonable for Samsung to expect the ordinary user to find an arbitration contract on page 97 of the 148-page booklet entitled "Health and Safety Warranty Guide." The use of bold font to bring the attention of the clause to the user was worthless since it was hidden in the booklet and the consumer would have had no reason to know that it was there.

Arbitration Agreements for Consumer Cases?

The cases cited here remain good law in the respective states. Relying on the basics of contract formation, the cases have demonstrated that parties must have the opportunity to assent to the terms of the contract regardless of its contents, i.e., if it contains an arbitration clause or not; or whether there is an objective or subjective manifestation of assent to the contract; or whether there is an unambiguous assent by a writing, clicking, words or acts. There can be no assent if the consumer never saw the terms on the computer screen. There can be no assent if the nursing home patient does not have the capacity to agree to a contract; neither can the family member assent to a contract on behalf of the patient, without legal authority to bind the patient. In the online transactions or the purchase of a boxed telephone, there can be no assent if the terms are hidden and not conspicuously brought to the attention of the consumers.

Care has to be taken by the drafters of such agreements to ensure the essential terms and conditions are brought to the attention of the consumer. Consumer advocates have be sure that the case law on which they rely is good law that will prevail in the highest courts. The pros and cons of arbitration must be shared with the average consumers who are bound by all the terms within the contract. Efforts must be made by arbitration administrators and courts to educate consumers about arbitration. ADR practitioners must be aware that the U.S. Supreme Court favors arbitration and disfavors state law schemes that attempt to prefer consumers. Parties who seek to eliminate the pre-dispute arbitration clauses are left only with the contract defenses that are applicable to the basic contract.

The authors offer that arbitration can be good for consumers who need a fast and inexpensive resolution to the dispute. There are several benefits to be derived for the consumer. Arbitration is faster than litigation in that a court case could take years to be resolved. Arbitration could take a few months, and less, if discovery is carefully managed. Arbitration has been touted as inexpensive. Opponents of arbitration point to its costs: The daily rate of the arbitrator(s), and the expense associated with the forum and the organization that manages the process. Yet, when this is compared to the costs of litigation, extensive discovery, and court scheduling delays, arbitration is less costly. The rules and procedures are informal and less adversarial than those in a court proceeding. A well-managed arbitration process could avoid hostilities that may take place in the courtroom. Finally, where trade secrets or embarrassing information may be implicated, arbitration is a confidential and private proceeding not subject to the scrutiny of the press or the public. Parties may then memorialize the arbitration agreement in a confidentiality agreement.

As practicing arbitrators, the authors recognize the opposing views of arbitration and the numerous articles and cases regarding pre-dispute arbitration clauses that make this article possible. Yet, as it may seem to be settled law in some states, in others and during the Obama presidency, there were continued efforts to effect changes for consumers in the judiciary and administrative branches. Opponents to pre-dispute mandatory arbitration have consistently called for steps to be taken to allow consumers to voluntarily make the choice of arbitrating or litigating. The answer may not be the court cases. Rather, the answer may come through legislative amendments to the FAA or the introduction of new legislation to reform arbitration.

Conclusion

Mutual manifestation of assent, whether written, spoken, or by conduct, is the touchstone of contract formation. "The conduct of a party is not effective as a manifestation of his assent unless he intends to engage in the conduct and knows or has reason to know that the other party may infer from his conduct that he assents."[26]

Arbitration was developed by businessmen to resolve disputes quickly, efficiently and privately. The use of arbitration then expanded into other areas such as consumer agreements. In these authors' minds, there is a distinction between the pre-dispute arbitration clauses that are the product of commercial parties and those consumer pre-dispute arbitration clauses. In the commercial setting, the parties actively negotiate and enter into the agreement and thus, there is hardly a question of contract formation. However, in consumer contracts, there are often questions of whether or not the consumer had reasonably conspicuous notice and then unambiguously assented to the terms of the contract.

The issue is compounded in the nursing home setting when the patient might not have full capacity. Each transaction should undergo a fact-intensive review of the conditions of each transaction to determine whether the consumer was aware and did indeed manifest assent. As an additional safeguard, the patient or the patient's representative should be given the option of re-affirming the arbitration clause. Such providers as the AAA (American Arbitration Association) and the American Health Lawyers Association refuse to administer nursing home arbitrations where there was a mandatory pre-dispute resolution clause in the admissions agreement.

Arbitration has many benefits and as Alternative Dispute Resolution (ADR) practitioners who espouse those benefits, the authors believe that many criticisms of arbitration are unjustified. However, in order to ensure the integrity and sustainability of the process, there should be education as to arbitration's benefits. Then, reasonable and conspicuous notice should be given in the contract as to whether fundamental rights such as the right to a jury trial are being waived. It is fundamentally important that consumers are not mandated to participate in a process to which they did not intentionally agree.

Arbitration has continued to evolve into a favorably recognized process, where the parties can select their own "nonjudicial tribunal that will arrive at a private and practical determination [of their dispute] with maximum dispatch and minimum expense."[27] Thus, parties choose to use arbitration to resolve their disputes because they want expediency, confidentiality, cost efficiency and finality and not because they have been compelled to arbitrate. In the long run, arbitration provides benefits if consumers are adequately informed and if negative articles and misunderstanding of the process are reduced.

Endnotes

1. *Arbitration Everywhere, Stacking the Deck of Justice* and another *In Arbitration "A Privatization of the Justice System."*
2. *Meyer v. Uber Technologies, Inc.*, 2017 WL 3526082 (2d Cir. Aug. 17, 2017).
3. *First Options of Chicago, Inc. v. Kaplan*, 514 U.S. 938, 943, 115 S. Ct. 1920, 131 L.Ed.2d 985 (1995).
4. 9 U.S.C. §§ 1-16.
5. *See Rent-A-Center, West, Inc. v. Jackson*, 561 U. S. 63 (2010); *see also Buckeye Check Cashing, Inc. v. Cardegna*, 546 U. S. 440, 443 (2006).
6. *Kindred Nursing Centers L.P. v. Clark*, 581 U.S. ___ (2017).
7. *AT&T Mobility LLC v. Concepcion*, 131 S.Ct. 1740, 179 L. Ed. 2d 742 (2011).
8. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (ruling on a Federal Alien Registration law that conflicted with an identical Pennsylvania law. The federal law preempts the state law).
9. *Specht v. Netscape Communications Corp.*, 306 F.3d 17 (2d Cir. 2002).
10. *Specht*, citing *Windsor Mills*, 25 Cal.App.3d at 992, 101 Cal.Rptr at 351.
11. *Specht*, citing *Commercial Factors Corp. v. Kurtzman Bros.*, 131 Cal. App.2d 133, 134-35, 280 P.2d 146, 147-48 (1955) (internal quotation marks omitted).
12. *Id.*
13. *Atalese v. Legal Services Group.*
14. *See, e.g., Marmet Health Care Ctr.*, 132 S. Ct. 1201 (2012); *see also Doctor's Assocs., Inc. v. Casarotto*, 517 U.S. 681, 683 (1996) (the U.S. Supreme Court invalidating a Montana law that required conspicuous front page notification of arbitration clauses).
15. *See Otis Elevator Co. v. Stafford*, 95 N.J.L. 79, 82, 111 A. 695 (Sup. Ct. 1920) (where the court required clear evidence that the party was aware that the right to file a mechanics lien was being waived."); *Christ Hosp. v. Dep't of Health & Senior Servs.*, 330 N.J.Super. 55, 63-64, 748 A.2d 1156 (App. Div. 2000) (requiring "clear and unmistakable waiver" of statutory right to hearing following refusal to renew license); and *Red Bank Reg'l Educ. Ass'n v. Red Bank Reg'l High Sch. Bd. of Educ.*, 78 N.J. 122, 140, 393 A.2d 267 (1978) (holding that any waiver of a statutory right to file grievances "must be clearly and unmistakably established").
16. *Benjamin v. Jewish Home Lifecare*, 2015 N.Y. Slip Op. 30742(U) (N.Y. Sup. Ct., 2015).
17. *Friedman v. The Jewish Home for the Aged*, 2015 N.Y. Slip Op. 06478 (131 A.D.3d 421).
18. *Bair v. Manor Care of Elizabethtown, PA*, 108 A.3d 94—Pa: Superior Court (2015).
19. *Extendicare Homes, Inc. v. Whisman*, 478 S.W.3d 306 (Ky. 2015).
20. *Kindred Nursing Centers L.P. v. Clark*, 581 U.S. ___ (2017).
21. *Supra,* at 2.
22. 834 F.3d (2d Cir).
23. *Specht v. Netscape Communications Corp.*, 306 F.3d 17 (Fed. 2d Cir. 2002).
24. *Guadagno v. E*TRADE Bank*, 592 F. Supp. 2d 1263, 1271 (C.D. Cal. 2008).
25. *Noble v. Samsung Electronics America Inc.*, No. 16-1903 (3d Cir. 2017).
26. *Binder v. Aetna Life Ins. Co.*, 75 Cal.App.4th 832, 848, 89 Cal.Rptr.2d 540, 551 (1999); *cf.* Restatement (Second) of Contracts § 19(2) (1981).
27. *In re Arbitration between Murray Siegel, Respondent, and Henry Lewis, Appellant*, 40 N.Y.2d 687 (1976).

NEWS flash

What's Happening in the Section

Recent Events

The Health Law Section held a Networking Reception on March 28, 2018 for colleagues to connect, advance their careers and enhance their practices. Attendees met other health law attorneys, as well as leaders in the Section. The event was sponsored by the Health Law Section, with special thanks to Albany Law School for being the host. Thanks to Health Law Section Membership Committee Co-Chairs Mishka Woodley, Esq., Shenker Russo Clark LLP, Albany, and Lisa D. Hayes, Esq., Brookdale Hospital Medical Center, Brooklyn, for their work on the reception.

Upcoming Events

Emerging Liability Issues for the Health Care Industry

Thursday, April 26th | 9:00 a.m. - 12:00 p.m. |
NYC & Webcast
New York State Society of CPA's | 14 Wall St., 19th Fl. |
NYC | 3.0 MCLE Credits: 3.0 Skills

NYSBA Member: $135
General Practice Section Member: $110
Co-Sponsoring Section Member: $135
Non-Member: $235

This half-day practical seminar will familiarize you with many of New York's laws regulating claims against health care facilities and will help you develop the skills necessary to prepare and review the claim, navigate discovery, and advocate through arbitration or in court.

Who Should Attend: Attorneys who represent health care facilities, especially nursing homes; attorneys representing patients of residential health care facilities; attorneys interested in the burgeoning field of health care liability.

Sponsors:

Health Law Section
Torts, Insurance and Compensation Law Section
Committee on Continuing Legal Education

Visit www.nysba.org to register.

Save the Date: October 26—Health Law Section Fall Meeting—NYSBA, Albany

Mark your calendars and save the date, the Health Law Section will hold its Fall Meeting on Friday, October 26, 2018. Join more than 100 health law attorneys from around the state for this full-day CLE on hot topics.

Recorded Programs Now Available Online

The 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 Affiliations Among Large Systems and Physician Practices: Tales from the Trenches
- Medical-Legal Implications and Sustainability of SHIN-NY Regulations in Health Care Delivery System
- Concierge Medicine/Telemedicine/Direct Primary Care
- Ethics of Health Information Technology Privacy

3. E-Health Clinical Records and 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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