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Health Law Journal

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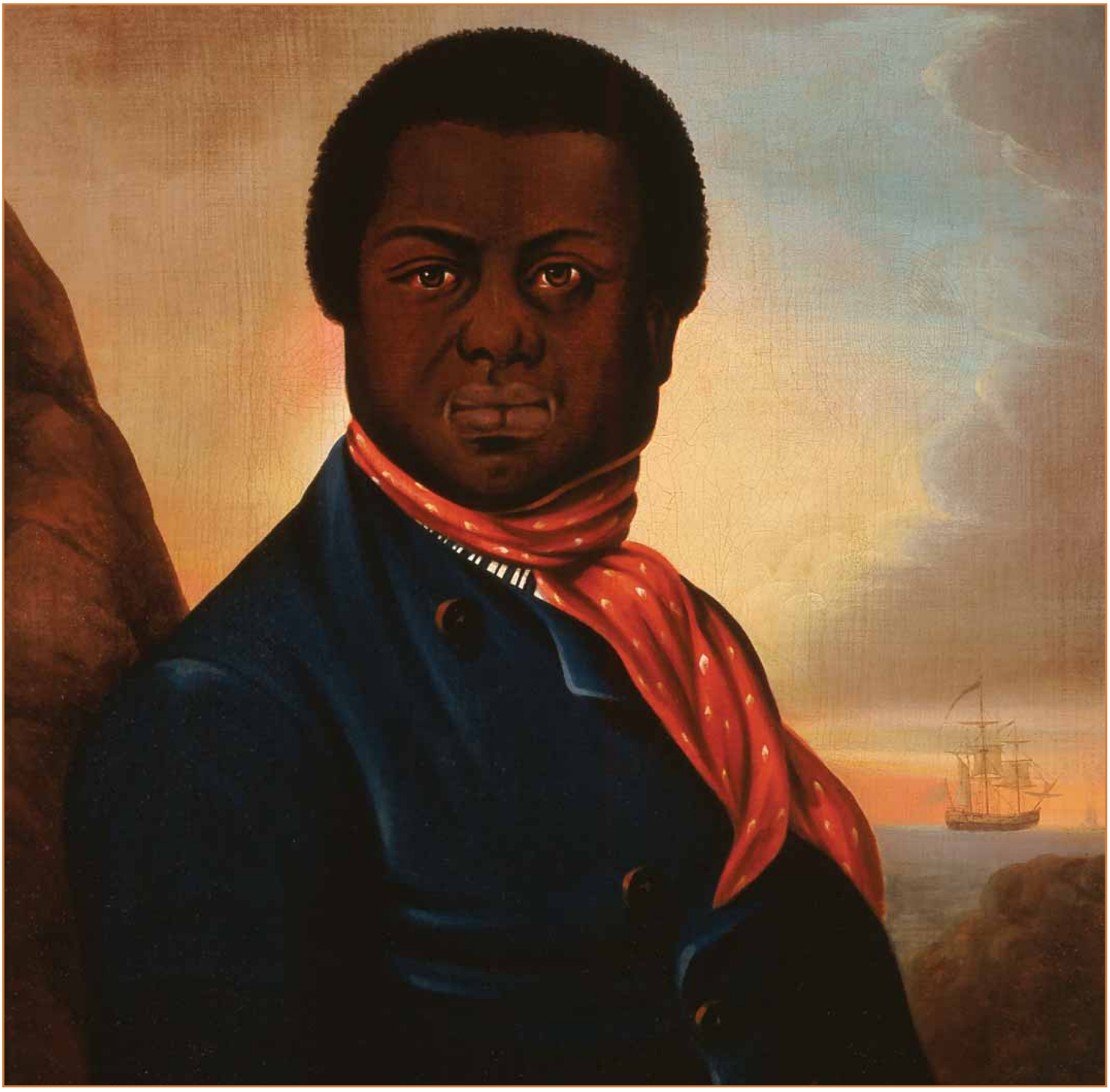


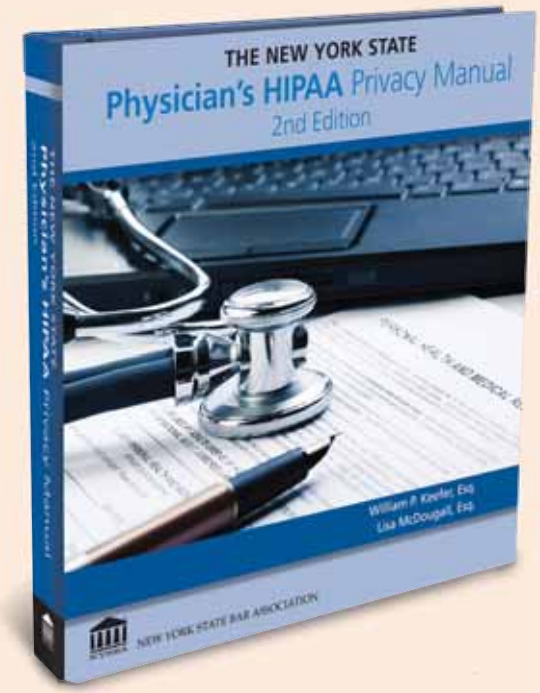
From the NYSBA Book Store

The New York State Physician's HIPAA Privacy Manual, 2d ed.

This one-of-a-kind, hands-on tool helps health care providers and their legal counsel navigate the often murky waters of the HIPAA Privacy Act. Containing 37 policies and procedures and the forms necessary to implement those policies and procedures, the *Manual* provides the day-to-day guidance necessary to allow the physician's office to respond to routine, everyday inquiries about protected health information, as well as the framework to enable the Privacy Officer and health care provider's counsel to properly respond to even non-routine issues.

The *Manual* is organized in a way that parallels the various aspects of the HIPAA Privacy Rule and covers areas that include General Policies, Uses and Disclosures of Medical Information Without Patient Authorization, and Operational Issues and Patient Rights.

The second edition incorporates changes required by the Health Information Technology for Economic and Clinical Health ("HITECH") Act and the most recent regulations. Changes of particular note include breach notification and new rules that directly require compliance from business associates.



AUTHORS

William P. Keefer, Esq., Lisa McDougall, Esq.

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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Cover artwork:
***Portrait of a Black Sailor* possibly by Paul Cuffe**

Message from the Section Chair

Since our fall publication, we have sponsored a number of successful CLE programs capped by the Section's Annual Meeting in January. We are pleased to be hosting several informative meetings and programs this Spring.

On December 16, 2015, our Ethical Issues in the Provision of Health Care Committee co-sponsored a program entitled "Aid in Dying: A Terminally Ill Patient's Right to Choose and What Practitioners Need To Know." The program addressed a patient's right to choose physician-assisted death with dignity. During the program, there was a discussion of current law, litigation and legislative proposals, the ethical implications of the right to die, an in-depth discussion of case studies and counsel's role in these situations.

On January 27, 2016, the Health Law Section's annual program, entitled "Hot and Upcoming Topics in New York Health Law," was held. The subjects addressed included many cutting edge topics, such as the current state of the DSRIP program, the Implication of the 60-Day Window for Reporting and Repayment of Overpayments, Ethics for Health Care Lawyers, and Developments in Behavioral Health. The program was both well-attended and well-received.

There were two programs held in March of 2016. The first was entitled "Brave New World: Exploring Today's Health Law Career Paths." The program was co-sponsored by the Health Law Membership and Diversity Committees and featured a distinguished group of speakers addressing how the changing world of health care delivery is transforming their practices.

The second program, "Senior Housing in New York State," took place on March 11, 2016 and explored the various senior housing options available in New York, the applicable regulatory trends, and a discussion of the current and emerging employment and financing topics related to these businesses.

As Chair of the Section, I firmly believe our Committees are the heart of the Section and vital to our continued success. Membership in a Committee allows you the opportunity to meet with colleagues and work on substantive issues in your respective fields. Many of our Committees held individual meetings on the morning of the NYSBA's Annual Meeting. For instance, our Professional Discipline Committee heard from multiple senior members of various offices in the Department of Health, who discussed issues of interest to the Committee members. The dialogue was informative and gave Committee members the opportunity to interact with their colleagues in the Department of Health and raise issues of concern to them.

The Committee descriptions and workplans for all of our Committees are listed on the Health Law Section page of the NYSBA website at www.nysba.org/health/. Please review the Committee descriptions and consider joining and participating in a Committee.

We look forward to your continued involvement with the Section.

Kenneth R. Larywon
Chair

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In the New York State Courts

By Leonard M. Rosenberg

Court of Appeals Holds That Healthcare Providers Owe Duty to Third Parties to Warn Patients That Medication May Impair Patient's Ability to Safely Operate a Motor Vehicle

Davis v. South Nassau Communities Hospital, 2015 WL 8789470 (N.Y. 2015). An accident victim ("Davis") appealed the Appellate Division's decision affirming dismissal of his action against South Nassau Communities Hospital (the "Hospital") and two individual medical providers (the "Island Medical Defendants") (collectively, "Defendants") for failing to warn their patient that medication administered to her impaired her ability to safely operate an automobile.

Nonparty Lorraine Walsh was treated at the Hospital by the Island Medical Defendants, who administered to Walsh an opioid narcotic painkiller and a benzodiazepine drug, both of which might impair her ability to safely operate an automobile. Soon thereafter, while driving herself from the Hospital, Walsh was involved in an auto accident, crossing a double yellow line and striking a bus driven by Davis.

Contending that the accident occurred while Walsh was in a state of disorientation under the influence of the drugs, Davis claimed that the Hospital and Island Medical Defendants breached their duty to warn Walsh of the effects of the medications administered. Specifically, Davis alleged that, in commiting this breach, the Hospital and Island Medical Defendants committed medical malpractice.

Defendants moved to dismiss the complaint on the basis that they did not owe Davis, a third party to Walsh's treatment, any duty of care. The Supreme Court granted the motion to dismiss, and the Appellate Division affirmed, holding that the

Hospital and Island Medical Defendants owed no duty of care to Davis, as only Walsh had a physician-patient relationship with them.

Reversing the Appellate Division's decision, the Court of Appeals held that the duty of care is most appropriately assigned to the party that can most effectively fulfill such obligation, at the lowest cost. While acknowledging its historical reluctance to expand the duty of care "from physicians past their patients to members of the community individually," the Court held that the Hospital and Island Medical Defendants, as Walsh's treating professionals, owed Davis a duty to warn Walsh that her medications impaired her ability to safely operate a vehicle.

The Court's analysis identified numerous factors weighing in favor of establishing a duty of care to the general public: (i) convenience and cost of administration; (ii) capacity of the parties to bear the loss; (iii) public policy; (iv) moral blame attached to the wrongdoer; and (v) expectations of the parties and society in general. Considering these factors, the Court held that Defendants were the only ones who could have provided warning of the disorienting effects of Walsh's medications, so as to avoid danger to all drivers in her vicinity.

The Court stated that its earlier opinions addressing the duty of care had left open the possibility of recognizing a duty in cases such as this one. In one case, the Court had held that no duty arose because the plaintiff's injury had not arisen from the physicians' actual treatment of the patient. In another case, the Court had held that no duty arose because there was no special relationship such that a nursing home and physician employed there (who had not treated the particular resident involved) had any obligation to attempt to control the nursing home resident's behavior.

Another previous decision had recognized a duty running from a pediatrician to the parents who engaged the physician to care for their infant; there, the Court held that members of a patient's immediate family or household, susceptible to harm as a result of medical care the physician renders to the patient, are owed a duty of care by the physician.

The Court stated that its decision imposed no additional obligation on physicians who administer medications, as it is already a physician's responsibility to advise patients of drug side effects. To fulfill their duties, health care providers need only issue the appropriate warnings, and are under no obligation to actually prevent patients from leaving the premises. The Court also distinguished treating health care providers from other providers, holding that the duty established by its decision did not extend to those who do not personally treat or prescribe medicine to the tortfeasor.

Justice Stein's dissenting opinion asserted that a physician's duty should be extended beyond the patient only to one who is: (i) a readily identifiable third party of a definable class; and (ii) someone the physician knew or should have known could be injured by the physician's affirmative creation of a risk of harm through treatment of the patient. Concerned that the Court's decision cultivated an unrestricted, unidentifiable class of potential plaintiffs, the dissenting opinion centered upon five rationales.

First, while the physician-patient duty arises from a private and individual relationship between the physician and patient, the physician has no relationship with the public and

cannot foresee with whom patients will come into contact. Second, no social benefit is added, as the duty will not render it any more or less likely that the patient will heed the physician's warning not to drive. Third, for fear of liability, physicians might become overly cautious in prescribing medications and issuing warnings, such that patient care is compromised. Fourth, additional lawsuits against physicians will result, which might ultimately limit the availability of competent medical care as physicians face high litigation costs and rising malpractice insurance premiums. Fifth, an injured party need not pursue recovery against a medical provider in cases such as this, because he can seek recovery directly against the patient who caused his injury.

The dissenting opinion also noted that physician-patient confidentiality might render litigating these actions difficult, as physicians cannot reveal patient information to defend themselves, nor can patients' medical records be disclosed to injured third parties seeking recovery.

District Court Allows Lawsuit to Proceed Against Hospitals Under False Claims Act, Affordable Care Act, and New York False Claims Act for Failure to Adequately Investigate, Report, and Return Medicaid Overpayments

Kane ex rel. United States v. Healthfirst, Inc., No. 11 Civ. 2325(ER), 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015). Relator is a former employee of Defendant Continuum Health Partners, Inc. ("Continuum"), a network of hospitals that includes Defendants Beth Israel Medical Center d/b/a Mount Sinai Beth Israel Medical Center ("Beth Israel") and St. Luke's-Roosevelt Hospital Center d/b/a Mount Sinai St. Luke's and Mount Sinai Roosevelt ("SLR"). Beth Israel and SLR are participating providers in the Medicaid health plan offered by Healthfirst, Inc. ("Healthfirst"), a private insurance program that contracted with the New York State Department of Health (the "DOH") to enroll Medicaid participants and provide certain "covered services" in exchange for fixed monthly payments from the DOH. All providers participating in Healthfirst's network must agree that payment received from Healthfirst for covered services constitutes full payment for such services, and are prohibited from billing enrollees and secondary payors, including Medicaid.

Beginning in or about January 2009, Healthfirst experienced a software glitch whereby its remittances to participating providers displayed codes indicating that the providers were allowed to seek additional payment for covered services. As a result, Continuum automatically generated and submitted improper bills for covered services to the DOH for Medicaid funds, many of which were mistakenly paid. The New York State Comptroller's office (the "Comptroller") first contacted Continnum regarding the incorrect billings in September 2010, and through further discussions discovered the problem with Healthfirst's software.

In an effort to "comprehensively 'identify' all claims potentially affected by the software glitch," Continuum asked Relator to determine which claims were improperly billed to Medicaid. On February 4, 2011, Relator sent an email to several members of Continuum's management that attached a spreadsheet identifying over 900 claims for covered services provided by its member hospitals that contained the erroneous billing code. Relator specified that further analysis was needed to confirm that an overpayment had been made in connection with each claim, but that the analysis offered insight into the potential scope of the overpayments. Relator's employment was terminated four days after he sent the email and spreadsheet, and Continuum did nothing further to investigate or confirm Relator's analysis.

Continuum reimbursed the DOH in February 2011 for only five improperly submitted claims. The Comptroller, on further investigation, identified further categories of improperly paid claims and informed Continuum in March 2011. It was not until June 2012, however, when the United States government (the "Government") issued a Civil Investigative Demand in connection with the overpayments, that Continuum reimbursed the DOH for more than 300 improperly submitted claims.

Relator filed this action in the United State District Court for the Southern District of New York on April 5, 2011, alleging that numerous health care providers violated, *inter alia*, the federal False Claims Act (the "FCA") and the New York False Claims Act (the "NYFCA") by failing to timely report and return payments that were received from Medicaid in response to improperly submitted claims. On June 27, 2014, the Government and the State of New York (the "State") both filed complaints in intervention against Continuum, Beth Israel, and SLR (collectively, "Defendants"), alleging violation of the FCA's "reverse false claims provision," 31 U.S.C. § 3729(a)(1)(G), and an analogous provision of the NYFCA, New York Financial Law § 189(1)(h), respectively. On September 22, 2014, Defendants moved to dismiss both intervenor complaints.

The court began its analysis by reviewing the history of the FCA and the relevant statutory language. The court noted that the FCA, which was enacted during the Civil War to redress fraud in defense contracts, has always been interpreted expansively to cover all fraudulent attempts to cause the government to pay out money. The reverse false claims provision, which was enacted in 1986 as part of a Congressional effort to strengthen the enforcement regime, broadens the scope of liability to encompass fraudulent attempts to avoid making payments owed to the government. In 2009, Congress enacted the Fraud Enforcement and Recovery Act (the "FERA"), which added language to the reverse false claims provision imposing liability on any person who "knowingly con-

ceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." The court noted that the FCA defines "knowing" and "knowingly" to include "situations in which a person 'acts in deliberate ignorance' or 'reckless disregard' for the truth or falsity of information." Furthermore, the court stated that the FERA defined "obligation" as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of an overpayment."

The court then addressed the Patient Protection and Affordable Care Act of 2010 (the "ACA"), which, among its broad health care reforms, included a provision, codified at 42 U.S.C. § 1320a–7k(d), requiring a person who receives an overpayment of Medicare or Medicaid funds to "report and return" the overpayment to the U.S. Department of Health and Human Services, the state, or another appropriate party. The court recognized that the ACA requires compliance with such provision within 60 days of the "date on which the overpayment was identified," and that an overpayment retained beyond this time frame will constitute an "obligation" under the reverse false claims provision of the FCA. The court also observed that while the ACA provides that "knowing" and "knowingly" shall have the definition provided under the FCA, it does not define the term "identified."

Defendants first contended that it did not have an "obligation" under the FCA. The Government argued that Defendants "identified" overpayments when Relator sent the email and spreadsheet to several of its managers, and thus they were put on notice that overpayments may have been issued. Defendants claimed, however, that Relator's email did not identify any overpayment with certainty so as to trigger the 60-day report and return requirement under the ACA. Instead, Defendants argued, Relator's email merely apprised them of potential overpayments for further investigation.

Finding no plain meaning of the term "identify," the court turned to canons of statutory construction. On review of the legislative history, the court found that "Congress intended for FCA liability to attach where, as here, there is an established duty to pay money to the government, even if the precise amount due has yet to be determined." The court rejected Defendants' claim that the Government's proposed standard—*i.e.*, that the 60-day report and return requirement runs from notice that an overpayment may have occurred—imposes an onerous burden on health care providers, because the FCA is only violated when an obligation is "knowingly concealed" or "knowingly and improperly avoided or decreased." The court further found Defendant's proposed standard unworkable, as it would give providers a perverse incentive to halt their internal investigations and remain willfully ignorant in order to avoid their obligation to reimburse the government. The court then held that Defendants' interpretation of the ACA would frustrate Congress' legislative purpose, particularly in light of the pattern of legislative efforts since the passage of the FCA to strengthen the government's enforcement capabilities in order to combat fraud.

The court also looked to agency interpretations of "identified" as used in the report and return provision, finding them persuasive but not binding. Specifically, in 2014, the Centers for Medicaid and Medicare Services ("CMS") issued a final rule concerning Medicare Part D that defined "identified overpayment" to include situations where a provider "should have determined through the exercise of reasonable diligence" that it "has received an overpayment." The court noted that CMS responded to comments urging that "identified" be interpreted to mean "actual knowledge" by stating that such interpretation would defeat the purpose of the ACA by making it too easy for providers to avoid returning improperly received payments to the government. Moreover, the court referenced a 2012 proposed Medicaid rule in which CMS expressed its belief that Congress included the term "knowing" in the report and return provision's definitions section because it intended to use the same standard in determining whether an overpayment has been identified. Although these agency rules were not determinative because they applied only to Medicare and/or were never enacted, the court stated that their logic was applicable in interpreting the ACA's report and return provision in the context of Medicaid.

Having decided that the Government properly pled that Defendants identified an overpayment and thus had an obligation, the court next addressed Defendants' claim that the Government failed to allege that it "knowingly concealed" or "knowingly and improperly avoided or decreased" such obligation. First, the court held that "avoid" has a plain meaning, which includes "behavior where an individual is put on notice of a potential issue, is legally obligated to address it, and does nothing." Noting that the Government ultimately must prove that Defendants actually avoided payment of an obligation, the court held that the Government adequately pled avoidance. The court also stated that under the plain language and legislative intent of the FCA, as amended by the FERA, and the ACA, the retention of an overpayment beyond 60 days must be construed as an avoidance. Second, the court found that the Government had alleged facts sufficient to demonstrate that Defendants' avoidance was "knowing" under the FCA, in that they acted recklessly or with deliberate indifference. The court relied on the allegations that Defendants terminated Relator four days after he sent his email and spreadsheet, did not task anyone else with investigating the claims that he

identified, and did not bring his analysis to the Comptroller's attention.

Lastly, the court rejected Defendants' claim that they owed an obligation, if at all, to the State, rather than the federal government. The court rested its holding on the fact that Medicaid is funded jointly by the federal and state governments and that "Congress has repeatedly and specifically provided that claims submitted to Medicaid constitute false claims for the purposes of the FCA."

The court then turned to the State's complaint in intervention. The State alleged violation of the reverse false claims provision of the NYFCA, which contains language identical to the relevant provision of the FCA and applies specifically to monetary obligations to the State. Because the State's complaint was substantively identical to the Government's complaint, the court rejected Defendants' contention that the State had failed to state a claim against them.

Defendants also argued that liability under the NYFCA's reverse false claims provision should not apply because the statute was enacted in March 2013, after the events underlying the action took place. The court first asserted that the New York Legislature expressly intended that the law be retroactively applied to any pending cause of action and any false claim or obligation made or incurred on or before April 1, 2007. The court then addressed whether retroactive liability would violate the *Ex Post Facto* Clause, which applies to criminal sanctions and "civil disabilities that 'disguise criminal penalties.'" Finding that the Legislature intended to create a civil penalty scheme, the court assessed several factors in order to determine whether the punitive effect of the statute is sufficient to negate the Legislature's intent. On review of such factors, the court found that Defendants had not met their burden to demonstrate, by the "clearest proof," that the NYFCA's civil penalties were disguised criminal sanctions. Accordingly, the court held that the State could seek to impose retroactive liability on Defendants.

Second Circuit Denies Qualified Immunity to Medicaid Fraud Prosecutor for Misleading Grand Jury

Morse v. Fusto, 804 F.3d 538 (2d Cir. 2015). Defendants John Fusto, a former prosecutor in the Attorney General's Medicaid Fraud Control Unit, and Jose Castillo, a former audit-investigator in the Unit, suspected that Dr. Morse, a Brooklyn dentist, was perpetrating Medicaid fraud by submitting false claims to Medicaid. During their investigation, the Defendants conducted an audit of Dr. Morse's billings and created spreadsheet summary charts of the billings to highlight select information that they considered suspicious. The charts were presented to the grand jury, which "based in part on that evidence" returned an indictment against Dr. Morse on charges of grand larceny and offering a false instrument for filing in the first degree. Although Dr. Morse was later acquitted of all charges, he lost his dental practice and incurred other damages as a result of the prosecution.

After his acquittal, Dr. Morse commenced a civil lawsuit in the United States District Court for the Eastern District of New York, alleging that that Defendants deprived him of his constitutional right to a fair trial by intentionally manipulating the information contained on the spreadsheets to create the false impression that Dr. Morse billed Medicaid for dental services that he did not provide. Specifically, Dr. Morse alleged that the Defendants manipulated the data by (i) indicating that Morse billed for nine separate procedures on the same patient on the same day, when records showed he had only billed for three; (ii) failing to distinguish between treatments received by three different patients, each named "Edwin Gonzalez," to make it appear that he had performed all three procedures on the same patient; and (iii) omitting information in the "tooth number" field of the chart to create the impression that Dr. Morse billed Medicaid repeatedly for the same procedure when Dr. Morse was in fact billing "per tooth" for a procedure performed on different teeth of the same patient. Finding that the Defendants knowingly created "false or fraudulently altered documents," the jury returned a verdict in Dr. Morse's favor, awarding him $6.7 million in compensatory damages and $1 million in punitive damages.

The Defendants thereafter moved for judgment as a matter of law or, in the alternative, a new trial on the basis that: (i) the contents of the spreadsheet were "facially true" and therefore could not have been reasonably found to be either "false or fraudulent;" and (ii) the Defendants are entitled to either qualified or absolute immunity. The district court denied the Defendants' motion, concluding that although one of the factual bases underpinning Dr. Morse's claim was not sufficiently supported by the evidence to have been properly considered by the jury, the evidence was "sufficient to support the jury's verdict that the Edwin Gonzalez page and the omission of tooth numbers… constituted false or fraudulently altered evidence." Rejecting Defendants' argument that they were entitled to qualified immunity, the district court held that qualified immunity is unavailable on a claim premised on proof that a Defendant knowingly fabricated evidence which denied the individual the right to a fair trial. Similarly, the court held that although a prosecutor's preparations for the initiation of judicial proceedings or for trial are protected by absolute immunity, a prosecutor's investigatory functions that do not relate to an advocate's preparation for the initiation of a prosecution are not. Because the jury was entitled to simply disbelieve Defendants' testimony regarding when they created the fraudulent documents, the court denied Defendants absolute immunity. Finally, the district court denied Defendants' motion for a new trial with respect to liability but granted a new

trial with respect to damages unless Dr. Morse elected to accept a remitted award of $4.6 million compensatory and $100,000 punitive damages. Dr. Morse accepted the remitted award.

On appeal, the Defendants contended that the district court erred in (i) failing to accord them qualified immunity as a matter of law; and (ii) failing to order a new trial pursuant to the "general verdict rule" because the court decided as a matter of law that one of the factual bases offered in support of Dr. Morse's claims lacked sufficient evidentiary support.

The Second Circuit affirmed the district court's decision on appeal. Discussing qualified immunity at length, the Court held that "qualified immunity protects public officials performing discretionary functions from personal liability in a civil suit for damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known." Rejecting the Defendants' argument that they had no constitutional duty to include all material information in the spreadsheet summaries, the Second Circuit held that notwithstanding the legally permissible one-sided nature of grand jury proceedings, every individual has the "distinct right not to be deprived of liberty as a result of the fabrication of evidence by a government officer acting in an investigative capacity." Finding that the Defendants violated this right by knowingly omitting material information in the billing summaries, the Court upheld the district court's denial of qualified immunity. The Court also rejected the Defendants' attempt to distinguish between misleading statements or omissions and affirmative falsehoods, concluding that "both threaten the integrity of the judicial process by injecting it with falsity." As for the Defendants' claim that the court's decision would "paralyze" prosecutorial investigations and preparations for the grand jury, the court responded that it "ought not to be difficult, even for the most single-minded of prosecutors, to avoid misconduct of the scope and seriousness of that in which the Defendants engaged." As to whether the falsifications violated clearly established law that sufficiently warned the Defendants that their conduct was unconstitutional, the Court held that it was not "objectively legally reasonable" for the Defendants to believe it was permissible for them to knowingly make material omissions in the creation of the billing summaries.

Finally, the Court rejected Defendants' argument that the district court erred when it failed to order a new trial after concluding, post-trial, that one of the factual bases offered in support of Dr. Morse's claims lacked evidentiary support. Defendants based this argument on the "general verdict rule," which requires a new trial where there is no way to know whether an invalid claim was the sole basis for the verdict. In rejecting this argument, the Court held that by failing to request a special verdict form, interrogatories to supplement a general verdict, or otherwise object to the verdict form during the district court proceedings, the Defendants waived any objections based on the general-verdict rule.

New York State Supreme Court Holds Constitutional State's Criminal Ban Against Provision of "Aid-In-Dying" to Mentally Competent, Terminally Ill Patients

Myers et al, v. Schneiderman, Index No. 151162/15 (New York County, Oct. 16, 2015). Plaintiffs, three terminally ill patients, five medical professionals, and an advocacy group, brought three causes of action seeking declaratory and injunctive relief regarding Section 125.13(3) of the New York Penal Law, which states: "A person is guilty of manslaughter in the second degree when… He intentionally…aids another person to commit suicide." New York State moved to dismiss Plaintiffs' complaint.

Plaintiffs sought to de-criminalize the provision of "aid-in-dying" to mentally competent, terminally ill patients who request such assistance. In particular, the patients wished to legally obtain prescriptions they would use "to achieve a peaceful death," stating that they desired to determine their own fates when their diseases became unbearable. Likewise, the physicians sought to aid their patients in exercising their would-be right to die without risking prosecution for second degree manslaughter. The physicians asserted that providing this assistance is both medically and ethically acceptable, and stated that they have each treated terminally ill patients who sought the physicians' aid in ending their lives.

Plaintiffs pled the following causes of action: (i) a declaration that the penal law does not provide a valid statutory basis to prosecute them for providing aid-in-dying (as well as an injunction prohibiting prosecution thereof); (ii) lack of equal protection; and (iii) denial of the right to due process.

The Court dismissed the action in its entirety, first addressing whether a justiciable question was before the Court, and subsequently evaluating Plaintiffs' individual claims.

The Court noted that, for a controversy to be justiciable, the Plaintiff seeking declaratory judgment must possess an interest sufficient to constitute standing to maintain the action. The Court held that all parties to the matter had "more than just a passing interest in the outcome of this case," and that Plaintiffs had raised recurring issues of public importance. The Court also held that to contest the constitutionality of a criminal statute, a Plaintiff need not expose himself to actual prosecution. Rather, a credible threat of prosecution is sufficient where a Plaintiff has alleged the intention to engage in arguably protected activity that is proscribed by statute.

Next, the Court cited Supreme Court precedent as to Plaintiffs' equal protection and due process claims and the separation of powers doctrine

as to Plaintiffs' claim for declaratory and injunctive relief.

Regarding the latter, the Court held that the judiciary may not encroach upon the legislature's domain where a statute is clear, unambiguous and unequivocal in meaning. Stating that the role of the courts is to protect rights rather than to make policy, the Court held that the state's action as to complex societal issues is left solely to the discretion of the political branches of government. Similarly, the Court held that it would exceed its authority by interfering with district attorneys' executive power to orchestrate all phases of criminal prosecution. In so holding, the Court stated that its jurisdiction provides neither for its prohibition of, nor its compulsion of, prosecution for any alleged violation of law. As such, the Court declined to issue a declaration or injunction concerning the penal law.

As to Plaintiffs' civil rights claims, the Court cited the United States Supreme Court's holding in *Vacco, et al. v. Quill et al.*, 117 U.S. 2293 (1997), which involved an identical action. In *Vacco*, the Court held that New York's prohibition of assisted suicide does not violate the civil rights of terminally ill, mentally competent patients, despite these patients' confirmed right to refuse lifesaving medical treatment. Specifically, the *Vacco* Court held that, because statutes banning assisted suicide neither entail suspect classifications, nor infringe upon fundamental rights, such statutes are entitled to a strong presumption of constitutionality, subject only to rational basis scrutiny.

In *Vacco*, the Court enumerated New York's bases for criminalizing assisted suicide despite patients' right to refuse lifesaving treatment, including: prohibiting intentional killing; preserving life; maintaining physicians' role as healers; shielding vulnerable patients from psychological and financial pressure to end their lives; and avoiding a possible slide toward euthanasia. *Vacco* held that the aforementioned reasons, among others, "are valid and important interests that easily satisfy the constitutional requirement that a legislative classification bear a rational relation to some legitimate end." Accordingly, the Court deferred to *Vacco's* holding that the distinction between "letting" a patient die and "making" a patient die is constitutional.

Federal Court Holds That a HIPAA Authorization Is Not Limited to Release of Medical Records; It Also Permits Oral Communication of a Patient's Medical Information

Soto, et al. v. The City of New York, et al., 2015 WL 6503819 (S.D.N.Y. October 28, 2015). Plaintiffs brought suit against the City of New York, alleging that its officers used excessive force against them in violation of 42 U.S.C. § 1983. Plaintiffs' claims in this case relate in part to the injuries they received as a result of Defendants' conduct. Approximately ninety medical providers treated the Plaintiffs. In an attempt to conduct oral interviews with Plaintiffs' medical providers to determine their involvement and whether they may be called as trial witnesses, Defendants sought an order compelling Plaintiffs to provide HIPAA compliant releases authorizing such interviews, as deposing ninety medical professionals would be burdensome and wasteful.

Plaintiffs argued that any oral discussions between their medical providers and Defendants' attorney are an attempt to obtain "ex parte" interviews with the medical providers. They also asserted that Defendants' request should be denied because Defendants' have not sufficiently shown a "need" to conduct such interviews.

The Court first noted that by bringing the suit, Plaintiffs waived any privilege or right of privacy in the records of their medical treatment. The Court rejected Plaintiffs' argument that Defendants must show a "need" for the requested information, as the same information can be sought through deposing Plaintiffs' medical providers. The Court also noted that New York law permits an attorney to interview an adverse party's treating physician privately if the party has placed his or her medical condition in controversy and the procedural requirements of HIPAA are met.

The Court also noted that it is well-settled that it has the authority to order Plaintiffs to sign a release for the written medical information at issue. Accordingly, it held that it was not any less inappropriate to require authorization that permits the transmission of such information orally rather than in writing.

The Court held that HIPAA authorizes the oral transmission of medical information to Defendants' counsel, as Plaintiffs placed their medical information at issue by commencing this lawsuit, and HIPAA and its governing regulations impose no substantive restrictions on the type of health information a provider may release, nor the manner in which the information is communicated or transmitted. Accordingly, the Court granted Defendants' motion and directed Plaintiffs to execute authorizations that permit the oral transmission of the medical information to Defendants' counsel.

Second Department Holds That a Free-Standing Surgery Center Cannot Be Held Vicariously Liable for the Negligence of a Private Attending Physician

Doria v. Benisch, 130 A.D.3d 777, 14 N.Y.S.3d 95 (2d Dep't 2015). Defendant, Melville Surgery Center, LLC ("MSC"), a free-standing surgery center, appealed the denial of its summary judgment motion in a medical malpractice action. The injured Plaintiff commenced this action against the treating physician and other physicians, various professional corporations, and MSC. Because the treating physician was a private attending physician, MSC moved for summary judgment. The trial court denied the motion. The Appellate Division reversed.

The Court first explained that generally a hospital may not be held vicariously liable for the negligence of a private attending physician chosen by the patient. Furthermore, so long as the resident physicians and nurses employed by the hospital carried out the private attending physician's orders, the hospital may not be held vicariously liable for resulting injuries. The Court noted three exceptions to the general rule: (1) when the private physician's orders greatly deviate from normal medical practice such that the employees should have intervened; (2) when the hospital's employees have committed independent acts of negligence; and (3) under the theory of ostensible or apparent agency.

The Appellate Division reversed and held that MSC was entitled to summary judgment because it did not fall into any of the exceptions previously noted. MSC established that the treating physician was not an employee of MSC, Plaintiff selected the physician as his surgeon without awareness of any connection to MSC, none of the treating physician's orders were so egregious that MSC's employees had a duty to inquire as to their correctness, and none of its employees committed any independent act of negligence.

The Court did not address the fact that MSC is an ambulatory surgery center ("ASC"), not a hospital; it simply applied case law developed in the hospital setting to an ASC.

Third Department Upholds License Revocation of Psychiatrist Who Engaged in Sexual Misconduct With Patient

Smith v. State Bd. for Prof'l Med. Conduct, 126 A.D.3d 1144, 4 N.Y.S.3d 757 (3d Dep't 2015). Petitioner, a board-certified psychiatrist, brought an Article 78 proceeding to review a determination of Respondent Administrative Review Board for Professional Medical Conduct ("ARB"). Respondents revoked Petitioner's license to practice medicine in New York based upon disciplinary actions taken against him in Texas. Petitioner resides in Texas but is also licensed in New York. Specifically, the Texas Medical Board found in 2009 that Petitioner had engaged in a sexual relationship with a patient and in 2011 had failed to keep adequate medical records.

Petitioner did not dispute that his conduct that led to the 2011 order, inadequate medical records, was professional misconduct under New York law, but argued that the conduct that gave rise to the 2009 order did not constitute professional misconduct because it involved a former patient. After a hearing at which Petitioner chose not to personally appear, the Hearing Committee found Petitioner guilty of misconduct based upon both orders. Noting that Petitioner had been disciplined twice and failed to express remorse for his actions, the Hearing Committee determined that revocation of Petitioner's license was the appropriate penalty. The ARB affirmed.

The Appellate Division found the ARB determination was not arbitrary and capricious. Petitioner's main argument was that the 2009 order did not constitute misconduct because Education Law § 6530(44) prohibits "any physical contact of a sexual nature between licensee and patient," but does not expressly preclude a sexual relationship with a former patient. The Court found this argument to be "dubious," but did not decide it, as there was evidence supporting the conclusion that the relationship had been with a current patient, not a former patient. Specifically, the Texas Medical Board had found that Petitioner saw the patient for medication management, and on the day their sexual relationship began, the patient visited his office to obtain a prescription. After the encounter, Petitioner warned the patient to remain silent about it because he was a psychiatrist.

Finally, the Court upheld the penalty of revocation. The Court noted that "the refusal to accept responsibility for prior wrongful conduct is a significant factor in assessing an appropriate penalty," and the ARB appropriately considered that issue in deciding to revoke Petitioner's license. The Court rejected Petitioner's argument that he was being penalized for disputing the allegations against him. The Court also noted that license revocation is appropriate where a physician engages in sexual misconduct, and the penalty did not "shock one's sense of fairness."

Federal Court Permits Class Action Against Medical Record Retrieval Company for Violation of Public Health Law § 18's Per-Page Copying Cost Limits

Ruzhinskaya v. HealthPort, 14-CV-2921 (PAE) (S.D.N.Y., Nov. 9, 2015). Plaintiff Tatyana Ruzhinskaya filed a motion for class action certification in the United State District Court for the Southern District of New York, alleging that defendant HealthPort Technologies, LLC ("HealthPort")—a company that retrieves, copies, and distributes medical records on behalf of providers in response to patient requests—systematically overcharged her and others similarly situated for copies of records. Plaintiff's underlying complaint alleged a claim under New York Public Health Law ("PHL") § 18, amongst other claims, including injunctive relief and unjust enrichment. The PHL limits the amount a provider may charge for copying a medical record to that provider's "costs incurred," up to a cap of 75 cents per page. HealthPort acts as the agent of over 500 New York health care providers, with whom it contracts to receive and process requests for medical records.

The Court partially denied and partially granted the motion for class certification, allowing Plaintiff and others who sought records of their treatment at Beth Israel Medical Center to proceed, while declining to broaden the class of plaintiffs to include all New Yorkers who sought copies of medical records from

HealthPort, regardless of the source of the underlying medical records.

The Court began its analysis by parsing PHL § 18's language, legislative history, and the case law that had previously interpreted the statute, holding that a "reasonable charge" for copies of records as defined by the statute is the lower of: (a) 75 cents; or (b) the provider's "costs incurred," with HealthPort conceding that it stands in the shoes of the providers with whom it contracts. The Court agreed with Plaintiff that the "costs incurred" by a provider include "direct costs," such as the cost of paper, ink, toner, and the portion of the salary of the person making the copies attributable to an individual request. The Court held, however, that "costs incurred" also include all "indirect costs"—the result urged by HealthPort—including other labor costs, overhead expenses like electricity, rent, and insurance, and the costs associated with analyzing requests for records and retrieving the records from hard-copy and electronic sources.

To certify a class under FRCP 23, Plaintiff was required to establish several elements, including that: 1) the individual class members are too numerous to be joined individually; 2) there are issues of law and fact common to all class members; 3) Plaintiff's claims are typical of those of other class members; 4) that Plaintiff adequately represents the class insofar as she has no claims antithetical to other class members' claims and her legal counsel is qualified to represent the class; and 5) that the proposed class is ascertainable such that individual class members are easily identifiable. In addition, a Plaintiff seeking class action certification must demonstrate that the questions of law and fact common to all class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly adjudicating the controversy.

Applying its holding on the meaning of "costs incurred" to the test for whether class certification is appropriate under FRCP 23, the Court reasoned that the Plaintiff had certainly satisfied the "numerosity" prong of the test by showing that the members of the class were too numerous to be joined individually. HealthPort, the Court found, had processed over 500,000 requests for medical records from New York-based providers between March 2011 and December 2014. Over 17,000 of those were requests from New York customers, with regard to whom HealthPort would be bound by PHL § 18's provisions. Further, the Court held that the "commonality" prong had also been satisfied because the Court's construction of PHL § 18 would be common to all putative class members. The Court also found common questions of fact, such as whether HealthPort had routinely billed 75 cents per page to fill requests for records, which it appeared to have done in the overwhelming majority of cases.

Likewise, the Court held that Plaintiff had met her burden to demonstrate that her claims were "typical of the claims of the class." To establish typicality, a class action Plaintiff must show that her claims and each class member's claims arise from the same course of events, and that she and each class member must make similar legal arguments to prove the defendant's liability. Although HealthPort argued that certain of Plaintiff's factual allegations made her claims atypical from those of other class members, the Court was not persuaded and held that Plaintiff had satisfied this requirement. The Court also held that Plaintiff satisfied the "adequacy" prong of the test, insofar as HealthPort could identify no interests of Plaintiff that were antagonistic to the interests of other class members, and Plaintiff was represented by counsel who were qualified, experienced, and capable of conducting the litigation. Thus, reasoned the Court, Plaintiff was an adequate class representative. Finally, the Court held that the class itself was reasonably ascertainable, insofar as it would be administratively feasible for the Court to determine whether a particular individual was, in fact, a member of the class.

The Court, however, was not persuaded by either party's argument regarding whether the common questions of fact or law predominated over questions affecting only individual members. Plaintiff argued that common questions predominated sufficient to define a statewide class because HealthPort charged a uniform per-page fee and because the "costs incurred" by HealthPort were calculable on a statewide basis that could be averaged across all record requests within the state. HealthPort countered that the cost incurred for fulfilling each putative class member's request for records must be calculated individually.

The Court noted that HealthPort stands in the shoes of the 507 providers who delegated responsibility to it for responding to patient requests, and that its contracts with these providers differed in ways that would vary the steps that HealthPort would need to take to gather and produce records from each. Because HealthPort's costs vary from provider to provider, the Court reasoned, a trier of fact would potentially be obligated to make different liability findings on a provider-by-provider basis, rendering Plaintiff's proposed class too broad for certification. For some providers, for example, HealthPort's costs were well below 75 cents per page, and for others, significantly more, according to the expert reports presented to the Court. Accordingly, "provider-level inquiries would invariably predominate, and overwhelm common inquiries, in establishing both liability and damages at trial." In partially granting Plaintiff's motion, however, the Court held that "a class drawn at the level of requests to Beth Israel, [Plaintiff's] provider, would satisfy the predominance requirement, because HealthPort has

failed to show that it can establish a per-page cost for each separate request made to that institution or for any narrower group of requests than at the provider level."

Finally, the Court noted that the class action form in this instance was superior to other methods of resolution since the out-of-pocket costs of any individual class member would likely "[dwarf] even the highest realistically imaginable recovery for that individual," even without considering legal fees. The Court, accordingly, certified a class as follows: "All persons who, at any time from March 2011 to the present (the 'Class Period'), paid for, or are obligated to pay for, copies of an individual's patient information from Beth Israel Medical Center by a 'qualified person' as defined in New York PHL § 18(1)(g), for which copies HealthPort Technologies, LLC charged 75 cents per page (the 'Class')."

Federal Court Rules False Claims Act Allegations Sufficient to Survive Hospital's Dismissal Motion

United States and State of New York ex rel. Xiomary Ortiz and Joseph Gaston v. Mount Sinai Hospital et al., 2015 WL 7076092 (S.D.N.Y., November 9, 2015). Ortiz and Gaston ("Plaintiffs") filed an Amended Complaint (the "Complaint") under the qui tam provisions of the False Claims Act, 31 U.S.C. §§ 3729 et seq. ("FCA"), New York State False Claims Act, and N.Y. State Finance Law §§ 187 et seq. ("NYFCA") against Defendants Mount Sinai Hospital and two of its affiliates, Mount Sinai School of Medicine and Mount Sinai Radiology Associates (collectively "Mount Sinai"). The United States Government and State of New York declined to intervene after investigating Plaintiffs' allegations.

Plaintiffs, employees of Mount Sinai Radiology Associates and Mount Sinai Hospital, allege that Defendants committed improper billing and wrongful payment retention misconduct against the federal Medicare Program and New York State Medicaid Program. Specifically, that the Hospital violated the FCA and NYFCA by: (a) billing in the name of a physician who did not provide the service and/or was not the referring physician (doctor swapping); (b) overstating diagnoses and procedure codes (upcoding); (c) billing for services not performed (phantom billing); (d) billing twice or more for the same service (multiple billing); (e) committing more than one of the foregoing acts simultaneously (combination misbilling); and (f) retaining overpayments that were received through improper billing activities and practices (wrongful retention). The Complaint provided specific examples of each of the categories of alleged fraud.

The Hospital moved to dismiss the Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), arguing: (1) Plaintiffs are not entitled to rely on the patient records because they are confidential and were improperly obtained; (2) additional medical treatment records, which Mount Sinai attached to its motion to dismiss, directly contradict Plaintiffs' allegations; (3) Plaintiffs did not plead fraud with specificity, failed to allege specific facts demonstrating scienter, and improperly allege wrongful retention based on "information and belief"; (4) Plaintiffs failed to state a claim for Medicaid fraud; and (5) Plaintiffs employed aggregate pleading, failing to identify which specific Mount Sinai entities were responsible.

The Court denied the motion. First, the Court found that it was premature to conclude that Plaintiffs improperly obtained Mount Sinai's medical records, as such a conclusion should be made only after a hearing. Moreover, the Court would still review the documents as part of the Complaint given the strong public policy in favor of protecting the government against fraud. Second, the Court held that Mount Sinai could not introduce new documents in its motion, and limited its review of the sufficiency of Plaintiffs' allegations to the face of the Complaint. Third, turning to the specific examples of fraud set forth in Plaintiffs' Complaint, the Court held that fraud was adequately pled for the three bases of liability under the FCA, mainly, submitting false claims, using false records in support of those false claims, and avoiding the obligation to refund overpayments to the Government. Fourth, the Court held that Plaintiffs adequately pled Medicaid fraud by pointing to specific example of false or fraudulent Medicaid billing. Finally, the Court held that all three Plaintiffs were properly named, as Plaintiffs pled specific allegations of wrongdoing against each of all three Mount Sinai entities.

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.

In the New York State Legislature

By James W. Lytle

At deadline, the 2016 New York State legislative session is just underway, still weeks away from the April 1st budget deadline that preoccupies the Legislature during the early months of the year. A few major health-related issues have, however, already emerged that might be the focus of 2016 legislative consideration. Here's a sampling;

Health Republic and Insurance Reform. After the collapse of Health Republic, an ACA-authorized co-op operating on the New York State of Health ("NYSOH") exchange, legislators and regulators have begun to discuss reforms that might prevent a similar collapse—or at least ameliorate its effects. The fall of Health Republic left many healthcare providers with substantial unpaid claims—estimated in excess of $200 million in the aggregate—and created uncertainty for its beneficiaries, including those whose providers might not have been otherwise available through other plans on the exchange.

Although every other state has health insurance guaranty funds to protect against this sort of collapse, New York does not have any fund that can pay providers and consumers if a health insurance company suffers financial collapse. Legislation was introduced early in this session (A9311 (Gottfried)/S6667 (Valesky)) to create a health insurance guaranty fund, which would be funded and dispersed under the direction of the Superintendent of Department of Financial Services ("DFS"). The fund would only become active if DFS instituted a proceeding to rehabilitate or liquidate a health insurer, pursuant to article 74 of the Insurance Law. Article 74 would be amended to allow rehabilitation to occur in the event that an insurer is unable to make prompt payments of claims, as required by section 3224-a of the Insurance Law. The guaranty fund

could then be used to advance the insurer funds in order to assist in the rehabilitation process or, in the event DFS sought to liquidate an insurer, the funds could be used to reimburse any unpaid claims left after disbursement of any remaining assets.

Whether a proposal to create a health insurance guaranty fund might be enacted over the strong opposition of the insurance industry remains to be seen. The guaranty fund proposal has received a tepid reaction from the Insurance Committee Chairs, Senator James Seward and Assemblyman Kevin Cahill, but it remains to be seen if their concerns over that proposal might be overcome during the course of the legislative session and if other proposals might emerge to address the Health Republic failure.

From the health plans perspective, the Health Republic situation demonstrated the failure of the current premium regulation process. The insurers have urged repeal of the prior approval process, which, they contend, resulted in the politically driven approval of lower rates than were warranted and helped result in the failure of Health Republic. While repeal of prior rate approval may be unlikely, the Legislature may consider other reforms to the insurance law, including proposals that may make the prior approval process more transparent and potentially subject to appeal.

Responding to Health Republic subscribers' concerns, some of whom found themselves potentially unable to continue to receive care from their Health Republic participating providers who may not have contracted with other health plans on the NYSOH Exchange, the Legislature may also consider proposals that strengthen and extend requirements pertaining to the enrollees' right to continue care with their existing providers under such circumstances, as well as heightened requirements for network adequacy to ensure that all health plans have sufficiently robust networks to meet enrollees' needs.

Minimum Wage and its Impact on Health and Human Services Delivery. After being unable to secure legislative support for a minimum wage increase last year, the Cuomo Administration convened a Wage Board in the summer of 2015 to examine wages in the fast food industry, which resulted in minimum wage increases for fast food workers that will reach $15 an hour by December 31, 2018 in New York City and by December 31, 2021 for the rest of the State. Additionally, Governor Cuomo committed to raising state employees' pay to at least $15 an hour by 2018 in New York City and by 2021 in the rest of the State, and ordered the State University of New York to do likewise. He then introduced legislation this year to enact an across the board $15 minimum wage to be phased in on the same timetable.

It is expected that increasing the State minimum wage by statute, as was last done in 2013, will be a contentious issue during the 2016 legislative session—and the issues were already rehearsed by both sides during a lengthy hearing before the Senate Committee on Labor at the outset of the 2016 session. While the impact of the wage on the economy has been hotly debated, public support for an increase may be sufficient to bring the reluctant Senate Republican Majority to the table to negotiate its terms. Of perhaps greatest relevance to the health and human services field—especially in the areas for which state and/or Medicaid funding is the

exclusive source of funding for safety net services—is whether the State will fully pay for the increased wages for the lowest paid workers in that sector.

In his 2016-17 Budget and the thirty day amendments to the Budget, the Governor did not provide any funding for the potential costs of the minimum wage for health and human services employees, where low wages still predominate in the home health, nursing home, developmental disability, child care and behavioral health service systems. The Cuomo Administration has publicly defended that position by pointing out that nothing has been enacted yet and, if it is enacted, the relatively gradual phase-in of the minimum wage can be accommodated, at least in the short run. Estimates from the affected health and human fields run into the billions of dollars, at least when the full impact of the minimum wage increase is felt—which may not even recognize the full impact on more experienced or supervisory personnel, whose compensation arguably will be "compressed" by the increased minimum wage.

Assuming the minimum wage increase is enacted, whether and how the State will help pay for it remains to be seen. Past experience does not inspire much confidence: beginning in March, 2012, as a result of the recommendations of the Medicaid Redesign Team, a so-called "wage parity" requirement for home care workers was enacted in the downstate region, which was intended to increase these employees' compensation to be comparable to wages received by unionized workers pursuant to collectively bargained agreements. While adjustments were made to both fee-for-service reimbursements to providers and to managed care premiums to plans, who were responsible for paying for these services, the amount of payment increases fell substantially short of the actual cost of the wage parity mandate.

End of life issues. While hospice and palliative care advocates continue to explore how New York might expand upon recent initiatives to incorporate palliative care more seamlessly into the healthcare delivery system, renewed debate in 2016 has already begun relating to the issue of "end of life options" or "aid in dying"—also sometimes known as assisted suicide. Legislation was introduced last year (Senate Bill No. 5814-A (Bonacic)/Assembly Bill No. 5261-C (Paulin)), which would allow terminally ill, mentally competent adult patients to end their own lives by giving themselves lethal medication that would be prescribed for them by a physician. A similar proposal, also introduced last year, would create an "End of Life Options" Act (Senate Bill No. 3685 (Savino)/ Assembly Bill No. 2129-A (Rosenthal)) that would generally authorize the same practice. These proposals may be given more prominent consideration as litigation by three mentally competent, terminally ill patients (*Myers v. Schneiderman)* begins to wend its way through the state court system.

Organ donation and transplantation: New York continues to lag behind the rest of the country in access to organ transplantation, compounded by an organ donor registry that is among the worst performing in the country. In recent years, the Legislature has authorized the Department of Health to contract out for the operation of the registry and has enacted Lauren's Law, which is intended to require that driver's license applicants at least consider whether to enroll as potential organ donors.

The contract for the operation of the registry by a not-for-profit mission-driven organization is almost finalized and 2015 changes to Lauren's Law to strengthen its requirements have already begun to bear fruit, as substantially more New Yorkers have joined the organ donor registry toward the end of 2015 and early 2016. Meanwhile, it is expected that the Legislature may consider proposals to lower the age for registry participation (New York is one of only a few states that require a registrant to be eighteen years of age), to utilize other state "portals" to sign up potential organ donors and to make long-debated changes to New York statutes to bring them more into alignment with the Uniform Anatomical Gift Act.

Jim Lytle is a partner in the Albany office of Manatt, Phelps & Phillips, LLP.

Editor's Note: During the production of this edition, the NYS Legislature passed the 2016-17 Budget. In the next edition, Mr. Lytle will describe key legislation in the Budget and thereafter.

In the New York State Agencies

By Francis J. Serbaroli

Chronic Renal Dialysis Services (CRDS)

Notice of Adoption. The Department of Health amended Part 757 of Title 10 NYCRR to update the CRDS provisions concerning Medicare and Medicaid Programs for coverage for End Stage Renal Disease Facilities. Filing date: November 3, 2015. Effective date: November 18, 2015. *See* N.Y. Register November 18, 2015.

Early Intervention Program

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 69-4 of Title 10 NYCRR to conform existing program regulations to Federal regulations and State statute. *See* N.Y. Register November 18, 2015.

Sexually Transmitted Diseases (STDs)

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 23 of Title 10 NYCRR to control of Sexually Transmitted Diseases (STDs); Expedited Partner Therapy for Chlamydia Trachomatis Infection. *See* N.Y. Register November 25, 2015.

Protection Against Legionella

Notice of Emergency Rulemaking. The Department of Health added Part 4 to Title 10 NYCRR to protect the public from the immediate threat posed by Legionella. Filing date: November 13, 2015. Effective date: November 13, 2015. *See* N.Y. Register December 2, 2015.

Implementation of the Protection of People with Special Needs Act and Reforms to Incident Management

Notice of Adoption. The Office for People With Developmental Disabilities amended Parts 624, 633, 687; and addition of Part 625 to Title 14 NYCRR to enhance protections for people with developmental disabilities served in the OPWDD system. Filing date: November 17, 2015. Effective date: December 2, 2015. *See* N.Y. Register December 2, 2015.

OASAS Treatment Services: General Provisions

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 800 and added a new Part 800 to Title 14 NYCRR to add general provisions applicable to all OASAS treatment services: definitions, incorporation by reference, and staffing. Filing date: November 19, 2015. Effective date: December 9, 2015. *See* N.Y. Register December 9, 2015.

Medical Assistance for Chemical Dependence Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 841 of Title 14 NYCRR to update for Medicaid managed care implementation; coordinate with amendments to Parts 822, 820 and 800, and technical amendments. Filing date: November 19, 2015. Effective date: December 9, 2015. *See* N.Y. Register December 9, 2015.

Residential Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services added Part 820 to Title 14 NYCRR to add residential services restructured for Medicaid managed care and Medicaid redesign. Filing date: November 19, 2015. Effective date: December 9, 2015. *See* N.Y. Register December 9, 2015.

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

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed of Part 822 and added a new Part 822 to Title 14 NYCRR to accommodate Medicaid managed care and Medicaid redesign; phase out APGs; amendments to Part 800. Filing date: November 19, 2015. Effective date: December 9, 2015. *See* N.Y. Register December 9, 2015.

Incident Reporting in OASAS Certified, Licensed, Funded, or Operated Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 836 and added a new Part 836 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: November 19, 2015. Effective date: December 9, 2015. *See* N.Y. Register December 9, 2015.

Implementation of the Protection of People with Special Needs Act and Reforms to Incident Management

Notice of Adoption. The Office of Mental Health amended Parts 501 and 550; repealed Part 524; and added a new Part 524 to Title 14 NYCRR to enhance protections for people with mental illness served in the OMH system. Filing date: November 23, 2015. Effective date: December 9, 2015. *See* N.Y. Register December 9, 2015.

Personal Care Services Program (PCSP) and Consumer Directed Personal Assistance Program (CDPAP)

Notice of Adoption. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the

provision of continuous PC and continuous CDPA services. Filing date: December 2, 2015. Effective date: December 23, 2015. *See* N.Y. Register December 23, 2015.

Patient Access of Laboratory Test Results

Notice of Adoption. The Department of Health amended Parts 34 and 58 of Title 10 NYCRR to give patients a right to access medical records directly from clinical, including completed lab test reports. Filing date: December 7, 2015. Effective date: December 23, 2015. *See* N.Y. Register December 23, 2015.

General Provisions Concerning State Aid Eligibility

Notice of Proposed Rulemaking. The Department of Health proposed amending section 40-2.1 of Title 18 NYCRR to clarify that rent and maintenance of space in lieu of rent (MILOR) remain eligible for state aid. *See* N.Y. Register December 23, 2015.

Children's Camps

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 7-2 of Title 10 NYCRR to include camps for children with developmental disabilities as a type of facility within the oversight of the Justice Center. *See* N.Y. Register December 23, 2015.

Prohibit Additional Synthetic Cannabinoids

Notice of Adoption. The Department of Health amended section 9.1 of Title 10 NYCRR to add additional chemicals to the list of explicitly prohibited synthetic cannabinoids. Filing date: December 15, 2015. Effective date: December 30, 2015. *See* N.Y. Register December 30, 2015.

Visitation and Inspection of Facilities

Notice of Adoption. The Office of Mental Health amended Part 553 of Title 14 NYCRR to provide clarification of the term "facilities under the jurisdiction of the Office of Mental Health," for purposes of Part 553. Filing date: December 22, 2015. Effective date: January 1, 2016. *See* N.Y. Register January 6, 2016.

Computed Tomography (CT) Quality Assurance

Notice of Adoption. The Department of Health amended section 16.25 and added section 16.59 to Title 10 NYCRR to protect the public from the adverse effects of ionizing radiation. Filing date: January 5, 2016. Effective date: January 20, 2016. *See* N.Y. Register January 20, 2016.

Visitation and Inspection of Facilities

Notice of Adoption. The Office of Mental Health amended section 553.5 of Title 14 NYCRR to address visitation and inspection of facilities. Filing date: January 12, 2016. Effective date: January 27, 2016. *See* N.Y. Register January 27, 2016.

Article 16 Clinic Services and Independent Practitioner Services for Individuals With Developmental Disabilities (IPSIDD)

Notice of Revised Rulemaking. The Office for People With Developmental Disabilities amended sections 635-10.4, 671.5 and Part 679; and added Subpart 635-13 to Title 14 NYCRR to discontinue off-site article 16 clinic services and to add requirements for IPSIDD. *See* N.Y. Register February 3, 2016.

Standards for Adult Homes and Adult Care Facilities Standards for Enriched Housing

Notice of Adoption. The Department of Health amended Parts 487 and 488 of Title 18 NYCRR to revise Parts 487 and 488 in regards to the establishment of the Justice Center for Protection of People with Special Needs. Filing date: January 25, 2016. Effective date: February 10, 2016. *See* N.Y. Register February 10, 2016.

Home Care Agencies to Obtain Written Medical Orders from Physicians

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 763.7 and 766.4 of Title 10 NYCRR to amend the clinical records rules for CHHAs and LHCSAs with regard to obtaining signed physician orders. *See* N.Y. Register February 10, 2016.

Perinatal Services

Notice of Proposed Rulemaking. The Department of Health proposed amending section 405.21 of Title 10 NYCRR to update the Breastfeeding Mother's Bill of Rights to conform with recommended standards of care. *See* N.Y. Register February 10, 2016.

Hospice Operational Rules

Notice of Proposed Rulemaking. The Department of Health proposed amending Parts 700, 717, 793 and 794 of Title 10 NYCRR to implement hospice expansion. *See* N.Y. Register February 10, 2016.

Extended Mammography Hours for General Hospitals and Hospital Extension Clinics

Notice of Proposed Rulemaking. The Department of Health proposed adding section 405.33 to Title 10 NYCRR to require those general hospitals and hospital extension clinics that offer mammography services to have extended hours. *See* N.Y. Register February 10, 2016.

Supplementary Reports of Certain Birth Defects for Epidemiological Surveillance; Filing

Notice of Revised Rulemaking. The Department of Health amended sections 22.3 and 22.9 of Title 10 NYCRR to increase maximum age of reporting certain birth defects to the Birth Defect Registry. *See* N.Y. Register February 17, 2016.

Valuation of Individual and Group Accident and Health Insurance Reserves

Notice of Adoption. The Department of Financial Services amended Part 94 (Regulation 56) of Title 11 NYCRR to address the valuation of Individual and Group Accident and Health Insurance Reserves. Filing date: February 3, 2016. Effective date: February 24, 2016. *See* N.Y. Register February 24, 2016.

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

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Part 52 (Regulation 62) of Title 11 NYCRR to prohibit a health insurance policy or contract from providing coverage for conversion therapy to insureds under the age of 18. *See* N.Y. Register February 24, 2016.

Rights of Patients

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending section 527.8 of Title 14 NYCRR to make clear that conversion therapy is not a permissible treatment for minors in facilities under OMH jurisdiction. *See* N.Y. Register February 24, 2016.

Amendments to Reimbursement Methodology for Continuing Residential Leases

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-6.3 of Title 14 NYCRR to make changes concerning reimbursement methodology for lease costs for continuing residential lease arrangements. Filing date: February 5, 2016. Effective date: February 24, 2016. *See* N.Y. Register February 24, 2016.

Protection Against Legionella

Notice of Emergency Rulemaking. The Department of Health added Part 4 to Title 10 NYCRR to protect the public from the immediate threat posed by Legionella. Filing date: February 11, 2016. Effective date: February 11, 2016. *See* N.Y. Register March 2, 2016.

Immediate Need for Personal Care Services (PCS) and Consumer Directed Personal Assistance (CDPA)

Notice of Revised Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to implement 2015 State law changes regarding Medicaid applicants and recipients with immediate needs for PCS or CDPA. *See* N.Y. Register March 2, 2016.

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, an associate of Greenberg Traurig's Health and FDA Business Group, in compiling this summary is gratefully acknowledged.**

Request for Articles

If you have written an article you would like considered for publication, or have an idea for one, please contact the *Health Law Journal* Editor:

Robert N. Swidler
St. Peter's Health Partners
5 Cusack
315 S. Manning Blvd.
Albany, NY 12208
(518) 525-6099
robert.swidler@sphp.com

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New York State Fraud, Abuse and Compliance Developments

Edited By Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions

Compiled by Margaret Surowka Rossi

Eric Ploumis, D.M.D. (DOH administrative hearing decision dated December 28, 2015, Ann H. Gayle, Administrative Law Judge). This was an audit of a dentist who was provided incentive payments for the adoption, implementation and upgrade and subsequent meaningful use of an electronic health record or EHR system. OMIG sought restitution of EHR Incentive Payments because the provider failed to adopt a certified version of the "Open Dental" software system during the 2012 payment year. Appellant dentist acknowledged that the EHR technology purchased provided a meaningful use for his orthodontic practice, but that it was not a certified EHR system. The dentist claimed the certified system "Open Dental" that he agreed to purchase would not have provided meaningful use for his orthodontic practice. The ALJ noted that the requirement of the statute is for the adoption of a certified EHR system. Since the Appellant did not dispute that the purchased system was not certified, the ALJ upheld the OMIG's determination to recover overpayments in the amount of $21,250.

Mercy Medical Center (DOH administrative hearing decision dated December 11, 2015, David A. Lenihan, Administrative Law Judge). This was an audit of an acute care general hospital. At issue were payments for services which resulted from the treatment of the hospital's inpatients by non-employee medical staff that independently submitted claims for professional services separate and distinct of the hospital. The issue related specifically to alleged overpayments arising from the ultrasound and diagnostic services rendered to Medicaid beneficiaries during the course of inpatient stays at the Medical Center. The Hospital was reimbursed by Medicaid on a "per case" basis according to the assigned "Diagnostic-Related Group" ("DRG") for inpatient services during the relevant period. There were no disputes or errors alleged with respect to those claims; rather, at issue were claims billed by and paid to individual physicians, not the hospital. The claims at issue erroneously omitted the modifier code indicating a claim is only for the physicians' professional services and not the technical component which is included in the DRG rate. The amount of the alleged overpayment totaled $9,533.96. Of note, the physicians reviewed the claims they submitted and each offered repayment of the disputed amount to OMIG (which would have obviated the need for a hearing). OMIG refused repayment from the physicians and insisted upon its right to recover these alleged overpayments directly from the hospital despite the fact that the hospital was not the entity that improperly billed. OMIG asserted joint and several liability. The ALJ rejected joint and several liability, finding "no nexus between the Appellant and the six non-employed physicians which would justify making the Appellant responsible for their acknowledged billing error." In fact, although at the hearing the OMIG cited to 18 NYCRR §518.3, the ALJ found that "OMIG has failed to specify in its Audit Reports, both draft and final, any regulatory authority that would justify recovering from one provider…funds erroneously paid to another independent provider." Moreover, assuming that the OMIG had given proper notice of its intention to rely on joint and several liability under 18 NYCRR §518.3, the ALJ further found no basis under any subsection of 18 NYCRR §518.3 to establish joint and several liability in the circumstances under review. As such, the overpayment determination was vacated.

Titiana Gouskova, M.D. (DOH administrative hearing decision dated December 5, 2015, Kimberly A. O'Brien, Administrative Law Judge). This was an audit of a physician who was provided incentive payments for the adoption, implementation and upgrade and subsequent meaningful use of an electronic health record or EHR system. OMIG sought restitution of an EHR Incentive Payment because the provider failed to produce records required to substantiate that at least 30 percent of her individual patient volume for the relevant continuous 90 day period constituted Medicaid patients. As part of the Incentive Payment, Appellant signed an attestation in which she agreed to keep records to substantiate her claim. The Appellant was a former provider in a group practice and had to produce documentation relating to her individual patient volume. Since the physician had left the group practice, she argued that she did not have access to her individual patient volume records. The physician claimed that if she had taken records when she left the group practice, it would have been a HIPAA violation. Despite Appellant's testimony that she provided methadone treatments to approximately 600 or more patients per week during the time period and that "99 percent" were Medicaid patients, the ALJ sustained the audit findings noting, "It was the Appellant's obligation as a provider to compile, maintain and produce on audit the pertinent patient volume records to substantiate her claim." The ALJ noted that Appellant failed to meet her burden and, therefore, af-

firmed the recovery of EHR Incentive Payments of $21,250.00.

Statewide Ambulette Service, Inc. (DOH administrative hearing decision dated October 28, 2015, John Harris Terepka, Administrative Law Judge). This hearing was to review a determination by OMIG to exclude a transportation provider from Medicaid and to recover alleged overpayments. The determination arose out of a Proposed Agency Action following a Credential Verification Review in which OMIG claimed certain contracting arrangements to be improper subcontracting and, therefore, an unacceptable practice. The Appellant Ambulette submitted claims under review for transportation services by drivers who were employed by other entities. After being notified that OMIG deemed the arrangement improper, the Ambulette immediately cancelled the subcontracting arrangements. At issue was whether the Ambulette engaged in unacceptable practices, whether sanctions were properly imposed and whether recovery of alleged overpayments was correct. The primary issue was the interpretation of the MMIS Provider *Transportation Manual Policy Guidelines* on subcontracting. The ALJ rejected the Appellants' attempt to characterize its arrangement as a "minor corporate restructuring" of the Appellant Statewide. Moreover, the ALJ found that the *Medicaid Provider Manual* and Medicaid Update were explicit in prohibiting billing for Medicaid services by one transportation provider when they were performed by employees of another. Although Appellant argued the drivers were employees since it maintained control over them and their schedules, the ALJ rejected the argument, finding the lack of "maintain[ing] employment records to be particularly significant." With respect to the *Transportation Manual*'s ambiguous reading, the ALJ noted it could have been revised with more precision, but it is quite clear in its intent. As such, the ALJ found there to be improper subcontracting. In addition, the ALJ reviewed the determination as to claims in which there was a typographical error relating to the driver's license number. Related to such, the ALJ stated: "In charging unacceptable practices in this case because an electronically submitted claim contained a typographical error, the OMIG is confusing documentation in support of a claim, which is what Department regulations…require, with the claim itself." Those disallowances were therefore reversed. In reviewing the sanction that the OMIG imposed, the ALJ found that OMIG had failed to consider the six factors set forth in 18 NYCRR 515.4(b). In considering those factors, he concluded that censure, not exclusion, was warranted. Finally, in reviewing the overpayments that were claimed as a result of the subcontracting, the ALJ found that "[t]here is no reason in this hearing record to conclude that the unacceptable practices in this case were motivated by dishonesty or corner-cutting, resulted in any inappropriate care or took any financial advantage of the Medicaid Program, or that the Appellants engaged in the subcontracting knowing or intending it to be an unacceptable practice." The ALJ stated, "In the absence of any reason to believe or even suspect that any wrongdoing or intent to take advantage of the Medicaid Program is involved in this case, it is unreasonable to demand complete restitution for services that the Appellants were able to document were provided and billed in the appropriate amount." Therefore, the ALJ denied any restitution.

Norwegian Christian Home and Health Center (DOH administrative hearing decision dated September 10, 2015, Ann H. Gayle, Administrative Law Judge). This was an audit of an Article 28 skilled nursing facility relating to bed reserve payments made during the period July 1, 2007 to June 30, 2010. OMIG's Final Audit Report determined to recover Medicaid overpayments in the amount of $269,061, which included $221,373.87 in Bed Reserve/Vacancy Rate in Excess of 5% and $14,442.24 in Cash Receipt Assessment due. OMIG also sought $33,245.62 in interest on overpayments prior to the issuance of the Final Audit Report, to which Appellant had objected in response to the Draft Audit Report. The only issue for determination was whether the Department could collect interest for the period prior to the issuance of the Final Audit Report under the circumstances presented. The parties submitted the case for decision without hearing pursuant to 18 NYCRR §519.23. The Appellant argued that the audit was a "cost audit" of the facility and therefore imposition of the interest was in violation of 18 NYCRR §518.4(e). The ALJ disagreed, finding that "records were not reviewed here to revise the reimbursement rate, nor was the rate revised, therefore, the instant audit was not a cost-based audit; it was a claim based audit for the individual bed reserve days." As such, "this is not an audit of Appellant's costs, the language in §518.4(e) which provides for no interest to be imposed until at least 90 days after issuance of a notice of determination is not applicable." In addition, the ALJ held that it is the Appellant's burden to establish that the Department should have made a determination to waive interest and not OMIG's burden to establish why it did not waive. The ALJ said that Appellant offered no persuasive argument why the Department should be obligated to waive interest. Therefore, the ALJ affirmed the imposition of interest from the date of the overpayments.

Sunrise Handicap Transport Co. (DOH administrative hearing decision dated August 28, 2015, Kimberly A. O'Brien, Administrative Law Judge). This was an audit of a transportation provider seeking restitution of $27,609.11, which included overpayments and accrued interest. The claims at issue were disallowed due to incorrect driver's license information for dates of service. The Appellant submitted a spreadsheet with the valid driver license number. During the draft audit period, OMIG decided that it would not consider the spreadsheet because it determined it was not "contemporaneous," but OMIG did not notify Appellant about this deci-

sion until the first day of hearing. The ALJ noted that the spreadsheet was compiled from information in the Appellant's records and was very troubled by the OMIG's determination that it was not a "contemporaneous" document and its failure to consider the information of the valid driver license numbers that corresponded with the other information contained in the disallowed claims. As such, Appellant met its burden of showing that the claims submitted were due and payable and the ALJ reversed the OMIG's determination.

Meadowbrook Healthcare (DOH administrative hearing decision dated June, 2015, David A. Lenihan, Administrative Law Judge). This was an audit of a skilled nursing facility, specifically of its December 2006 Patient Review Instruments ("PRIs"). OMIG issued two draft audit reports disclosing numerous adjustments to Appellant's reported resource utilization groups ("RUGs"). The issues at the hearing included: (1) whether OMIG had jurisdiction to audit the PRI Submissions of Appellant, (2) whether OMIG was authorized to conduct the audit in the manner it did, (3) whether the audit was foreclosed by prior DOH action, and (4) whether OMIG's audit findings that disallowed level 5 toileting were based on a standard of documentation which was authorized by law and regulation and/or in conformity with legally enforceable interpretations of the statute and whether the toileting documentation factually met appropriate legally enforceable standards. As to the jurisdiction argument, the Appellant argued that DOH, not OMIG, is the agency that should conduct these audits. However, finding *New York State Health Facilities Association, Inc. v. Sheehan*, 100 A.D.3d 1086 (3rd Dep't 2012) to be controlling and noting that OMIG is in fact a part of DOH, the ALJ held that OMIG did have such authority. As far as the methodology, the ALJ determined that OMIG is not obligated to follow DOH/IPRO PRI protocols in its audit. The Appellant also argued that OMIG should be foreclosed from conducting the audit since the PRIs had been previously reviewed by DOH in a full-house assessment and determined that no adjustments were warranted. The ALJ rejected this argument, finding that the PRI review was not an audit. Appellant then tried to argue that the review was untimely. Again, the ALJ rejected the argument, stating there is no six-year time limit on PRI audits and, here, no prejudice to Appellant shown. Similarly, the ALJ rejected Appellant's estoppel argument, again finding the prior review of PRI submissions was not an audit. As to the substantive review and OMIG audit findings, however, the ALJ found that there were both errors of law and fact requiring reversal. The downscoring was based on a perceived failure to document the exact time each resident was toileted. The regulations do not require exact time recording, but simply require that the resident "be on a formal toileting schedule as documented in the medical record." Moreover, the flow charts that were maintained adequately met this requirement. The ALJ stated that the standard lacked clarity, making it arbitrary and capricious, and enforcing such a standard would constitute a change in interpretation that would require notification to providers. As such, OMIG's findings were held to be factually unsupported, arbitrary and capricious, and in violation of State regulations. Therefore, the determination of overpayments was reversed.

Amida Care, Inc. (DOH administrative hearing decision dated March 16, 2015, John Harris Terepka, Administrative Law Judge). This was a review of an OMIG determination to seek restitution for payments made pursuant to a Medicaid Managed Care ("MMC") agreement which provided for a capitation payment for each enrollee. There was no dispute that the alleged overpayments related to payments for enrollees who became incarcerated for an entire month in which a capitation payment had been made. The Appellant argued that the payments ensured that vital medications were provided to the individuals. The ALJ found that whether or not the prescriptions were provided was irrelevant as the MMC agreement only provided capitation payments be made until the individuals were incarcerated.

New York State Attorney General Press Releases

Compiled by Joseph Murphy, Aubrey Roman, Jamie Dughi Hogenkamp, and Bethany Hicks

Peekskill Home Health Care Agency Owner Charged with Failing to Pay Wages to Workers—February 8, 2016—A health care agency owner was arrested on charges of failing to pay his workers approximately $110,000 in hours worked. The owner was charged with one count of scheme to defraud in the first degree, a class E felony; four counts of falsifying business records in the first degree, a class E felony; two counts of offering a false instrument for filing in the first degree, a class E felony; five counts of failure to pay wages in accordance with the Labor Law, an unclassified misdemeanor; and six counts of willful failure to pay a contribution to the Unemployment Insurance Fund, an unclassified misdemeanor. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-peekskill-home-health-care-agency-owner-charged.

Medicaid Recipient Pleads Guilty to Collaborating with His Personal Care Aide in Kickback Scheme Orchestrated from His Jail Cell—February 4, 2016—An individual pleaded guilty to collaborating with his personal care aide, who submitted false time sheets for services allegedly rendered during the time that the individual was incarcerated. The aide then kicked back $100 per paycheck to the individual. The individual was sentenced to six months in jail. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-sentencing-medicaid-recipient-six-months-jail.

Cortland Nurse Aide Arraigned on Allegations of Abusing Nursing Home Resident—February 4, 2016—A

Cortland nurse aide was arraigned for charges based on allegations that she roughly placed a resident's feet, covered the resident's arms and legs, and slammed the resident's arms against a bedside table. The nurse aide is also alleged to have made a false statement regarding the incident. The nurse aide is charged with one count each of falsifying business records in the first degree, endangering the welfare of an incompetent or physically disabled person in the first degree, and willful violation of health laws. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arraignment-nurse-aide-who-allegedly-abused-nursing-home.

Social Worker Arrested for Allegedly Pushing Nursing Home Resident to the Ground—January 27, 2016—A Cheektowaga social worker was arrested on charges that she pushed and kicked the legs out from under a 68-year-old nursing home resident. The social worker was charged with one count of endangering the welfare of an incompetent or physically disabled person in the first degree, a class E felony, and one count of willful violation of health laws, an unclassified misdemeanor. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-social-worker-allegedly-pushing-nursing-home-resident.

Albany Transportation Company to Pay Over $1 Million to Settle Claims of Overbilling Medicaid—January 27, 2016—A transportation provider entered into a settlement agreement with the Attorney General to repay over $1 million in Medicaid reimbursements that the company was not entitled to receive after an audit revealed that from 2008-2009 and from 2011-2014 the company received reimbursement for services that were not rendered. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-over-1m-albany-transportation-company-overbilling.

CenterLight Healthcare to Pay $47 Million to Settle Claims It Fraudulently Used Social Day Care Centers to Enroll Ineligible Members—January 21, 2016—CenterLight Healthcare entered into a settlement with the Attorney General requiring it to pay back approximately $47 million and to be checked for compliance with its Medicaid Managed Long Term Care Plan contract and Department of Health policies by an independent monitor and the AG's Medicaid Fraud Control Unit for two years. Additionally, CenterLight Healthcare admitted that it fraudulently enrolled Medicaid beneficiaries, referred by social adult day care centers, even though the beneficiaries were not eligible to receive managed long term care. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-47-million-settlement-centerlight-healthcare-fraudulently.

Drug Maker Extends Agreement to Cut and Cap Price of Heroin Overdose Antidote Across New York State—January 19, 2016—Amphastar Pharmaceuticals, Inc. entered into an agreement with the Attorney General to extend a price cut for the heroin overdose drug, naloxone, for another year. This agreement extends to all public entities, regardless of whether the drug is bought from Amphastar or a third party, and applies even if a separately negotiated discount exists. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-extension-agreement-cut-and-cap-price-heroin-overdose.

A.G. Schneiderman Calls on the Federal Government to Adopt Proposed Guidelines for Prescribing Opioids for Chronic Pain—January 14, 2016—The Attorney General has called on the CDC to adopt its proposed guideline for prescribing opiates for chronic pain, emphasizing the need for greater physician guidance on proper opioid prescribing practices. The proposed guidelines encourage health care providers to review their patients' history of controlled substance prescriptions using a state monitoring system to assess risk for overdose, something already required in New York. Other key components include preference for nondrug/nonopioid therapy for chronic pain; adding opioid therapy only if the benefits for pain and function outweigh the risks to the patient; and periodic assessments of the risk of opioid abuse and overdose. http://www.ag.ny.gov/press-release/ag-schneiderman-calls-federal-government-adopt-proposed-guidelines-prescribing-opioids.

Monroe County Nurse Pleads Guilty to Falsifying Records—January 14, 2016—Christine Deisenroth, a registered nurse, was sentenced to a conditional discharge, requiring her to meet certain conditions, including nursing re-education, for failing to give a nursing home patient anti-blood-clotting medication on more than one occasion in July and August of 2015, despite initialing that she had done so on the patient's Medication Administration Record. She pleaded guilty to falsifying business records in the second degree, a class A misdemeanor. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-plea-and-sentencing-monroe-county-nurse-falsifying-records.

Wayne County Nurse Sentenced to 99 Days of Jail for Diverting Narcotics from Nursing Home Patients—January 7, 2016—A Licensed Practical Nurse, who had been accused of stealing 493 narcotic pills from elderly patients residing at a center, was sentenced to 99 days in jail after violating conditions of her plea. Over a roughly one-month period, the nurse falsified records indicating that she administered narcotic drugs to fourteen separate residents, when she actually diverted the drugs for her own personal use. http://www.ag.ny.gov/press-release/wayne-county-nurse-sentenced-99-days-jail-diverting-narcotics-nursing-home-patients.

United Health Group Settles with State Over Elder Care Competition Concerns—January 7, 2016—The Attorney General entered into a settlement with UnitedHealth Group to resolve concerns that United's business practices in New York unlawfully restrained competition in the market for certain elder and long-term care insurance products. Under

the settlement, United has agreed not to require Skilled Nursing Facilities (SNFs) to participate in its institutional special needs plan (I-SNP) as a condition of participation by that SNF in one of United's other insurance plans, and United may not penalize a SNF for declining to participate in United's I-SNP by offering the SNF lower reimbursement rates than similarly-situated SNFs. United has also agreed to make a monetary payment to New York State in the amount of $100,000. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-united-healthgroup-protecting-competition-elder.

Nursing Home Pleads Guilty to Covering Up Resident Abuse and Neglect—January 4, 2016—A nursing home pleaded guilty to Falsifying Business Records in the second degree, a class A misdemeanor, and was sentenced to a $5,000 fine for adding an employee's name to the staffing sheet on a day the employee did not work to allegedly cover up two instances of patient abuse and neglect. In a separate civil settlement agreement, the facility agreed to return $1,000,000 in overpayments to the Medicaid program, hire an independent monitor to implement compliance program reforms, and divest ownership of two of the convicted defendants and a related investor who owned 44% of the company. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-plea-involving-owners-other-top-officials-mohawk-valley.

Two Laboratories Agree to Stop Prohibited 'Direct Access Testing'—December 30, 2015—Direct Laboratories LLC ("DirectLabs"), a Louisiana-based company that sells requisitions directly to consumers, and Laboratory Corporation of America ("LabCorp") are prohibited from providing New Yorkers access to clinical laboratory testing without required medical provider oversight. Under the settlement, DirectLabs will no longer operate in New York State and must refund all customers with requisitions that have not yet been presented to a laboratory for testing. LabCorp agreed its New York patient service centers will no longer accept specimens for examination pursuant to DirectLabs', or any other similar company's, requisitions. DirectLabs is obliged to pay a $24,500 penalty, while LabCorp will pay a $225,000 penalty. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlements-stop-prohibited-%E2%80%98direct-access-testing%E2%80%99.

Albany Urgent Care Center to Pay $17,000 to Settle Charges That It Misled Customers About Participation in Health Plan—December 29, 2015—A provider of occupational and urgent care services agreed to enhance its disclosure policy about its participation with health plans and to pay $12,500 in costs and penalties to the state. While attempting to contract with UnitedHealthcare/Empire Plan, WorkFit represented to consumers that it participated in the network, and then billed consumers for the entire cost of the visit—over and above consumers' co-payment. WorkFit must provide nearly $17,000 in restitution to consumers who paid for services rendered in excess of the amount of co-payment required by UnitedHealthcare/Empire Plan for seeing an in-network participating provider. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-agreement-albany-urgent-care-center-misled-consumers-about.

Children's Leukemia Foundation Officials and Their Auditor Settle Claims of Fundraising Abuses for $1 Million—December 17, 2015—Through a settlement subject to court approval, a Brooklyn-based charity will be permanently closed and defendants banned from working in the non-profit sector. Under the settlement, former company officials admitted to financial misconduct and to years of fundraising abuses and misrepresentations, including falsifying audit reports. The Attorney General will also recover $380,000, most of which will be directed to charities helping children with leukemia. The company founder forfeited claims to an additional $612,844 in back pay, in addition to a claim to a life-time pension and other benefits. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-1-million-settlement-officials-so-called-children%E2%80%99s-leukemia.

Qualitest Pharmaceuticals Agrees to $39 Million Settlement in False Claims Act Case—December 16, 2015—A manufacturer of generic pharmaceutical products, and its parent company, resolved civil allegations of unlawful labeling practices by agreeing to a $39 million settlement with New York, the federal government and 47 other states. According to the whistleblower lawsuit, the company unlawfully labeled and marketed multivitamin tablets as containing the American Dental Association (ADA) recommended amount of fluoride, when the tablets actually contained less than half that amount. By mislabeling the strength of its fluoride products, the company caused healthcare providers to submit false reimbursement claims to Medicaid and various federal health care plans. The company has agreed to pay over $5 million resolving claims relating to New York's Medicaid program. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-39-million-national-settlement-principle-qualitest.

Mid-Hudson Nursing Home Chain That Delayed Patient Discharges Agrees to $600k Settlement—December 16, 2015—A Mid-Hudson area nursing home chain will pay $600,000 to resolve claims that it delayed the discharges of short-term residents at its facilities. As part of the settlement, it admitted that between 2008 and 2011, it postponed discharges of residents with Medicare or Medicaid coverage who were clinically ready to leave, against the wishes or without the informed consent of the residents or their families. The nursing home also admitted that it transferred several long-term residents to one of its financially troubled facilities to improve that facility's financial condition. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-600k-settlement-mid-hudson-nursing-home-chain-delayed.

Nurse Pleads Guilty to Defrauding State Medicaid System of Nearly $5k—December 9, 2015—A Licensed Practical Nurse employed to provide private nursing services to special needs young adults pleaded guilty to stealing nearly $5,000 from the Medicaid program by billing for numerous hours of care never provided, amounting to $4,910.57 in false billings. The grand larceny in the third degree, a class D felony, and seven counts of offering a false instrument for filing in the first degree, a class E felony, charges carry a potential sentence of up to seven years in state prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-nurse-arrested-defrauding-state-medicaid-system.

Hospital Employee Charged with Obtaining Narcotics Using Forged Prescriptions—December 8, 2015—A former hospital employee was arrested on charges that she obtained narcotics by presenting prescriptions with the forged signature of a physician assistant at the hospital. The Complaint alleges that the former employee presented seven prescriptions for hydrocodone-acetaminophen to pharmacies in Rotterdam, New York that bore a forged signature. In total, the former employee received over 600 pills in less than four months and now faces up to seven years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-hospital-employee-charged-obtaining-narcotics-using.

Two Capital Region No-Show Personal Care Aides Plead Guilty to Stealing from Medicaid—December 7, 2015—Two personal care aides pleaded guilty for submitting false time sheets to Capital District Physicians Health Plan, causing over $1,000 in Medicaid theft each. Both aides submitted false claims for providing care to a Medicaid recipient that never occurred. Both defendants agreed to pay restitution and to refrain from seeing the Medicaid recipient and will be sentenced to incarceration in the Albany County Jail. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-two-capital-region-no-show-personal-care-aides.

Medical Center Agrees to Settlement to Prevent Future Patient Privacy Breaches—December 2, 2015—The Attorney General and a medical center reached a settlement under the Health Insurance Portability and Accountability Act ("HIPAA") that requires the medical center to train its workforce on policies and procedures related to protected patient health information, notify the AG's office of further breaches and pay a $15,000 penalty for its HIPAA violations. The settlement was in response to a data breach that occurred in early 2015 when a nurse practitioner gave a list containing over 3,000 patient names, addresses and diagnoses to her future employer without first obtaining patient authorization. Her future employer then used the information to mail letters to the patients advising them of how to switch to the nurse practitioner's new practice. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-university-rochester-prevent-future-patient.

Novartis Pharmaceuticals Agrees to $390 Million Settlement of National Kickback Case—November 20, 2015—The Attorney General and Novartis Pharmaceuticals Corporation reached an agreement in principle to settle claims that Novartis paid kickbacks to three specialty pharmacies to incentivize them to push Medicaid patients to order refills of the drug Exjade. Novartis has agreed to pay $390 million to the United States, New York and over 40 other states that sued the drug maker under their respective False Claims Act statutes. About $18.5 million of the settlement will resolve claims relating to New York's Medicaid program. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-390-million-national-kickback-settlement-novartis.

Dutchess County Doctor Convicted of Illegal Practice of Medicine—November 16, 2015—A medical doctor was found guilty by a Dutchess County jury of three counts of unauthorized practice of medicine and one count of offering a false instrument for filing in the first degree. The conviction came after a jury trial revealed that between 2008 and 2013, the physician operated under the name "Physicians Who Make House Calls." Notwithstanding the name, the physician sent a nurse to treat homebound patients and to prescribe medications to patients, using blank prescriptions provided by the physician. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-conviction-dutchess-county-doctor-who-illegally-practiced.

Astrazeneca LP and Cephalon, Inc. Pay $54 Million in Multistate Settlement to Resolve Allegations of Overcharging Medicaid for Drugs—November 4, 2015—New York, along with 48 other states, the District of Columbia, and the federal government, announced an agreement to settle allegations with AstraZeneca LP and Cephalon, Inc. for overcharging Medicaid programs for their pharmaceutical products. The companies were alleged to have falsely treated certain fees paid to wholesalers as "discounts," thereby falsely decreasing the price reported to the federal government and lowering the rebates paid to the states. The companies will pay the states and federal government $54 million, of which AstraZeneca will pay $7.5 million and Cephalon will pay $996,110.12 to the New York State Medicaid Program. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-54-million-multistate-settlement-astrazeneca-lp-and-cephalon.

Rochester Nurse Who Allegedly Defrauded Medicaid Pleads Guilty to Petit Larceny—November 3, 2015—An LPN pleaded guilty to Petit Larceny after stealing $8,838 from the Medicaid program. The guilty plea followed an investigation conducted by MFCU and OMIG which revealed that the LPN repeatedly billed Medicaid for work she never performed. The LPN faces three years' probation and restitution to the state. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-

plea-rochester-nurse-who-allegedly-defrauded-medicaid.

Two Former Group Home Workers Convicted for Endangering Welfare of Developmentally Disabled Residents of a State-Run Group Home—October 30, 2015—A former direct service assistant at a state run group home was found guilty of violently punching a 53-year-old, severely impaired, intellectually disabled resident in February of 2014. Another assistant at the group home, Allexy Chambers, recently admitted that in February 2014, he punched a 56-year-old disabled adult in the face even though the resident did nothing but sit in a chair. Both men are awaiting sentencing. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-convictions-two-former-group-home-workers-endangering.

Long Island Nursing Home Workers Convicted in Patient Death and Cover-Up—October 29, 2015—Two respiratory therapists and three nurses, all former employees of a nursing home, were sentenced to jail in October 2015 after being found guilty for their roles in the 2012 death of a 72-year-old rehabilitation patient and their attempted cover-up of the circumstances that led to her death. Jurors in the case found that the rehabilitation patient was neglected when her ventilator was not connected when she went to sleep and subsequent visual and audible respire and cardiac alarms were ignored when the patient stopped breathing. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-jail-terms-long-island-nursing-home-workers-convicted.

New York State Office of the Medicaid Inspector General Update

Compiled by Jamie Dughi Hogenkamp

MCO Annual Program Integrity Report Form and Reporting Instructions Now Posted on OMIG's Website—February 2, 2016—https://www.omig.ny.gov/latest-news/879-mco-annual-program-integrity-report-form-and-reporting-instructions-now-posted-on-omig-s-website.

2016-17 Budget Testimony: Joint Legislative Budget Testimony of Dennis Rosen, Medicaid Inspector General, Office of the Medicaid Inspector General—January 25, 2016— https://www.omig.ny.gov/latest-news/880-2016-17-budget-testimony.

Compliance Webinar Series Follow-Up Questions Now Posted on OMIG's Website—December 17, 2015— https://www.omig.ny.gov/latest-news/875-compliance-webinar-series-follow-up-questions-now-posted.

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Ms. Zambri is a partner in the Albany Office of Barclay Damon, LLP and the Co-Chair of the Firm's Health Care and Human Services Practice Area, focusing her practice on enterprise development and regulatory guidance for the health care industry. She is also an Adjunct Professor of Management at the Graduate College of Union University, teaching Legal Aspects of Health Care.

Ms. Rossi is Counsel to Barclay Damon, LLP in its Albany Office, focusing her practice on health care law, advising health care providers on federal and state statutory and regulatory compliance, and representing health care providers in response to audits, investigations and disciplinary matters.

Mr. Murphy is a litigation associate in the Albany Office of Barclay Damon, LLP, with a focus on health care litigation, audits and investigations of health care providers and white collar crime.

Ms. Roman is a litigation associate in the Albany Office of Barclay Damon, LLP. Her practice includes health care litigation, commercial litigation, labor and employment, and torts defense.

Ms. Dughi Hogenkamp is an associate at Barclay Damon, LLP in its Albany office. She is a member of the Firm's Health Care and Human Services, Health Care Controversies, and Financial Institutions and Lending Practice Areas.

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Mishka A. Woodley expects to receive both a JD from Albany Law School and a MS in Bioethics Policy from Icahn School of Medicine at Mount Sinai/Union Graduate College in June 2016.

Bioethics and the Law: Trends and Future Directions

Mary Beth Morrissey and Wendy J. Luftig

History: The Legal Foundation of Bioethical Analysis

In recent decades, almost no theoretical discipline has exerted more influence on the practice of health law policy in this country than bioethics. Shaped by historical events such as the Nuremberg Trials and the Tuskegee Syphilis Study conducted by the U.S. Public Health Service (1932-1972), bioethical principles first entered our legal lexicon through the Belmont Report, issued by the National Commission for the Protection of Human Subjects (1979)[1] and the 1991 Federal Policy for the Protection of Human Subjects in Experimentation, referred to as "the Common Rule."[2] The core principles comprising traditional bioethical analysis—*patient autonomy* from which informed consent and privacy interests are derived; *beneficence* requiring a risk/benefit analysis for all medical procedures; *non-maleficence*, embodying the standard that medical professionals should "do no harm"; and *justice,* referring to the equitable distribution of medical services and advances among all populations, including vulnerable populations—were articulated in a landmark work by Beauchamp and Childress (1983).[3] In turn, these principles have shaped the legal foundation for the conduct of clinical care and medical research, as well as provided guidance for the behavior of physicians, hospitals, insurers, pharmaceutical companies and other stakeholders in the health care system.

In coming years, bioethical principles will continue to exert a powerful sway on health law policy in the face of rapidly changing medical and technological advance. As one example, the Common Rule was recently revised to address issues concerning the use of bio-specimens such as blood, tissue and other biological material. Are these substances individual property or a donation? Do patients and research subjects providing such samples retain privacy rights over genetic information? How should these samples be collected, stored and eventually used for future investigations? As medical knowledge advances, these types of questions will invariably arise.

Human rights law has also influenced the development of bioethics. From a policy perspective, the pursuit of health and well being is the goal of all developed and developing societies, recognized by the World Health Organization and under international law as a fundamental human right. But this goal remains elusive for many peoples across the globe, even in light of the inalienable human right to health.[4] The International Covenant for Economic, Social and Cultural Rights established the right to "the enjoyment of the highest attainable standard of physical and mental health,"[5,6] which is operationalized by nations through availability and accessibility of adequate health systems and services. Through the early work of Jonathan Mann and Lawrence Gostin, it is now well understood that there is a reciprocal and interdependent relationship between health and human rights such as rights to food, housing, education, and dignity.[7, 8] Yet in the practical sphere many individuals and peoples are denied equitable access to care and live in states of chronic pain and suffering and the absence of dignity. In the United States, the Institute of Medicine reported in 2011[9] that an estimated 100 million Americans are living with chronic pain. The locus of these concerns may be an ethics of rights or an ethics of care, sometimes competing frameworks. Within these frameworks, bioethical inquiry explores questions of moral experience, ethics and law from the perspectives of seriously ill persons, as well as professionals, and asks the overarching questions: what is the relationship between health and well-being and ethics? And what is the relationship of health and ethical interests to the law? There is a growing tension between a broad professional, common sense understanding of health as an achievement of technical rationality and natural science paradigms upon which health systems and services have been built, and the lived experience of health as an achievement of ethics grounded in social practices.

Recent trends in scholarship suggest that there are converging perspectives between bioethics and public health, ecological ethics, humanism, as well as the qualitative research movement. These influences are expanding the boundaries of bioethics beyond traditional domains of interest, and affording bioethics opportunities to engage meaningfully in dialogues with professionals, scholars and advocates across diverse forms of inquiry and policy. For example, compelling narratives of suffering experience for which natural science provides no cure or solution, and stories of responsive care, caregiving and community that locate possibilities for agency and self-actualization, well-being, resilience, recovery and human flourishing in relationship to others, are challenging the advances of medicine and technology.

Medical Research: The Regulatory Schemes of the NIH and the FDA, and Legislative Protections for Patients and Clinical Trial Subjects

Medical research in America occurs under the legislative auspices of the National Institutes of Health ("NIH"), the largest source of funding for scientific investigations in the world, acting through the Public Health Services Act[10] and other legislative mandates, as well as through the Food and Drug Administration ("FDA"), the regula-

tory agency empowered to enforce the Food, Drug & Cosmetic Act ("FDA Act").[11] Funded by the congressional budgetary process, the NIH's research mission is impressive. In a related fashion, the FDA oversees the process whereby pharmaceutical and medical device companies receive regulatory approval for marketing, advertising and distributing safe and effective products. Some notable controversies have surrounded the drug approval process, including the thalidomide incident of the late 1950s and the push to hasten or "fast track" drug approval during the height of the AIDs crisis in the 1990s.

Most recently, landmark federal legislation in the form of the 21st Century Cures Act[12] is currently pending in the U.S. Congress. Designed to stimulate a more robust research environment, leading to the streamlined approval of drug and device therapies, the Act has garnered widespread bipartisan support. At its core, the Act significantly increases funding for projects at the NIH that will target diseases with no known cure, including many forms of cancer. In addition, the Act infuses the FDA with budgetary and other enhancements designed to accelerate the process of drug development, testing and agency approval for marketing.

The pace and direction of medical research have also been affected by patient advocates eager to gain access to promising but not yet authorized treatments. Beginning with the *Abigail Alliance* case (2008),[13] individuals have been more assertive in pressing for a right to promising drugs that have not completed the process of regulatory review. Although a constitutional right to obtain experimental treatment for terminally ill patients was ultimately rejected by the court in *Abigail Alliance,* many states have taken up this cause and recently passed "Right to Try" laws intended to promote access to investigational drugs by the terminally ill. Indeed, such a law is currently pending in the New York State legislature.[14] While the likelihood of the New York bill's passage remains uncertain, it is clear that health law policy will play an important role as the public becomes more involved in advocating for treatments and cures for intractable medical conditions.

Brave New World: Legal Challenges Posed by Biotechnologies, Stem Cell Research and Genetic Testing

Few would dispute that emerging biotechnologies, stem cell research and access to the human genome have sparked notable changes in the legal landscape with respect to reproductive rights and access to innovative treatments. As some illustrations, laws governing parental surrogacy, the *in vitro* creation of embryos, and fetal testing and surgery—topics beyond imagination not that long ago—are now the norm in many states.

At the same time, however, medical progress has also triggered an increased awareness of the sensitivity of personal health and genetic data, as well as the potential for discrimination as a result of the misuse of these categories of information. The first key federal legislation directed at such individual privacy concerns is, of course, the Privacy Rule of the Health Insurance Portability and Accountability Act ("HIPAA") of 1996.[15] More recently, the completion of the Human Genome Project in 2003 and the subsequent ability to map an individual's unique genomic profile have reignited the discussion about how such information will be used.

A key challenge to the characterization of genetic information was at the heart of the *Myriad Genetics* case,[16] in which the U.S. Supreme Court held that naturally occurring DNA is a product of nature and not patent eligible, while also observing that the artificial creation of new DNA sequences *might* be patent eligible. It is important to emphasize that preserving rights related to genetic information may pose unique legal challenges, since an individual's genomic profile contains not only key health information about the particular individual, but also about children and other relatives. The Genetic Information Nondiscrimination Act of 2008,[17] dubbed by some as the first civil rights legislation of the twenty-first century, was a landmark statute designed to prohibit the misuse of genetic information for purposes of obtaining health insurance and in the employment arena. Currently, several challenges under this law have focused on the use of "wellness programs" by employers. No doubt, as further progress is made in understanding the blueprint of our genetic code, additional legal challenges may be anticipated.

Organ Donation and Transplantation: The Legal and Ethical Rationing of Scarce Medical Resources

Since the first successful kidney transplantation operation in the U.S. in 1954, the ethical and legal ramifications associated with these procedures have been debated. The dramatic medical success of transplantation surgery and its record of achievement in saving the lives of desperately ill patients cannot be denied. Yet, numerous controversies continue to surround this medical specialty. Among these issues are: (a) formulating criteria for determining when death occurs so that organs may be harvested; (b) developing an equitable process so that scarce organs may be fairly allocated; and (c) establishing guidelines relating to the decision-making process for organ donation.

This innovative field of medicine is governed by three key statutes: (a) the Uniform Anatomical Gift Act and revisions thereto (1968, 2005);[18] (b) the National Organ Transplant Act ("NOTA") and subsequent amendments (1984, 1990)[19] which outlaw the sale of human organs and provide for an Organ Procurement and Transplantation

Network; and (c) the Uniform Determination of Death Act (1981)[20] which was intended to provide a "comprehensive and medically sound basis for determining death in all situations."

Despite the strength of this foundational legislation and the overarching structure for managing an equitable system of organ allocation, NOTA has come under criticism primarily because it prohibits any form of compensation for the donation of human body parts. As one example, in *Flynn v. Holder*,[21] a 2012 Ninth Circuit case, the court issued a narrow yet noteworthy ruling, holding that the selling of bone marrow extracted through a special technique would not violate the NOTA ban. Other challenges have been brought relating to the organ allocation regulations and guidelines used by the United Network for Organ Sharing. As transplantation techniques become more sophisticated and increasing numbers of US citizens are eligible for life-saving transplantation, the challenge will be to insure that the legal guidelines in place are equitable and fair in terms of access, and that as many patients as possible are able to benefit from this medical breakthrough.

Serious Illness and the End of Life: Controversial Legal and Bioethical Decisions

Advances in biomedical technology have enabled physicians to sustain life under circumstances that would have caused certain death just a few decades ago. In this regard, some of the most challenging issues in bioethics concern the provision of marginally beneficial or non-beneficial care, or the prolongation of suffering in serious illness or at end of life. In light of judicial policy making in the landmark case of Karen Ann Quinlan *(In re Quinlan 1976)*[22] and in U.S. Supreme Court decisions in *Cruzan v. Dir., Mo. Dept. of Health* (1990),[23] *Vacco v. Quill* (1997)[24] and *Washington v. Glucksberg* (1997),[25] issues such as individual rights and liberty interests, as well as the legal authority of health care agents and surrogates to make decisions when an individual no longer has capacity, have taken center stage. Federal and state legislation and regulations have been designed to address these difficult circumstances, including the Federal Patient Self-Determination Act,[26] the New York Health Care Proxy Law,[27] the New York Family Health Care Decisions Act[28] and the MOLST Program.[29] In New York, there is a right to palliative care under existing palliative care laws.[30, 31]

Historically viewed as legally and ethically distinct from decisions to forgo life-sustaining treatment, Aid-in-Dying is being actively debated in many states. Bills have been introduced in the New York State legislature (A. 5261-C (Paulin)/S. 5814-A (Bonacic);[32] S. 3685 (Savino) /A. 2129A (Rosenthal)[33]). However, public policy issues such as the basis of social allocation or who benefits, the benefits to be allocated, how the benefits will be financed and delivered, and impact upon the public's health, especially vulnerable persons and groups who may not have equitable access to palliative and end-of-life care, have not been addressed in proposals advanced to date.

Bioethics as Lived Social Practice: Education and Training

The existential structure of this orientation is grounded in a view of ethics as giving expression to and making visible lived moral experience that is socially constituted. The focus of this orientation is on practice and the life-world, not on expertise or technique. Ethics is not imposed from the outside through appeal to expertise or authority. Methodology is instead viewed as a tool that gives access to lived moral experience and social practices, but in itself is not a source of authority. The focus under this orientation is on the life-world, the intentionalities of the patient, evaluation of the patient's pain and suffering, and processes of engagement with the patient that involve an ethical stance of non-neutrality and surrendering of authority in order to respond responsibly to the call of the patient as the suffering other. It envisions the full integration of ethics into a palliative approach to care, which seeks to relieve pain and suffering through provision of both appropriate medical care and social support to the patient and family as the unit of care. This view is also grounded in the notion that ethics is accessible to all persons who participate in the social world, and is not a property of the elite.

On the professional side, integration of bioethics education in medical and graduate school curricula, as well as in mandated continuing professional education for physicians and all health care practitioners, is imperative. Such education is consistent with goals of the Affordable Care Act to strengthen the generalist level workforce. Equally important, however, is diffusion of bioethics content into education and end-of-life decision counseling for seriously ill persons and their family caregivers.

Conclusion: The Integration of Bioethical and Legal Paradigms in Formulating Future Health Law Policy

As this discussion has suggested, applying a bioethical perspective has enabled policymakers to address numerous challenging legal issues emerging from advances in medicine and biotechnology. Whether the topic is clinical care, human subject research, the implications of genetic knowledge, the role of the professional in treating illness and the alleviation of suffering, organ donation and transplantation, or the controversies surrounding medical interventions at the beginning and the end of life, in each instance bioethical principles have offered an indispensable framework for developing laws and policies grounded in individual autonomy, equity and human rights. As medical and scientific knowledge moves inexorably forward, it is likely that the union of bioethics and

law will continue to serve as a touchstone in the evolution of health law policy.

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Mary Beth Morrissey, PhD, MPH, JD, is Chair, Bioethical Issues Committee, New York City Bar Association, and Research Fellow, Fordham University Global Health Care Innovation Management Center; Adjunct Professor and Program Director, Post-Masters Health Care Management Certificate Program in Palliative Care, Long-Term Care and Public Health, Fordham University Gabelli School of Business, New York.

Wendy J. Luftig, JD is an Adjunct Professor of Law at Fordham Law School. A former Chair of the Bioethical Issues Committee of the New York City Bar Association, she works in the Office of Science and Research at NYU School of Medicine managing contract negotiations for grant agreements with private foundations and governmental entities such as the NIH, the CDC, and the New York State and New York City Departments of Health, as well as other legal documentation relating to the conduct of medical research.

Aid in Dying: A Terminally Ill Patient's Right to Choose

The Past, Present and Future; New York State Law and Beyond

By Ruth Scheuer, R.N., DrPH, J.D.

In January 2014 a young woman, Brittany Maynard, a 29-year-old with an inoperable brain tumor, moved to Oregon in order to die with dignity under Oregon's Death With Dignity law. In doing so she and her family went public about her decision, the reasons and the importance of being able to have the right to decide to end her life when the pain and suffering she was enduring and was expected to endure would become too much to bear.[1]

The Maynard case has again sparked the Nation's attention, as have previous cases, about the right of a patient to aid in dying and a movement that would protect that right under the law. Although the numbers fluctuate by year, according to the organization Death with Dignity, as of March of 2016 18 states have Aid in Dying bills pending.[2]

The purpose of this article is to provide an abbreviated historical perspective of how we evolved as a society in acknowledging the rights of patients and the obligations health professionals have in the delivery of care both in extending life, but also helping patients achieve a peaceful death.[3]

Aid in dying encompasses the concept of providing mentally competent patients who are terminally ill with six months to live who have the capacity to make a rational, autonomous decision as to when and under what circumstances they choose to die peacefully.[4] New York and other states are debating enlarging those rights to include the right of a patient to request aid in dying, and in doing so it is important to acknowledge the undercurrents this has created from a political, ethical, religious, legal and societal perspective.[5]

The modern evolution of aid in dying can be traced to advances in the right of patients to make choices on their own behalf through the passage of time, and as noted above, the powerful confluence of history, ethics, religion, politics and the law If one looks back in time, the Schloendorff case, decided in 1914, in which Justice Cardozo held: "Every human of adult years and sound mind has a right to decide what shall be done with his own body…." serves as the first case in the nation as forerunner to this debate.[6]

In 1975 a family in New Jersey fought and won the right to remove the respirator from 19-year-old Karen Ann Quinlan under a right to privacy.[7] Following removal of the respirator, Karen Ann Quinlan remained in a persistent vegetative state until her death almost 10 years later.

Five years after Quinlan, two cases were decided in New York's Court of Appeals. One involving a 52 year old severely mentally retarded man receiving blood transfusions for bladder cancer (Storer) whose mother asked that the blood transfusion be discontinued. The other of an 83 year old retired clergyman, Brother Fox (Eichner)left in a persistent vegetative state following surgery, who friends argued had indicated in the past that he would never want to be kept alive under those circumstances. That Court held that patients have a common-law right to decide the course of their treatment, including life sustaining treatment (with no hope of recovery), provided there was" clear and convincing" proof that the patient was competent at the time the patient made his wishes known The Court distinguished the Eichner case from Storer. Storer never was competent to make decisions on his own behalf, therefore his mother could not substitute her judgment for her son's and stop his life sustaining treatment. Brother Fox (Eichner) had made his wishes known while competent clearly not wanting to be kept alive with life sustaining treatment if in a persistent vegetative state.[8]

In 1987 Julianna Delio,[9] on behalf of her husband, Daniel, won the right to have all treatment discontinued for her husband who, then in his 30s, was left in a persistent vegetative state following minor surgery. After a lengthy legal battle Mrs. Delio was able to prove, based on clear and convincing evidence, that her husband would want all treatment discontinued and, for the first time, this included artificial nutrition and hydration. The Court recognized that some institutions would be going against their religious convictions if forced to discontinue treatment. In that case the hospital should transfer the patient to an institution which would honor the patient's wishes.

In 1990 the case of *Cruzan v. Director, Missouri Department of Health* went before the U.S. Supreme Court, which ruled that a state may require "clear and convincing evidence" of a patient's wishes prior to the removal of life support.[10] In 1990 the U.S. Congress passed the Patient Self Determination Act requiring hospitals to inform patients they have a right to refuse treatment.[11]

However, these cases and others continued to highlight the problem of proving clear and convincing evidence of a patient's wishes, absent a written document or a means to designate a person authorized to make a health care decision on behalf of the patient in the event that s/he no longer had the capacity to do so. This spurred efforts to legalize "Advanced Directives" such as "Living Wills "and the "Health Care Proxy."[12]

While advance directives such as living wills were becoming accepted in state after state, it was not until 1990 when Julianna Delio and others went on to fight in New York for a law that would permit a person with capacity to designate someone who would make decisions on his/her

behalf when the person no longer had capacity. Because of problems in interpreting living wills, New York on July 22, 1990 passed the New York State Health Care Proxy Law (PHL Article 29-C). This was followed twenty years later by the Family Health Care Decisions Act in 2010 (PHL29-CC Section 2994A-U.) The Health Care Decisions Act for Persons with Mental Retardation (NYSCP 1750B) was passed in 2003, included both general authority to make medical care decisions and specifically provided for end of life decisions for persons falling within that law. Medical Orders for Life Sustaining Treatment (MOLST) authorize both non-hospital and hospital do not resuscitate (DNR) and do not intubate (DNI) orders.[13]

The hospice and palliative care movements are critical in understanding the evolution in establishing the rights of terminally and chronically ill patients. The hospice, and flowing from that, the palliative care movement, began in 1948 with Dame Cicely Saunders' work with the terminally ill in London. In 1967 she created Saint Christopher's Hospice. In 1969 Dr. Elizabeth Kubler-Ross wrote a seminal book, *On Death and Dying* identifying the five stages of grief patients go through when they learn they are terminally ill.[14] She spoke of the importance of patients determining their care at the end of life and that such care might best be provided outside of the hospital. With this the hospice movement was born in the United States.[15] As the movement in hospice care was growing, so eventually was the realization that physicians and other health care providers were not adequately trained in palliative care or pain management.[16] Patients were dying with, or experiencing years of, agonizing pain without effective relief. Inadequate training in pain management may also be attributed to the fear that doctors would be prosecuted for abusing the narcotic laws. Some doctors and even the terminally ill and their families feared that the patient would become addicted to pain medications. It was not until August 2010 that the New York Legislature passed the Palliative Care Information Act (See the provisions governing Palliative Care Information Act (PHL § 2997-C) followed by the Palliative Care Access Act (PHL § 2997-D) and The Palliative Care Education and Training Act (PHL § 2809-N).

While the hospice and palliative care movement were critical in helping patients who either were terminally ill or faced with a chronic devastating painful illness, doctors were noting that some of their patients, especially those who were terminally ill, wanted to control the time and manner of their death. Their concerns were that they be allowed to die with dignity at home or outside the hospital, and to do so before they might suffer intractable pain which could only relieved by high doses of "pain killers," and which in turn would render them incapacitated.[17]

It was because of patients' concerns left without a legal way for doctors to assist them without suffering criminal penalties based on laws making assisted suicide illegal that two cases came before the U.S. Supreme Court in 1997. The first *Washington v. Glucksberg* brought by five doctors and three patients challenging Washington State's ban on assisted suicide as applied to doctors, argued that it violated the 14th amendment's due process clause as it denied patients their liberty interest to determine the time of their death. The U.S. Supreme Court held in a unanimous decision there was no due process liberty interest in permitting a doctor to assist a patient in dying, and Washington had a rational basis in protecting medical ethics, shielding the lives of disabled and terminally ill patients from abuse, and preserving human life.[18] The second case argued before the U.S. Supreme Court, *Vacco v. Quill* held that New York's ban on assisted suicide did not violate the Equal Protection Clause by allowing patients with capacity to withdraw or remove life sustaining treatment, but did not allow doctors to prescribe lethal drugs for patients which would allow them to take at a time and place of their own choosing. The Court also held the ban to be rationally related to a legitimate state interest.[19]

These decisions by the U.S. Supreme Court were undoubtedly the impetus for patients and doctors to look for other ways to have Aid in Dying legalized. While the movement was slow to evolve, four states, Oregon in 1994[20] (however, Oregon's law did not go into effect until 11/4/1997), Washington[21] in 2008 both by ballot initiative, Vermont[22] in 2013, and California[23] in 2015 by legislation, have defined the conditions under which a physician may prescribe a lethal dose of medicine for a terminally ill patient, with capacity, allowing that patient to take medication at a time and place of his/her own choosing.[24] Notably, three state courts have recently dealt with Aid in Dying. The Supreme Court in Montana[25] has ruled on behalf of patients (and their physicians) who choose to die with dignity. A lower court in New Mexico held aid in dying to be a constitutionally held right under that State's Constitution. That decision was recently reversed 2 to 1 by the states Appellate Court and is now under appeal to the State's Supreme Court.[26] New York is now the third state as will be discussed below.

U.S. State Legislation Covering Aid in Dying

In reviewing the legislation in the four states with defined criteria for AID, most have the following characteristics in common.

The Patient

- Must be an adult (18 years of age).
- Demonstrate capacity to make an informed decision.
- Suffer from a terminal disease which will result in death within 6 months.
- A resident of the state with elements of proof defined.
- Make a written request for medications which are self-administered.
- Make an oral request for medications.

- Wait 15 days between the two oral requests before a prescription by the doctor is issued.
- Wait another 48 hours after the written request before the prescription may be obtained.

The Doctor

- Must determine all of the above characteristics as noted.
- A second physician must confirm the findings of the first physician.
- Obtain a consult if there is a question of psychiatric/psychological or mental disorder.
- Must provide evidence to the state regarding all such transactions.

International Aid in Dying

At the same time Assistance in Dying is a topic long discussed in Europe and North America. There are many differences compared to the legislation in the United States including the terms used to describe aid in dying by retaining historical terms such as euthanasia and/or assisted suicide.[27] Additionally, unlike the United States, the criteria under which patients qualify for Aid in Dying may differ in other countries, e.g., as to condition, age, and residency requirements. See Appendix C for a more detailed analysis of a comparison of the international laws noted below.

Switzerland[28]

- A ban in 1947 covers aiding a person from killing himself for selfish reasons. Aiding a person for unselfish reasons is not a crime.
- Aid in dying can be provided by someone trained to do so, other than a doctor, for patients who request help.
- The patient need not be terminally ill although each case is carefully reviewed by physicians.
- The person must be able to take the medicine without assistance.
- There is no requirement that the person be a citizen of Switzerland.

Belgium[29]

- Extended its so-called Euthanasia Laws passed in 2002 to include children in rare cases of "unbearable and irreversible suffering" provided the child is terminally ill, close to death and deemed to be suffering beyond any medical help." The child must be able to request euthanasia and demonstrate an understanding of that request and the decision must also be made with the consent of the parents.
- The patient need not be terminally ill with a limited life expectancy.
- Consideration is given to a patient who is not physically ill but suffers from a depressive or psychiatric condition which is not relieved by medication.

The Netherlands[30]

- The law of 2002 allows children over 12 to request Aid in Dying with a parent's consent. Proof of a terminal illness is not required. The critical criteria are establishing that there is unbearable suffering which can include mental illness where the patient is suffering hopelessly and intolerably and there is no other hope for a reasonable solution.
- Guidelines include assisting a patient's wishes where there is no physical ailment, but the patient suffers from a condition which is unacceptable, incurable and considered over time.[31]

Luxembourg[32]

- In 2009, Luxembourg passed two laws; one governing palliative care, and the use of advanced directives, and a second law governing euthanasia and assisted suicide.
- The patient must be in a severe and incurable terminal medical situation and have constant and unbearable physical or mental suffering without prospects of improvement.
- The patient need not be a resident of the country but must have a close relationship with the doctor who confirms the request.

Canada[33]

- Canada legalized physician assisted suicide effective in 2016. The decision allows a consenting person to terminate his/her life if faced with a grievous and irremediable medical condition, an illness, disease or disability causing enduring suffering (including psychological) that is intolerable. In the decision it was noted, "We do not agree that the existential formulation of the right to life *requires* an absolute prohibition on assistance in dying, or that individuals cannot 'waive' their right to life. This would create a 'duty to live.'"

In the New York State Courts

New York is now addressing the legal issues associated with Aid in Dying on two fronts. In February 2015, nine plaintiffs filed suit in Supreme Court, New York County (*Myers et al v. Schneiderman, et al*) seeking interpretation of the "Assisted Suicide Statute" (Penal Law Sections 120-30 and 125-15). Plaintiffs allege that the penal code as cited does not "encompass the conduct of a New York licensed physician who provides aid in dying to a mentally competent, terminally ill individual…." or that, if it does encompass such conduct, that patients have a right to aid in dying under the due process and equal protection clauses (lack of equal protection and denial of due process

(privacy) under the Constitution.[34] However, on October 16, 2015 Justice Kenny granted the State's Attorney General's motion to dismiss. In her decision, Justice Kenny acknowledged that plaintiffs in the case have "more than just a passing interest in the outcome of the case."[35] Nevertheless, the court, relying heavily on the case of *Vacco*,[36] rejected the constitutional arguments offered by the plaintiffs in *Myers et al v. Schneiderman*.[37] That decision is now on appeal to the Appellate Division, First Department.

New York Legislative Initiatives

At the same time, a number of bills were introduced in the New York State's Assembly and Senate. AO 5261 sponsored by Assemblywoman Paulin et al. to amend Article 28 to add 28F, The Patient Self Determination; identical to S. 5814 sponsored by Senator Bonacic. S. 3685, sponsored by Senators Savino and Hoylman, adds a new provision Article 29-CCCC New York End of Life Options Act; identical to, AO2129 sponsored by Assemblywoman Rosenthal et al., "A Death with Dignity Act," also creating a new Article 29-CCCC.

The bills now in the New York State Senate and Assembly are in their infancy and changes are and will continue to be made until one final bill is passed and signed into law. Nevertheless, while there are many similarities between the two bills and those passed by the four states, there are notable differences. A side-by-side comparison is found in Appendix D. The key differences are noted below.

	28-F	**29-CCCC**	**OTHER STATE LAWS**
Age	21	18	18
Waiting Periods Prior to Prescriptions	None	None	15 days between requests/ Rx48 hrs.
Residency Requirement	Yes	No	Yes

Ethical Issues

It is important to understand some of the ethical issues raised by proponents and opponents of Aid in Dying.

Proponents for Aid in Dying argue that under ethical principles it embraces:

- Respect for autonomy.
- Fairness or justice.
- Compassion.
- The importance of honoring the interest of the patient versus that of the State.
- Encouraging better communication between doctor and patient (non-malfeasance).

Opponents argue:

- The sanctity of life, all life is precious and must be preserved.
- There is a difference between passive versus active means which have the effect of hastening a patient's death.
- The need to uphold professional integrity, often citing to the Hippocratic Oath "to do no harm." While some still quote the provision in the Oath "I will not administer poison to anyone where asked," that portion of the oath has since been omitted in modern versions recited by medical students.[38]
- The potential for abuse by the profession, by a patient's family or society.
- The potential for errors or the fallibility in diagnosis or prognosis.
- Patients who are disabled or poor will be disproportionately subject to aid in dying.
- This is the beginning of the slippery slope slide… from voluntary to involuntary "euthanasia."[39]

It should be noted that there is no evidence from the data on Aid in Dying that there has been abuse by the profession, or that it affects the disabled or the poor. In addition, researchers have found that patients who seek Aid in Dying do so for fear of loss of autonomy; loss of dignity; inability to enjoy life. Lower on that list is inadequate pain control and financial concerns.[40]

Current Pain Management in New York

As noted earlier, while palliative care management has been shown to significantly improve the lives of patients experiencing severe pain who have a condition for which there is no hope of recovery or who are terminally ill, there are patients whose pain becomes intractable or who continue to live under circumstances for which they no longer have control and, for them, current law in New York only provides for the following options:

- Continued pain care management.
- Withholding or withdrawing treatment including life sustaining treatment.
  - If requested by a patient with capacity.
  - If provided for in an advanced directive by the patient.
  - If there was clear and convincing evidence of the patient's wishes absent an advanced directive.
  - If under the laws providing for appointment of a family member or other legally defined person who can act on behalf of the patient.

Pain Medication /duel or double effect phenomena:

> This provides significant pain relief by increasing the amount of pain medication which, because of the amount and side effects, is known to depress respirations and thus hastens death. This is recognized and supported by health professionals and the courts, and is *not* considered a form of "assisted suicide"[41]

- Palliative Sedation:

> Palliative sedation is used when a patient is experiencing intractable pain which seems impervious to pain management drugs. Sedation can occur for a period of time, but in most cases the patient remains sedated until death.

At the time of this printing, there is uncertainty as to whether any of the bills before the New York State legislature will be passed and signed into law. There is no final decision on the lawsuit filed in New York on behalf of doctors and patients which would allow aid in dying without criminal sanctions. The outcome of the myriads of Aid in Dying bills before other State legislatures is unknown. As has been true in the past, another case may come to the surface which might have further impact on patient choices. At a time when medicine offers more hope in treating patients who are terminally or critically ill or facing an incurable mental and/or physical degenerative disease, a few are seeking greater autonomy over their lives, including the manner and timing of a death when medicine may no longer offer hope of recovery, relief or even extended life. Doctors who want to honor the patient's choices cannot do so for fear of criminal liability. There is also a question of the role of the state in protecting its citizens. As has been so in the past, these issues are complicated and will continue to be the subject of religious, political, ethical, legal and, it is hoped, reasoned debate.

Endnotes

1. "Brittany Maynard Dies Using Oregon's Assisted Suicide Law," Victoria Cavaliere, November 2, 2014 Chicago Tribune (www.chicagotribune.com).
2. 25 States had introduced Death with Dignity bills Source: Death with Dignity Around the U.S. (US:http/www.deathwithdignity.org/advocates/national October, 5 2015). However, as also noted above according to the Death with Dignity organization, there are 18 states with legislation pending as of March 2016. See Appendix B.
3. For a more comprehensive time line, see "Chronology of assisted dying," Death with Dignity National Center, www.deathwithdignity.org/history/facts/chronology.
4. Countries outside the United States continue to use terms such as assisted suicide and/or euthanasia to describe their laws covering aid in dying. These terms are value laden and have a chilling effect and thus have been rejected in the United States where aid in dying is legal as they are not considered an appropriate or accurate description for doctors or their patients who seek assistance in dying. Stark, H, et al., "Physician Aid in Dying" Ethics in Medicine, University of Washington School of Medicine, April 2013 (dept.washington.edu). See Appendix C for a description of the international laws covering aid in dying. Also refer to footnote 27.
5. One only has to look to the Terri Schiavo case involving a patient in a persistent vegetative state. Her husband was able to show that there was clear and convincing evidence that she would never have wanted to live in that condition. However, because of the objections of her parents the case went on to involve 14 appeals, scores of motions, petitions and hearings in the Florida courts, five lawsuits in the federal district court, political intervention at almost every level of government including the Florida State legislature, the governor of Florida, Jeb Bush, the United States Congress, President George W. Bush, and four denials of certiorari by the United States Supreme Court. (Felos, George, J., Esq. (2005-03-24). "Respondent Michael Schiavo's opposition to application for injunction" Case No:04A-825 PDF. Blue Dolphin Publishing p. 9. Retrieved 2006-01-15 (Wikipedia). Also see, Eisenberg, D., "The Lessons of the Terri Schiavo Case," Time: The End of Life: Who Decides, April 4, 2005 Vol. 165 No. 14.
6. *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 105 NE 92 (1914).
7. *In the Matter of Karen Ann Quinlan, an Alleged Incompetent* [No Number in Original] Supreme Court of New Jersey, 70 N.J. 10; 355 A.2d 647; 1976 N.J. LEXIS 181; 79 A.L.R.3d 205. Argued January 26, 1976, decided March 31, 1976.
8. *In the Matter of John Storar*. Charles S. Soper, as Director of Newark Developmental Center, et al., Appellants; Dorothy Storar, Respondent. *In the Matter of Philip K. Eichner, On Behalf of Joseph C. Fox, Respondent, v. Denis Dillon, as District Attorney of Nassau County, Appellant. Dorothy Storar, Respondent. Court of Appeals of New York,* 52 N.Y.2d 363; 420 N.E.2d 64; 438 N.Y.S.2d 26 (1981); *cert. denied*, 454 U.S. 858, 102 S.Ct. 309 (1981).
9. *In the Matter of Julianne Delio on Behalf of Daniel Delio, Petitioner v. Westchester County Medical Center et al.,* 129 A.D. 2d 1, (1987).
10. *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990).
11. H.R. 4449-101st Congress 1989-1990.
12. In 1967 Luis Kutner, a notable human rights attorney from Chicago and a co-founder is credited with creating the original living will, advocating for a document allowing people to express their final wishes after watching a friend die a slow and painful death {Encyclopedia of Death and Dying. Deathreference.com.
13. The MOLST form (DOH 5003) has also been approved by the Office of Mental Health (OMH) and the Office for People with Developmental Disabilities (OPWDD) See Health.NY.Gov.

    Also see Non-Hospital Resuscitation Orders NYSPHL 29CCC.
14. Elizabeth Kubler-Ross, On Death and Dying, Scribner Press 1969 The five stages of grief found by Dr. Kubler Ross are: Denial and Isolation; Anger; Bargaining; Depression and finally, Acceptance.
15. "History of Hospice Care, National Hospice and Palliative Organization. http://www.nhpco.org/history-hospice-care. The document is a fairly comprehensive compendium of Federal and other provisions historical events.
16. According to the NY State Health Department's website: Palliative care, as defined by the Public Health Law, is "health care treatment, including interdisciplinary end-of-life care, and consultation with patients and family members, to prevent or relieve pain and suffering and to enhance the patient's quality of life, including hospice care." Palliative care is for patients who may be dying but also for patients who are experiencing long term chronic pain as noted. According to the World Health Organization's definition: "Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual." WHO Definition of Palliative Care [Internet] [cited 2010 Dec 22]. Available from: http://www.who.int/cancer/palliative/definition.

17. Patients were admitted initially into hospice with an expected 3 months to live expanded to 6 months. Many patients, however, did not meet those criteria and, therefore, were expected to live longer. Some patients did not have the pain relief or palliative care experts available to them outside of the hospice environment. This also impacted the palliative care movement which would ultimately include patients who were terminally ill as well as those with chronic diseases. Chapter 59 of the Laws of 2011. Added on April 1, 2011, which added The Palliative Care Access Act (PCAA) Section 2997-d to the Public Health Law, now commonly known as the Palliative Care Access Act ("PCAA").

    Also see section on the current legal methods by which New York doctors caring for dying patients treat patients by various means not considered as Aid in Dying.

18. *Washington v. Glucksberg*, 521 U.S. 702 (June 1997).
19. *Vacco v. Quill*, 521 U.S. 793 (June 1997).
20. Oregon Death with Dignity Act of 1994 ORS 127-800-897 (passed on a ballot initiative).
21. Washington Death with Dignity Act, Initiative 1000, codified as RCW 70.245, passed on November 4, 2008 and went into effect on March 5, 2009.
22. Vermont's law passed in 2013, "An Act Relating to Patient Choice and Control at the End of Life" (39 Sec 118 VSA Chapter 113).
23. California, SB 128 End of Option Life Act 2015.
24. See Appendix A for a summary of the provisions enacted into law by Vermont, Oregon, Washington and California.
25. *Montana/Baxter v. Montana,* 224 P.3d 1211: 354 Mont 234 (2009).
26. New Mexico (State of New Mexico, County of Bernalillo, 2nd Judicial District Court, *Katherine Morris M.D., et al, Plaintiffs v. No. D-202-CV 2012-02909 Kari Brandenburg, et al.,* January 2014. In the Court of Appeals of the State of New Mexico, No 33,630. Filed August 11, 2015: *K Morris, MD, A. Mangalik, MD and A. Riggs, Plaintiffs-Appellees v. K. Brandenburg, Defendant-Appellants*.
27. The term "euthanasia" is often used outside the United States as well as the term "assisted suicide." The word euthanasia is derived from the Greek—"eu," goodly or well + "thanatos," death = the good death. It can also be further defined as Voluntary Active where the patient is actively helped by another to hasten death; Voluntary Inactive, for instance, where forms of life saving treatment are discontinued at the patient's request; Involuntary Active, the intentional killing of a person without their consent as in Nazi Germany; Involuntary Inactive, where treatment is stopped without the consent of the patient. However, because the use of those terms engender fear of a time when euthanasia was used to kill innocent people and suicide suggests an illegal act under penal codes where it too is used for illegal or immoral reasons, these terms have been replaced by terminology as Aid in Dying that reflects the right of a patient to make a choice on the manner and timing of his/her death. See Ebbott, K. "A 'Good Death' Defined by Law: Comparing the Legality of Aid-in-Dying around the World," William Mitchell Law Review. Vol 37:1: pgs. 170-205 2010.
28. (Dignitas Correspondence 2011). *See* "How Dignitas Works," DIGNITAS—To live with dignity—to die with dignity, P.O Box 17, 8127 Forch, Switzerland/www.dignitas.ch/3rd edition/May 2014.
29. TIME http://time.com/7565/belgium-euthanasia-law-children-assisted-suicide (Feb 13, 2014).
30. (A Look at Right-Die laws around the world/Who has the right to die? http://globalnews.ca/news/1815431/a-look-at-right-to-die-laws-around-the-world/).
31. Schoevers, R. et al., *Physician Assisted Suicide in Psychiatry: Developments in the Netherlands, Psychiatric Services*, Vol. 49 No. 1, November 01, 1998.
32. Ministere de la Sante, "Euthanasia and Assisted Suicide, 25 questions 25 answers" Law of March 16, 2009. The Ministry of Health and the Ministry of Social Security.
33. On February 15, 2015 Canada legalized physician assisted suicide See Carter v. Canada (attorney general) 2015 SCC5. The court questioned whether extubating a patient in a persistent vegetative state was a homicidal act of commission vs. ceasing to feed the patient via his nasogastric tube was a humane act of omission and thus leaving the patient intubated but starved made a moral difference. The judge went on to comment about aid in dying, "A charge of hypocrisy because it can be asked why, if the doctor, by discontinuing treatment is entitled…to let his patient die, it should not be lawful to put him out of his misery straight away in a more humane manner by lethal injection rather than let him linger on in pain until he dies." Amir Attaran, *Unanimity on Death with Dignity—Legalizing Physician Assisted Dying in Canada*, N. Engl. J. Med 372;22 May 28, 2015 pgs 2080-2082.
34. Myers, S., Goldenberg: S., Seiff, E., Grossman, H., MD; S. Klagsbrun, MD; T. Quill, MD; J. Schwarz, PhD; C. Thornton, MD and End of Life Choices, New York, Plaintiffs against E. Schneiderman, Attorney General State of New York: J. DiFiore, District Attorney of Westchester County: S. Doorley, District Attorney of Monroe County: K. Heggen, District Attorney of Saratoga County: R. Johnson, District Attorney Bronx County: C. Vance, Jr, District Attorney of New York County.
35. See Index #151162/15, Supreme Court of New York County of New York Part 8.
36. *Vacco v. Quill*, 521 U.S. 793 (1997). The U.S. Supreme Court held (in part) in a 9-0 decision that New York's ban on the right to die (or its prohibition on assisting suicide does not violate the Equal Protection Clause. pp. 799-809).
37. An appeal of that decision was heard on February 3, 2016. A decision on the appeal is pending.
38. The critics arguing against AID have also pointed to the Hippocratic Oath provision:, "I will not give a lethal drug to anyone if I am asked, nor will I advise such a plan…," however, that part of the oath is generally omitted today. In addition, some have argued that that provision was placed into the oath, not as a prohibition against Aid in Dying, but to protect the medical profession from providing lethal drugs to persons who might use them on people not dying, but for other purposes. Thomas A. Preston, MD, former Chief of Cardiology at Pacific Medical Center and Professor of Medicine at University of Washington, has argued that: "…In the time of Hippocrates, physicians had no drugs of therapeutic efficacy by present standards, but they did have poisons which were sometimes used on non-dying patients for mischievous purposes. In this context, the Hippocratic injunction against the use of deadly drugs was good public relations for the medical guild, and had nothing to do with terminally-ill patients." Thomas A. Preston, *Physician Involvement in Life-Ending Practices*, 18 Seattle U. L. Rev. 531 (1995) at page 532.
39. Stark, H., et al., *Physician Aid-In-Dying*, Ethics in Medicine University of Washington School of Medicine et al (1998) pg. 2, https://depts.washington.edu/bioethx/topics/pad.html.
40. Lee, B., "Oregon's experience with Aid in Dying: findings from the death with dignity laboratory" Ann. N.Y. Acad. Sci. July 2014 1-7 (ISSN 0077 8923).
41. Stark, H., et al., *Physician Aid in Dying* Ethics in Medicine, U. Wash School of Medicine April 2013, depts.washington.edu.

Ruth Scheuer is Adjunct Assistant Professor of Medical Ethics in Medicine, Weil Cornell Medical College where she is involved in the 4th Year Bioethics teaching program: She is a facilitator in the First and Second Year Medical School Program in Bioethics. She also works with patient services in the Emergency Room, New York Presbyterian Hospital.

Appendix A: Aid in Dying Bills Comparison of Four State Laws

Category[1]	Vermont	Oregon	Washington	California
Section of law created	**The Patient Choice and Control at the End of Life Act, Chapter 113 39 18 VSA**	**The Oregon Death with Dignity Act, ORS §127.800 to 127.890 and §127.895 and §127.897**	**The Washington Death With Dignity Act, RCW, Chapter 70.245**	**An Act to Add Part 1.85 section 443 et al. to Division 1 of the Health and Safety Code relating to "End of Life Option Act" (approved by the Governor October 5, 2015)**
Patient must have capacity	Yes. §5281(a)(2)	Yes. §127.800 §1.01(3)	Yes. §70.245.010(3)	Yes. §443.1(e)
"Bona fide" doctor-patient relationship required	Yes. §5281(a)(1)	Has primary responsibility for care and treatment of patient's terminal condition §127.800 §1.01 (2)	Not as to issue of a "bona fide" relationship	Under §443.1(c)…"the physician who has primary responsibility for the health care of an individual and treatment of the individual's terminal disease"
"Health care facility" defined	Yes. §5281(a)(3)	No.	No.	See health care provider, below §443.1(h)
"Health care provider" defined	Yes. §5281(a)(4)	Yes. §127.800 §1.01(6)	Yes. §70.245.010(6)	Yes. §443.1(h)
Defines "aid-in-dying medication"?	No.	No.	No.	Under §443.1(b) a drug determined by a Physician…for qualified individual to choose to self administer to bring about his death
"Impaired judgment" defined	Yes. "Person does not sufficiently understand or appreciate the relevant facts necessary to make and informed decision," §5281(a)(5)	Not directly: A capable patient: a determination that a patient is "capable" by a court, or by a physician, psychiatrist or psychologist to make a communicated health care decisions….." §127.800.1.01(3)	Not directly: Defines competent as to patient: See §70.245.010(3)	Under §443.1(e) "Must be shown that the individual has ability to understand the nature and consequences of a health care decision, the ability to understand it significant benefits, risks and alternatives, and the ability to make and communicate an informed decision…"

Category[1]	Vermont	Oregon	Washington	California
"Interested person" defined	Yes. §5281(a)(6) (A)-(D)	Not defined as such	Not defined as such	Not defined
"Palliative care" defined	Yes. §5281(a)(7)	No.	No.	Not defined
"Patient" defined/AGE	Yes. "A person who is 18 years of age or older, a resident of Vermont and under the care of a physician." §5281(a)(8)	"A person who is under the care of a physician" §127.800 S1.01(9): Under §127.800 §1.01(1) An Adult must be 18 years or older	Same as Oregon §70.245.010(9) Age of Patient 18 under definition of an Adult §70.245.010(1)	Not defined as Patient: Under §443.1(a). An adult means an individual 18 years of age or older
"Physician" defined	Yes. "An individual licensed to practice medicine under 26V.S.A. chapter 23 or 33" §5281(a)(9)	Yes. A Dr of medicine or osteopathy licensed medicine by the Oregon Board of Medical Examiners §127.800 §1.01(10)	Yes. "A doctor of medicine or osteopathy licensed to practice medicine in state of Washington" §70.245.010(10)	"A doctor of medicine or osteopathy currently licensed to practice in the State" §443.1(m)
"Consulting MD" defined	No. Not defined	Yes. §127.800 §1.01(4)	Yes. §70.245.010(4)	Yes. §443.1(f)
"Medically confirmed" defined	No. Not defined per se but requires a second physician to confirm diagnosis/prognosis §5283(a)(7)	Yes. "medical opinion of the attending has been confirmed by a consulting physician who has examined the patient and the patient's relevant medical records" §127.800 §1.01(8)	Yes. Similar to Oregon §70.245.010(8).	Yes. §443.1(j)
"Terminal illness or condition" defined	Yes. "…an incurable and irreversible disease which would within reasonable medical judgment, result in the death of the patient within six months" §5281(a)(10)	Yes. "An incurable and irreversible disease that has been medically confirmed and will, with reasonable judgment, produce death within six months" §127,800 § 1.01(12)	Yes. See wording in Oregon and Vermont §70.245.010(13)	Yes. §443.1(q) "incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, result in death within six months"
Patient eligibility barred solely due to age or disability?	Not noted	Yes. §127.805 §2.01(2)	Yes. See §70.245.020(2)	No. §443.2(a)5(b)
Attending physician responsibilities specified?	Yes. §5283: 5(a)-(I)	Yes. See §127.815 §3.01	Yes. See §70.245.040	Yes. §443.5 (See entire section)

Category[1]	Vermont	Oregon	Washington	California
Confirmation of consulting physician?	Yes. §5283: 5(a)-(I)	Yes. §127.820 §302	Yes. See §70.245.050	Yes. §443.5(E)(3)
Informed decision required?	Yes. §5282	Yes. §127.800 §1.01(7)	Yes. §70.245.070	Yes. §443.5.(8) §443.1(I). Note: Request must be made by patient §443.2(c)
Standard of care	Not addressed as such but see	See §127.885 §401(7)	See §70.245.180(2)	Not addressed
Family notification required?	Not noted	Recommended. See §127.835 §3.05.	Recommended, not required. See §70.245.080	Not required but part of the process unless declines to or unable to §443.5(5)(C)
Provides written request for AID form?	Not in body of law	Yes. §127. 897, §6.01	Yes. §70.245.220	Yes. §443.11(a) Note also provides for interpreter in sections (b)(1)-(3)
Right to rescind decision?	Yes. §5283(a)(3) and (10)	Yes. See §127.845, §3.07	Yes. §70.245.090	Yes. §443.4(a)
Medical records documentation specified?	Yes. §5283(a)(14)	Yes. §127.855, §3.09	Yes. §70.245.120	Yes. §443.8
Reporting requirements?	Yes. §5283(a)(15)	Yes. §127.865, §3.11	Yes. §70.245.150	§443.19(a)-(c) Note there is also a section on the public's Right of Access SEC 2 See also §443.9(a)(b)
Physician immunity	Yes. "civil or criminal" if follows the legislation as provided §5290	Yes. §127.885, §4.01	Yes. §70.245.190	Yes. §443.14(a)-(c) Also see §443.16 (a)-(c)
Terminal patient rights	See right to information under §5282 and right to rescind §5283.12(c)	See right to rescind §127.845 §307 and right to informed consent §127.830 §3.04	See informed consent §70.245.070 and right to rescind §70.245.100	§443.4 To withdraw or rescind; §443.2(a) request an aid in dying prescription
Terminal patient friends & family protections	N/S; however, under §5284 Not subject to civil or criminal liability for being present, or for failing to prevent the act	Not specifically addressed. However, see §127.885 §40.1 no liability if present at the time patient takes medicine	Not specifically addressed but see §70.245.190(1)	Not specified per se but under §443.14 no civil liability by mere presence when qualified individual self-administers drug
Health care providers and administration of lethal dose	No duty to participate §5285(a)	No duty to participate §127.855 §3.09(4)	No duty to participate §70.245.190(1)(d)	Patient must self administer §443.1(i)

Category[1]	Vermont	Oregon	Washington	California
Health care provider protections	Protected from sanctions by their employer for acts taken, or refusal to act, per this article. §5285(b)	See §127.885 §4.01	See section §70.245.190	§443.14(b)(c)(d). Action law not reportable as unprofessional conduct etc. §443.15(a)(g) also see §443.16
Health care provider liability for negligent conduct/intentional misconduct	Remain liable, except as provided §5285 (c); see §5283(b)	Remain liable. §127.890, §4.02 (1)-(4); also see §127.995 (if not authorized)	Yes. See §70.245.200 Willful alteration/forgery coercion etc.	§443.17
Health care facility conscience clause	Can prohibit a physician from prescribing a lethal medication for a patient in their residence; written notice of such policy required. §5286	Similar to Vermont §127.855 §3.09(4)	See §70.245.190	§443.14(e)(1)(2)
Referral obligation and records transfer if you deny AID?	Not noted. However, under §5283(14)(E) attestation pat enrolled in hospice care	Yes. §127.855 §3.09(4)	Yes. §70.245.190(1)(d))	§443.14(e)(3)
Insurance	Benefits under life insurance policy cannot be denied §5287(a)	Cannot be denied benefits; nor can sale or procurement of a health, life, or accident policy be conditioned on AID. §127.875 §3.13	Yes. §70.245.170 Cannot affect the sale, procurement or issuance of any life, health, accident or annuity policy	§443.13(a)(1) Not affect life, health, or annuity policy, health care service plan contract or health benefit plan or the rate charged for a policy or plan contract and (2(b)) noted to be a natural death from the underlying disease
Wills, statutes and contracts can't be linked to AID decisions?	Not addressed	Yes. See §128.870, §3.12	Yes. See §70.245.160	§443.12(a) and (b)
Malpractice insurance	Access to it can't be restricted, and rates cannot be adjusted, §5287(b)	Not noted	Not Addressed. But see §70.245.190(b)	Not noted
Palliative sedation	No impact on its use. §5288	Not addressed	Not addressed	Not noted
Death certificate	Not addressed	Dr may sign death certificate §127.815 §3.01.(2)	Yes. §70.245.040(1)(B)(2) result of underlying illness as the cause of death	Not noted
Disposal of unused medicine	§5291	Not addressed	Yes. §70.245.140	§443.20

Category[1]	Vermont	Oregon	Washington	California
Statutory construction/ AID Not suicide, mercy killing/or homicide	§5292…"Actions taken in accordance with this chapter shall not be construed for any purpose to constitute suicide, assisted suicide, mercy killing or homicide under the law"	§127.880, §3.14…"Actions taken in accordance with ORS…shall not, for any purpose, constitute suicide, assisted suicide emrcy killing or homicide under the law"	§70.245.180(a)	§443.18. "Nothing…construed to constitute suicide, assisted suicide, homicide or elder abuse under the law"
Criminal penalties	Does not limit civil or criminal liability for gross negligence, recklessness or intentional misconduct §5283(15)(b)	1. Altering or forging a request for medications, or concealing or destroying a rescission of same which leads to a patient's death, is guilty of a Class A felony. 2. Coercing a patient to seek AID, or destroying a rescission, is a Class A felony. 3. Nothing in this article hinders further civil liability. 4. These criminal penalties do not preclude others in law. §127.890 §4.02 Also see §127.995(1)-(2)	See §70.245.200 Similar to Oregon	Yes. See §443.17(a)-(e)

Category[1]	Vermont	Oregon	Washington	California
Waiting period/oral/ written requirement	See §5283(a) (1) requires an oral request to a physician: (2) within 15 days or more a 2nd oral request: a written request signed and witnessed (3) can rescind (4) a further 48 hour wait for the physician to dispense the medicine or submit to pharmacy (12)(a)(b)(13)	§127.850 §3.08. 15 or more days must elapse between initial oral request and the writing of a prescription. §127.800 to 1 §27.897 and no less than 48 hours between written request and writing of the prescription	Under §70.245.090 requires an oral request, a written request and reiteration of the oral request. Under §70.245.110(1) At least 15 days elapse between initial oral request and writing; and (2) 48 hr. elapse between signing of written request and writing of Rx	Yes. §443.3(a) Has to "submit two oral requests, a minimum of 15 days apart, and a written request to his her attending physician. The attending physician shall directly, and not through a designee, receive all three requests…." If all provisions are complied with, including a physician checklist, and the oral requests and a written request obtained, the physician must still provide the "qualified individual" a "final attestation form, which must be filled out within 48 hours prior to the qualified individual choosing to self-administer the aid-in-dying drug" §§443.5(E)(11)(12) (there are, as in the other states, other requirements the doctor must meet)
Residency required	Yes. §5281(a)(8)	Yes. §127.860 §310 (1)-(4)	Yes. §70.245.130	Yes. §443.2(a)(3)
Consent form	Not included as part of statute	Yes. §127.897 §6.01	Yes. §70.245.220	
Severability clause?	No.	Yes. §127.895 §5.01	Yes. §70.245.902	Yes. §SEC 3
Effective date	Noted. See Sec 3 Some on passage, some in July 2016. Act signed into law May 20, 2013	March 5, 2009	Yes. §70245.903	2016

Endnote

1. Please note that some categories may be very detailed, such as informed consent requirements, physician obligations etc. Therefore, for a more in-depth analysis, one should review the entire statute.

Appendix B: Current State-by-State Citations of Proposed AID Analysis:*

States with Introduced Bills 2016	Bill Number/Intro	Title/or descriptive title
Alaska	HB 99 4/15 over to 1/16	An Act relating to the voluntary termination of life by terminally ill individuals
Arizona	SB 1136 1/16	Death With Dignity Bill
Colorado	HB16-1054/SB 1/27/15	Colorado End of Life Act
District of Columbia	B21-0038 1/14/15	Death with Dignity Act of 2015
Hawaii	SB2373 1/16	Death with Dignity Act
Iowa	SF2041 1/16	Iowa Death with Dignity Act
Kansas	HB 2150 1/28/15 rolled over 1/16	Kansas Death with Dignity Act
Maryland	HB 0404 S0418HB1021 2015	Death with Dignity Act
Massachusetts	HD 1991 1/15/15	The Compassionate Care for the Terminally Ill
Minnesota	SF1880/HF2095 S: 3/18/2015 H 3/23/2015 rolled over 1/16	Minnesota Compassionate Care Act 2015
Missouri	HB 1919 Status unk	Missouri Death With Dignity Act
Nebraska	LB 1056 1/16	Patient Choice at End of Life Act
New Hampshire	SB 426 1/8/2015	Death with Dignity descriptive
New Jersey	A 2451 2/16	Aid in Dying for the Terminally Ill Act
New York	A02129/05261/SB3685-2015/ SB5814-215Senate	New York Death with Dignity Act, (A): Patient Self- Determination Act (A): New York End of Life Options Act (S)/Patient Self Determination at End of Life Act (Senate)
Tennessee	SB/1362 3/30/2015	TBD
Utah	HB 264 2/16	End of Life Options Act
Wisconsin	AB67 SB26 3/30/2025A/2/11/2015S	Death with Dignity Bill

***This material was obtained directly from "Death with Dignity National Center, http://www.deathwithdignity.org/advocates/national updated March 2016. Note: It is not clear whether under Hawaii law that Aid in Dying is strictly prohibited. Note the website has been updated in March 2016; for current information go to http://www.deathwithdignity.org /take-action.**

The Georgia Supreme Court in F*inal Exit Network Inc. v. Georgia*, 2012 WL 360523 (Ga. Feb 6, 2012) concluded that the statute prohibiting advertising or offering to assist in the commission of a suicide was an unconstitutional restriction on free speech under the state and Federal Constitution.

The following statutes prohibit/or deal with physician assisted suicide: Arkansas Ark. Code Ann. § 5-10-106 (2007) (expressly prohibiting physician assisted suicide); Georgia Ga. Code Ann § 16-5(b),(d)(2012) (requires notification licensing board if convicted): *ibid.* Idaho code Ann. § 18-40175(a) (2011): North Dakota. N.D. Cent. Code Ann. § 12.1-16-04 (1991) (prohibiting the issuance of prescriptions for the purpose of assisted suicide) and Rhode Island: R. I. Gen. Laws §11-60-3 (prohibiting licensed health care practitioners from providing another the physical means to commit suicide) but does not prohibit medication which may lead to a patient's death as long as it is not intended to cause death... and potentially prohibited by other states under manslaughter statutes, http://euthanasia.procon.org/view.resource.php/resourceID=000132&print=true.

Appendix C: Comparison of Selected Aid in Dying Provisions in Five Countries

CATEGORY	CANADA[1 2*]	BELGIUM[3]	LUXEMBOURG[4]	NETHERLANDS[5]	SWITZERLAND[6]
Age: Adult	"Full age" Ch. II 6	Age of majority Ch II Section 3 §1	Yes. See questions and answers re: law	Yes, but see below. No longer capable of expressing will but had made a written request for termination	Not specified per se but the literature indicates that "All adults can become members of Dignitas." It also requires capacity to understand the risks etc.
Age: 16 and over	Not noted, see above	Age not specified, can be an emancipated minor: *Ibid*. above See note below.	According to the answer to question 15, neither a minor nor an adult under guardianship or trusteeship nor an incapable person may validly request euthanasia or assisted suicide. Parents can not decide on behalf of their minor child nor can guardians or trustees. (Euthanasia and Assisted Suicide Law of 16 March 2009, 25 questions 25 answers.)	Ch II Art2 2 or if age 16-18 and has reasonable understanding of interest after parent nor parents/guardian involved in decision. *Ibid*. 3	
Age: 12>16	Not noted, see above	NOTE: Under new legislation signed by King Phillipe March 2014 can be any age		With reasonable understanding of interests, must have parent or parents/guardian authority /agreement (*ibid*. 4)	

*See fn 1-2. This represents an act by the Quebec National Assembly. However, on April 14, 2016 Canada's Prime Minister announced new legislation on Assisted Death. Key provisions are: the patient must be 18 or older; a Canadian citizen; and does not include persons with psychiatric problems. *USA Today* April 14, 2016.

CATEGORY	CANADA[1 2*]	BELGIUM[3]	LUXEMBOURG[4]	NETHERLANDS[5]	SWITZERLAND[6]
Age: Under 12	Not noted see above	NOTE: under new legislation signed by King Phillipe March 2014 can be any age if terminally ill whose death is imminent and who suffer greatly (Belgium extends "Right to Die" to Terminally Ill Children, Reuters Thu Feb 13, 2015 Robert-Jan Bartunek)	No		
Condition: Terminal	Not noted see below	Not noted but expected to die in the near future See §3 Ch II Sec 3	"Patient is in a terminal medical situation and shows constant and unbearable physical or mental suffering without prospects of improvement, resulting from an accidental or pathological disorder" Chapter II Art 2 -1 3)	Not required	Not Required, noted to be "medically diagnosed, hopeless or incurable illness, unbearable pain or unendurable disabilities," Dignitas to Live and die with Dignity publication.

CATEGORY	CANADA[1] [2*]	BELGIUM[3]	LUXEMBOURG[4]	NETHERLANDS[5]	SWITZERLAND[6]
Condition: Physical	Requires: "1. Able to give consent: 2. Suffer from an incurable serious illness: 3. Suffer from constant and unbearable physical or psychological pain which cannot be relieved in a manner the person deems tolerable" Div II 26	Patient: "in a medically futile condition of constant and unbearable physical or mental suffering that can not be alleviated resulting from a serious and incurable disease caused by illness or accident," Ch II, Sec 3 §1. However, if the patient is not expected to die in the near future, patient must be in "constant and unbearable physical or mental suffering that cannot be alleviated" §3 (1) Ch.II Sec. 3. See also The Guardian, Fri 19, June 2015 indicating the children must be in "a hopeless medical situation of constant and unbearable suffering that cannot be eased and which will cause death in the short term." Requires psychiatric or psychologist consent as well as parental approval.	See above. Yes	Suffering lasting and unbearable/no other solution	Note that all requests are reviewed by a physician based on medical records supplied by the patient. Requires two doctor consultations 1.10.2.5.2.2
Condition: Psychiatric	See above	See above	See above	Yes[7]	See above
Resident	Not noted, assumed required	Not noted assumed required	Not required under law but in answer to the 25 questions and answers, the law does require a close relationship with the doctor and been under treatment in order for the condition of the patient to be known.	Not noted, assumed required	Not required

CATEGORY	CANADA[1 2*]	BELGIUM[3]	LUXEMBOURG[4]	NETHERLANDS[5]	SWITZERLAND[6]
Consult required	Yes	Yes. *Ibid* §2 .3) Note: if pt not expected to die, then a second consult must be by a psychiatrist or specialist in the order in question §3 (1) Ch.II Sec3	Yes. Ch. II Art 2-2 3	Yes. Chap II Art2(e)	Yes. See above, 2 doctors must approve
Specific waiting period	Not noted, but indirectly due to the provisions required to be completed by the doctor	Ch. II Sec 3 § 2 2) No, but MD must have had "several conversations with patient over a reasonable period of time" *ibid* above 2) Unless the patient falls under the section "where the patient is not expected to die in the near future, then at least one month between the patient's written request and the act of euthanasia"	Only in as much as there must be conversations with the patient, the consultation and the written requests.	Not noted, only as provided by the provisions the doctor must complete.	No specific waiting periods but according to Dignitas it takes about 3-4 months (of those who do request AID only about 14% opt to actually use it). It then takes about 3-4 weeks following the preliminary assessment. (Dignitas, How Dignitas Works, www.dignitas.ch/3d edition/May 2014 at 1.2-1.6)
Written request	Yes. Note the request must come from the patient but document can be signed by patient, or if incapable, by a third adult person or member of team caring for the patient Div II 26. Note: can do that in an advance directive	Yes. see above §4 of Ch II, Sec 3 Can be through an advanced directive in writing and witnessed if pt suffers from a serious illness and incurable disorder caused by illness or accident Ch III Sec 4 § 1 (there is a 5 year time limit prior to loss of the ability to patient unable to express him/herself)	Yes. Chapter II Art 2 7). If the patient is unable to draft and sign the request, noted in writing by an adult of the person's choosing[8]	See above	Yes. Person becomes member of Dignitas, and then receives patient's instructions/advance directives to complete etc. Request signed by interested person, or in rare circumstances if person can't sign a person designated to do so on the person's behalf. See above citation at 1.6.1
Reporting requirement	Yes	Yes	Yes. Also see Chapter V establish the National Commission for Control and Assessment	Yes	Oversight by Secretary General

CATEGORY	CANADA[1] [2*]	BELGIUM[3]	LUXEMBOURG[4]	NETHERLANDS[5]	SWITZERLAND[6]
Aid in Dying drug administered by	The Physician Div II 29	Unclear if this only applies to a physician	If by the doctor, must determine whether the end of life provisions have been registered with the Commission for Control and Assessment	By a physician who has terminated a life or assisted in a suicide Ch II Art 2 1 (f)	May not be performed by a physician, the patient must be able to self administer[9]
Palliative care noted	Yes. Proposed legislation includes Palliative care hospice Chap. 3 §2.	Must inform re: palliative care options Ch II Sec 3 §2 1	Yes. Also includes a guide to Palliative Care	Not noted	Yes, emphasized in Dignitas material

Endnotes

1. In 2015 the Supreme Court of Canada in Carter (et al) *v.* Canada (Attorney General) (et al.), 2015 SCC 5, [2015] 1 S.C.R. 331 held that: "the prohibition on physician-assisted dying is void insofar as it deprives a competent adult of such assistance where (1) the person affected clearly consents to the termination of life; and (2) the person has a grievous and irremediable medical condition (including an illness, disease or disability) that causes enduring suffering that is intolerable to the individual in the circumstances of his or her condition the prohibition against physician assisted suicide under its penal code is unconstitutional."
2. The Quebec National Assembly enacted Bill 52 "An Act Respecting end-of-life care." The material noted is from that Act. The act specifies "end-of-life care" as "palliative care provided to persons at the end of their lives, including terminal palliative sedation and medical aid in dying." Title II Chapter I 3(3) Act applies to all institutions as defined within the act. The act also provides that a nurse or physician may provide end of life care to a patient if "in association with the local authority of the territory where the facility is situated," chap II 17. This material only applies to that act and therefore may not reflect the law of Canada.
3. The Belgian Act on Euthanasia of May 28, 2002.
4. On March 16, 2009 the Luxembourg legislators enacted two important laws, one relating to Palliative care, advance instructions and end of life accompaniment, and the other the law on euthanasia and assisted suicide. Ministere de la Sante, "Euthanasia and assisted suicide, 25 questions, 25 answers.
5. The Termination of Life on Request and Assisted Suicide Act (April 2002) Definition of Assisted Suicide: "Intentionally assisting in a suicide of another person or procuring for that other person the means (to commit suicide). Permitted where a doctor meets the criteria
6. Switzerland does not have a statute regulating assistance in dying. Article 114 of its penal code prohibits killing on request; however, Article 115 of the Swiss Penal Code's prohibition against assisted suicide has a clause: :whoever from selfish motives, induces another person to commit suicide or aids him in it shall be confined to the penitentiary….." This has been interpreted to exclude persons who help someone under the law provided they are not acting out of self interest or gain. This is the basis for Aid in Dying in Switzerland. The information provided above is based on literature from Dignitas, "To Live with Dignity to Die with Dignity." Switzerland is the only country to allow foreigners to avail themselves of their aid in dying assistance. Attempts to put tighter controls on this practice were rejected by the Swiss Parliament in 2012, the rules in effect by organizations who provided this assistance, e.g. Exit and Dignitas, worked and protected individual freedoms. Swiss parliament rejects tighter controls on assisted suicide, Reuters Wed. Sept. 26, 2012.
7. Also see mention of this under FAQ Euthanasia published by the Netherlands Ministry of Foreign Affairs, answer to question number 12.
8. Any adult and capable person may make end-of life provisions in writing (advance directive) and the circumstances/conditions for "euthanasia" where a doctor documents the patients severe and incurable condition, the patient is unconscious and the situation is irreversible (Ch III Art 4.-1). In addition the person may appoint an adult to speak on the patient's behalf if or when the condition above is present. The document must be in writing and witnessed where the person is physically unable to draft the document. Ch III Art 4-1 and 2. Note the document must be registered with the National Commission for Control and Assessment.
9. If the patient is unable to swallow, e.g., has a stomach tube or a PEG, or a pre-existing intravenous drip, and if patient is able to press the plunger of a syringe (sans needle) unaided, the medication will be administered in that manner. If the person is unable to do so unaided, Dignitas can provide an "easy-to-handle remote control" which the person can activate with a minimal amount of movement to start the attached pump. If the person is breathing through an artificial device the patient must also activate the "Power Terminator" to shut down the artificial device. 1.11.4.2.

   In a separate correspondence with Dignitas, the issue of the demented patient was raised. The response was with a patient with Alzheimer's the diagnosis implies that it is progressive and inevitable. Where the patient with dementia knows "who he is and what he wants" (legally lucid) AID is possible providing it can be shown the patient is in the "lucid phase" and would be subject to a "special medical report" by a neurologist/psychiatrist/specialist in geriatrics confirming the diagnosis and has sufficient capacity to make a legal and rational decision.

Appendix D: Aid in Dying Bills Currently Before the New York State Senate and Assembly March 2016*

Category	Assembly Bill 5261C, "The Patient Self-Determination Act." Introduced by Paulin, Dinowitz, Galef, Zebrowski, Gottfried, Blake; also see Senate Bill 5814, Sponsor (Bonacic)	Senate Bill S03685 "New York End of Life Options Act": Assembly A02129A. Introduced by Rosenthal: Gottfried, Steck, Hooper. Also see Senate S3685, Sponsor Savino, Hoylman
1. Section of law created	**PHL 28-F**	**PHL 29-CCCC**
2. Patient must have capacity	Yes. §2899-d. 3	Yes. §2994-aaa 4
3. "Bona fide" doctor-patient relationship required	Yes. Attending who has primary responsibility for care and treatment §2899-d. 2	Has primary responsibility for care and treatment of patient's terminal condition §2994-aaa 3
4. "Health care facility" defined	Yes. §2899-d. 5	Included in §2994-aaa 7
5. "Health care provider" defined	Yes. §2899-d. 6	Yes. §2994-aaa 7
6. Defines "aid-in-dying medication?"	Yes. §2899-d. 8	Yes. §2994-aaa 2
7. "Impaired judgment" defined	Yes. §2899-d. 7	Not defined
8. "Interested person" defined	No	Not defined
9. "Palliative care" defined	Yes. §2899-d. 9	Not defined
10. "Patient" defined/AGE	Yes. A person who is twenty one years of age or older, § 2899-d 10 (a resident of the state and under care of a physician)	"Adult"…an individual who is eighteen years of age or older" §2994-aaa 1
11. "Physician" defined	Yes. Licensed to practice in New York State §2899-d. 11	Yes. §2994-aaa 10
12. "Consulting MD"	See §2899-d. 4 Can be a licensed psychiatrist or psychologist (under counseling. There is no requirement for a 2nd opinion as to terminal illness).	Yes. §2994-aaa 5 A physician who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding an individual's illness.

*Please note the citations were those in the most recent bills obtained at the time the *Journal* went to press but are subject to change as these they move through the legislative process.

CATEGORY	PHL 28F	PHL 29-CCCC
13. "Medically confirmed" defined	Not defined, but see §2899-e	Yes. 2994-aaa 9
14. "Terminal illness or condition" defined	Yes. §2899-d 12 "…an illness or condition which can reasonably be expected to cause death within six months, whether or not treatment is provided"	§2994-aaa 13 Yes..."an incurable and irreversible illness that has been medically confirmed and will, within reasonable judgment, result in death within six months"
15. Patient eligibility not barred solely due to age or disability?	Yes. §2899-e 2	Yes. §2994-bbb 2
16. Attending physician responsibilities specified?	Yes. §2899-g	Yes. See §2994-eee
17. Confirmation by consulting physician?	Not noted as to 2nd opinion Consulting as to whether person is depressed etc. See §2899-h	Yes. §2994-ggg
18. Informed decision required?	Yes. Under capacity §2899-d. 3 Also see §2899-f (written) and §2899-i oral documentation in record	Yes. §2994-iii and §2994-aaa(8)
19. Standard of care	Not defined	Yes. §2994-kkk
20. Family notification required?	Not noted	Not noted
21. Provides written request for AID form?	No form provided	Yes. §2994-jjj
22. Right to rescind decision?	Not noted per se but implied	Yes. §2994-ddd and §2994-eee(8)
23. Medical records documentation specified?	Yes. §2899-i, also see 2899-g(e)	Not noted, implied
24. Reporting requirements?	Yes. §2899-o	No
25. Physician immunity	§2899-k	Yes. §2994-nnn
26. Terminal patient rights	See §2899-k 3(c) to be transferred under the private health care facility provision.	See right to rescind §2994-ddd Also informed consent: §2994-iii and right to request aid in dying medicine §2994-bbb
27. Terminal patient friends and family protection	Yes. See §2899-k and l (unclear if this is a blanket protection for patients/family)	See §2994-nnn 2 as to patient protection
28. Health care providers and administration of lethal dose	No duty of a private facility to participate. §2899-k 3 Also see 2899-k-4 re: health care facility Note: must be self administered by patient §2899-k-4	No duty to participate, patient must self administer §2994-nnn
29. Health care provider protections	No duty to participate. See above §2899-k	No duty to participate §2994-nnn 4

CATEGORY	PHL 28F	PHL 29-CCCC
30. Health care provider liability for negligent conduct/intentional misconduct		Yes. §2994-ppp
31. Health care facility conscience clause	See §2899-k	Yes. §2994-nnn 4 see also §2994-ooo
32. Referral obligation and records transfer if you deny AID?	See §2899-k as to the facility	Yes. §2994.nnn 4
33. Insurance	Benefits under life insurance policy cannot be denied §2899-l	Yes. §2994-mmm (deals with life, health, annuity)
34. Wills, statutes and contracts can't be linked to AID decisions?	Yes. See §2899-l 3(a)	Yes. See §2994-111
35. Malpractice insurance	Yes. §2899-l 6	Not addressed per se but see 2994-nnn 2
36. Palliative sedation	Not addressed See definition §2899-d 9	Not addressed
37. Death certificate	Yes. §2899-n	Yes. §2994-fff
38. Disposal of unused medicine	Yes. §2899-m	Not addressed
39. Statutory construction/AID Not suicide, mercy killing/or homicide	Yes. §2899-l	Not addressed per se but implied §2994-nnn
40. Criminal penalties	Not noted	Yes. §2994-ppp
41. Waiting period/oral/written requirement	Not noted	Not noted
42. Residency required	Yes. §2899-J	Not noted
43. Consent form	Not included as part of statute	Yes. §2994-jjj
44. Severability clause?	Yes. §2899-p	Yes. §2994-qqq
45. Effective date	Yes. §3 Immediately	Yes. §3

Removing a Patient from Your Practice: A Physician's Legal and Ethical Responsibilities

By Eve Green Koopersmith and Samantha N. Tomey

A myriad of situations might bring about a doctor's discharge of a patient and termination of the physician-patient relationship. The physician might move, leave the insurance network, or determine that the patient needs the care of a different specialist. The physician also might want to end the relationship due to inappropriate patient conduct such as disruptive or violent behavior; repeatedly missing appointments and/or nonadherence to treatment plans; or refusal to pay for medical services.

Avoid discrimination

Physicians must avoid discriminatory practices that are prohibited by law, including refusing to treat or discharge a patient based upon the patient's race, nationality, religion, age, sex or sexual orientation.

What defines patient abandonment?

Patient abandonment generally is defined as the unilateral severance by the physician of the physician-patient relationship, without giving the patient sufficient advance notice to obtain the services of another practitioner, and at a time when the patient still requires medical attention.

While individual states have their own definitions of patient abandonment, the concept of reasonable notice is common to most jurisdictions. In New York, for example, the following is considered professional misconduct: "Abandoning or neglecting a patient under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care, or abandoning a professional employment by a group practice, hospital clinic, or other healthcare facility, without reasonable notice and under circumstances which seriously impair the delivery of professional care to patients or clients."

Significant liability, fines and/or restrictions or loss of the physician's professional license can result. In states such as California, Texas and Washington, D.C., patient abandonment is addressed in the medical malpractice laws, and significant liability may result if the physician abandons a patient without sufficient notice in advance of termination and injury results.

While some jurisdictions require a specific amount of time for providing notice to the patient, others simply allude to "reasonable" notice. In the absence of a specific legal notice period, 30 days generally is considered a reasonable amount of time to provide adequate notice to the patient in advance of termination.

The physician also should check his or her managed care contracts, which may include specific requirements concerning the termination of covered patients.

Most importantly, during the "notice" period, the physician must continue treating the patient and remain available for office visits.

Practical tips

The following strategies can help protect physicians from liability and accusations of patient abandonment:

- Provide written notice

The physician should issue a written termination letter to the patient prior to the effective date of termination. The letter should clearly state a termination date (we suggest 30 days in advance) and the reason for termination.

- Include a list of suitable alternative providers

We suggest that the letter contain a list of alternative healthcare providers in the area and if appropriate, referral to the patient's insurance network.

In addition, physicians can provide the patient with contact information from the local and state medical societies, which can be resources for finding a provider that fits their needs.

- Time the termination properly

Avoid withdrawing from treating the patient when the patient is in medical crisis, unless the patient requires the services of a different specialist and arrangements are made for transferring the patient's care to such specialist.

Continue providing effective treatment during the intermediate period following issuance of the termination letter and prior to the effective date of termination. Advise all office staff members that the patient is still welcome to schedule an office visit and/or arrange for services before the effective date of termination.

- Examine managed care contracts and communicate with health plans

If the physician is a participating provider in a managed care network in which the patient is covered, review the managed care agreement for specifications concerning termination of the physician-patient relationship. Some managed care contracts contain language requiring suitable justification for termination as well as specific notice requirements.

The best strategy is to contact the payer, explain the situation, and ensure everything is done properly per the contract to prevent problems later.

- Provide access to medical records

Offer to send a copy of the discharged patient's medical records to the patient's new doctor. Numerous states have laws which require that records not be withheld solely because of a patient's inability or refusal to pay.

- Communicate with everyone else in the practice

Be sure to apprise all physicians and office staff members of the termination to avoid inadvertent reestablishment of the physician-patient relationship.

For example, a receptionist or appointment scheduler who is unaware that a patient has been issued a withdrawal letter might schedule a new appointment for that patient following the termination date. In some jurisdictions, this has been construed as renewing the physician-patient relationship, regardless of whether such a result was intended.

Finally, the treating physician should always be the one who makes the determination to terminate the physician-patient relationship rather than another staff member. By remaining personally involved, the physician can ensure that all of the above concerns are addressed appropriately.

Eve Green Koopersmith, JD, is a partner, and Samantha N. Tomey, JD, is an associate with Garfunkel Wild, P.C., in Great Neck, New York.

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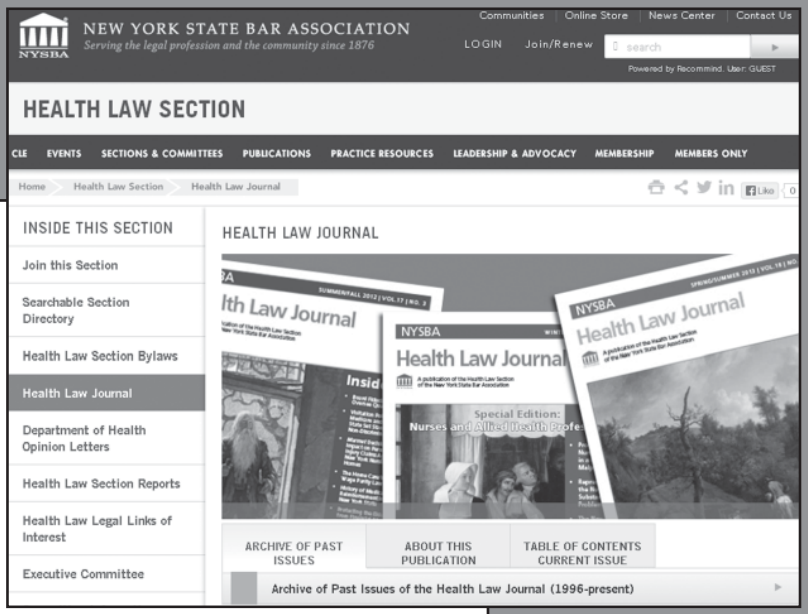

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Patients, Providers, Projects, Incentive Payments and Conflicts: The Role of Mediation and Arbitration in Meeting DSRIP PPS Objectives

By Joan Hogarth

A sense of urgency is gripping New York healthcare providers as they prepare to transform New York's healthcare delivery system, a transformation of the kind we have not seen in many years. It is the Delivery System Reform Incentive Payment ("DSRIP") Program, a Medicaid supplemental payment program, approved under Section 1115 waiver of the Social Security Act. Aimed at motivating provider-led efforts to transform the delivery of care to Medicaid beneficiaries, improve quality of care, and to promote population health, New York's DSRIP has a large incentive, i.e. $6.42 billion, to be distributed over five years. Recipients will be the 25 qualified Performing Provider Systems (PPSs)[1] comprised of healthcare providers and community-based organizations coming together to create a model for the State's integrated delivery system. They will be implementing anywhere from 5 to 11 quality improvement projects for the millions of Medicaid beneficiaries in the State. To understand the urgency of the effort, contemplate (i) a five-year deadline within which to demonstrate the program's effectiveness and ability to be a high-performing integrated delivery system; (ii) 25 PPSs caring for approximately 5.6 million targeted beneficiaries across the State; and (iii) 64,099 unique providers, managing 258 DSRIP projects for quality improvement in healthcare.[2]

Yet DSRIP is not unique to New York.[3] What is special about the State's program is that it comes after many others; and it attempts to take the best practices from those other programs to deliver a model for the nation, and certainly for other provider systems (Medicare and commercial) in the State. The terms and conditions that New York and CMS negotiated are the source of the intense efforts. For one, New York was able to keep the federal portion of the Medicaid savings that resulted from the earlier efforts of the Medicaid Redesign Team (MRT), and to use those savings to reinvest into Medicaid reform activities, such as DSRIP. In exchange, the State had to demonstrate a program that would be markedly improved over other integrated delivery systems. To effectuate the program, PPSs are being motivated by the $6.42 billion incentive payments. The State further committed to take full responsibility for the success of the program and to provide CMS with demonstrable performance feedback as the program progresses. The efforts to galvanize the diverse group of traditional and non-traditional providers that constitute the PPSs are sure to create challenges within the various entities themselves, within the PPSs, and across the PPSs.

This article summarizes the very ambitious commitments that have been made by the State and subsequently by the PPS and their participating providers. It highlights some of the challenges the PPSs could face in implementing and operating for the next five years. It discusses the planning documents, which require conflict resolution processes in anticipation of challenges and conflicts. Finally, the article suggests the use of formalized conflict resolution processes to contribute to a successful DSRIP PPS demonstration program.

The Commitments Creating the Intensity

The April 2014 waiver agreement between New York's Department of Health (DOH) and CMS specifically required the State to improve the care of Medicaid beneficiaries, manage Medicaid costs and improve population health. It would do so through the collaboration of providers in healthcare and in community-based organizations. Further, New York committed that it would (i) be responsible for the statewide success of the program (or lose the DSRIP funding); (ii) provide CMS periodic reports on performance metrics; (iii) leverage the use of capitated managed care payment systems as compared with the more expensive fee-for-service payments of today; and (iv) hold Medicaid spending to targeted levels where the cost of Medicaid in New York was approximately $59 billion in 2014 and growing.[4]

The PPSs and associated providers will be equally challenged over the next five years if one is to rely on the application responses[5] and master agreements[6] as indicators of the work to be done. Their commitments include:

- Reduce avoidable hospitalizations by 25%
- Contribute to the transformation of the State's healthcare delivery system
- Shift business models from inpatient and reactive care to outpatient and preventative care
- Integrate the community social services organizations into the program
- Commit resources to technology updates to facilitate data sharing for population health while complying with HIPAA and state confidentiality requirements
- Collaborate on, and comply with, the PPS clinical protocols

- Contract with managed care organizations
- Manage workforce shifts and re-balancing
- Report on measurable outcomes for clinical integration projects
- Be accessible and cooperative on audits from the lead PPS, OIG or CMS

The participating providers must remain cohesive to achieve the commitments and to demonstrate the characteristics of high-performing teams. The concept of the "high-performing" teams originated in psychology studies of group development. Before experiencing "high performance" the group must go through three other stages—"forming, "storming" and "norming."[7] "Storming" is the characterization for the stage in which the DSRIP PPS currently is as the lead provider attempts to create and maintain a cohesive group of diverse providers for 60 months while providing encouraging reports to the Project Approval and Oversight Panel (PAOP). Even the monetary incentives will not be sufficient to prevent the inevitable disputes as they manage the ostensible conflicting goals of delivering quality care while reducing costs. Moreover, while participating in DSRIP, providers will continue to compete in the Medicare and commercial payor environment. The PPS will need processes that foster collaboration, trust and cooperation in this kind of environment. The starting point is the executed master agreements and other arrangements that detail the terms and conditions, the partners' scope and responsibilities for the next five years of operations. To achieve the stated goal, more will be required than monitoring by the PAOP and DOH.

Role of Governance in Conflict Resolution

"An effective governance model is key to building a well-integrated and high-functioning DSRIP PPS network. The PPS must include a detailed description of how the PPS will be governed and how the PPS system will progressively advance from a group of affiliated providers to a high performing integrated delivery system…."[8]

Clearly governance has a role to play in managing the PPSs to become high-performing integrated delivery systems. And in that process is the task of guiding them through the "storming" phase of development. That means governing in a manner that instills trust, fosters teamwork, demonstrates transparency and ensures collaboration and engagement within and across the provider spectrum. The governance section of the PPS application required responses that demonstrated substantive structures and processes to maintain and move the collaborations forward. For example:

- How will the governing body ensure participation by representatives of the diverse array of providers in the PPS? Will they be engaged in the process, e.g. through the use of Project Advisory Committees (PAC) or some other vehicle?
- What types of critical support functions will be in place—i.e., operations, compliance, workforce, technology and finance structures?
- What types of oversight will there be for participating providers, e.g., performance objectives dealing with low performers, and sanctions?
- How will the governing body manage conflicts, e.g., policies and procedures, processes?

Storming in DSRIP PPS

If one subscribes to the theory related to group development, then "storming" is an inevitable stage for the DSRIP PPS. Here in New York, the characteristics of the "storming" phase are further compounded by the heightened sense of urgency for the program's success, i.e., meeting deadlines, reducing costs, being grilled by the PAOP, and being showcased to the nation. Thus the governing body must ensure that the expected disruptions are kept to a minimum and do not impact on the operations.

Take, for example, the rift that occurred between three IPAs, on one hand, and a DSRIP PPS, on the other. It was reported by *Crain's Health Pulse* that the dispute arose because the IPAs felt they were being left out of substantive discussions.[9] For them the dispute arose during the attribution phase.[10] Patients were not affected because the parties were in the early stages of the process. However, the PPS's finances were impacted as patients were removed. If this incident had occurred later in the program, the results could have been different, leading to patient confusion and perhaps loss of funding at the State level because the PPS' performance was ineffective. Certainly, there would be loss of incentives at the PPS level.

Other Possible Conflicts

- A community-based social service center has the capacity and capability to be engaged in nutritional and diabetes education, to name a few. The PPS leadership fails to recognize this and leaves the community-based organization (CBO) out of the PPS's substantive discussions. The CBO is very concerned as it sees itself as the so-called "last mile" to the patient. The CBO seeks to have its voice heard within the governing body, with little success. It decides to take more formal action because the master agreement does not restrict it from doing so.
- When a conflict arises between physicians regarding the use of a specific protocol, the physician expresses resentment for being relegated to working with a team whose ideas are diametrically opposed to his. A conflict simmers into a major dispute that

is addressed through an internal escalation process. It eventually reaches the Board or a designated committee of the Board. The physician still is not satisfied and is no longer trusting of the in-house conflict resolution process. He threatens further action. Safety and quality of care for the patients along with incentive payments are at issue. Additionally, the physician faces a potential breach of the participating provider agreement.

- A clinic alleges that the PPS owes it $125,000 in incentive payments, payments that will not be forthcoming because of an administrative snafu. The internal processes have yet to address the financially challenged clinic's concerns. Its agreement gives it the option of using internal mediation to settle the dispute. The clinic, not trusting the internal process, unilaterally decides to forgo it and to take the issue to court.
- A skilled nursing facility (SNF), with developing EMR, finds itself on the fringes of the referrals from the hospitals in the hospital-led PPS. It does not have sufficient funds to accelerate the development of its EMR. Having received no referrals and with a drop in census, the SNF's financial stability is affected.
- A home care agency, providing care to patients in the PPS, fails to follow the PPS procedures for encrypting new computers it had purchased. Two of the computers were stolen with protected health information for over 1,000 patients. The breach is reported to the OCR which sanctions the home care agency. The agency is also sanctioned by the PPS. The agency thinks that it is unfair and seeks to appeal the PPS sanction in the courts.
- Unionized staff are organizing a protest because certain workforce re-structuring activities have created major concerns that some jobs are being re-labeled to eliminate union positions. Under normal circumstances, conflicts involving frontline staff can be especially devastating on the delivery of care unless the issues are resolved rapidly. Now, the need for a resolution is more urgent in order to share in the incentive payouts.[11]
- A low-performing provider fails to meet the objectives of a clinical project. A high-performing provider is denied DSRIP incentive payments because of it. The PPS gets no funds despite the efforts of everyone.
- A participating provider fails to use the DSRIP funds for its designated use. The lead PPS investigates and decides to remove the provider from the program. The PPS provider is displaced and sues.
- Several PPS providers have failed to timely report the performance measurements to the lead PPS. Despite several outreach attempts the reports are not forthcoming. The providers are sanctioned. They feel that they were not given an opportunity to explain the circumstances of their inability to produce reports.
- A provider is being investigated by the OIG for providing unnecessary services. The investigation and outcome are not likely to affect the PPS. But in a preemptive move, the lead provider terminates the relationship with the offending provider.

Resolving Conflicts in High-Performing DSRIP PPSs

Healthcare providers are accustomed to conflicts and have been guided to finding approaches to resolve them. Indeed, the Joint Commission updated its Leadership standards for hospitals to put processes in place that (i) would result in the development of a conflict management process; (ii) have skilled individuals to assist in its implementation; and (iii) have a process that is prepared to address the conflict immediately as it arises.[12] DSRIP PPSs are no exception to conflicts and are expected to experience some. It is with this expectation that the PPSs were required to identify ways by which they would resolve such conflicts. An audit of their responses reveals numerous approaches running the gamut of conflict resolution techniques. They include (i) using veto power; (ii) consulting with regulatory bodies such as DOH; (iii) relying on open discussions among the disputants; (iv) relying on majority voting; (v) referring the conflict to the PPS lead for the ultimate decision; (vi) using committees; (vii) having discussions; (viii) negotiating; (ix) deferring to legally necessary actions; and (x) mediating the dispute.[13]

These techniques could be strengthened by incorporating structured conflict resolution approaches such as those used by organizations in other industry segments. The structured conflict resolution approaches could be instructive for the DSRIP PPS and they acknowledge the appropriate use of litigation but rely, in the first instance, on alternative dispute resolution to settle the conflicts. They include effective conflict resolution policies and procedures outlining the conflict resolution process; training and education to facilitate discussions and negotiations; ongoing collaboration between legal and operations to avert rapid escalation of tensions to lawsuits; and pre-determined triggering events that lead to the consideration of various conflict resolution alternatives such as mediation and arbitration.[14]

What Is Mediation?

Mediation is defined as a non-adversarial process used for resolving disputes where the parties are committed to addressing the issues for continued working relationships. Mediation utilizes the services of a trained

third party (a neutral or the mediator) who helps the parties to negotiate an agreement. The trained mediator could reside within the DSRIP or be appointed from any one of the several ADR service providers that are available.[15] The terms of the mediation could be negotiated in the master service agreements before the dispute arises. Pre-dispute clauses are preferable but certainly terms and conditions of a mediation may be developed after a dispute arises. The DSRIP PPS would be well-positioned for rapid action if there are pre-dispute not post-dispute clauses.

Several known characteristics of mediation make it well-suited for DSRIP. For example: Parties in the mediation sessions are in control of the outcome. It is self-generated, usually because internal negotiations may have been started but reached an impasse. Only the involved parties are engaged in the process. The governing body does not have to be involved in the decision making at this level. The mediator simply facilitates the discussion of those directly involved. In DSRIP, this alternative approach would work to stem the disruption of a project, thereby ensuring incentive payments and measureable outcomes of care.

Another of the benefits of mediation is that it costs less than litigation. Litigation costs are incurred through the extensive use of discovery or the length of time that a case takes from the first filing to a judgment. Mediation would not include discovery and the issue could be resolved as quickly as the parties desire, avoiding the loss of incentive payments or, worse yet, loss of State funds from CMS because a project is incomplete. Further, because mediation is confidential, the PPS could avert a viral dispute that could lead to the unraveling of the project along with associated projects that may be linked with the same provider. As an added benefit, if proprietary information is shared or if protected health information is part of the discussion, they will be deemed confidential.

As an added benefit, if proprietary information is shared or if protected health information is part of the discussion, they will be deemed confidential.

Arbitration

On the other hand, to the far right of the ADR continuum, is arbitration. It is a private adjudicative process that allows an impartial independent arbitrator or a panel of arbitrators to decide the resolution to the dispute. The arbitrator is usually an attorney, trained in arbitration skills and with the expertise of the industry in which she provides services. As in mediation, the DSRIP PPS could utilize the master agreement to specify the terms and conditions of the arbitration process before the dispute arises. Details of the process could also be specified pre-dispute. Such details could include: the numbers of arbitrators to resolve the dispute; the scope of authority afforded the arbitrator; the length of the process from filing the claim to an award; the length of time spent on document requests or depositions; the type of documents to be exchanged; whether or not "time is of the essence" for issuing an award; the venue; and the specific timelines for filings and hearings.

While the arbitrator is not a judge, she usually is guided by similar procedures and ethical considerations as would a judge, but in a less formal manner. This creates a forum that is typically less adversarial than that of the courtroom. In addition, arbitration proceedings are confidential and decisions are not generally published. Despite the resemblance to litigation, the arbitration process is considerably shorter than a court hearing—a necessary requirement for DSRIP given the short timeframe for the demonstration project.

Conclusion

As participating providers reflect on the role they must play to ensure the success of the DSRIP PPS, they would find that the less conflict they have the more they could expect to accomplish. If that is a goal of the DSRIP participants, then serious consideration must be given to building in mediation and arbitration as a dispute resolution mechanism in lieu of litigation. There is little doubt that conflicts will occur. To avoid being reactive to these conflicts, there should be a comprehensive set of policies and processes that have been shared with the governing body, the workforce and across the PPS. Both the lead PPS and representation from the participating providers and other interested parties should negotiate the terms and conditions, the process and the clauses to ensure that the process will work at the time it is needed. This is a function for operations and legal to ensure that litigation is kept to a minimum, if not avoided, during the five years and that the issues are satisfactorily resolved for showcasing the New York PPS model.

Endnotes

1. PPSs are defined as an array of entities which contain public and/or safety net hospitals collaborating on DSRIP projects. Safety net providers are those who care for the underserved and vulnerable populations in the State.
2. For more statistics, read the report prepared by New York State's Office of Budget and Policy Analysis entitled *Medicaid in New York: The Continuing Challenge to Improve Care and Control Costs,* March 2015.
3. DSRIP has been established in Texas, New Jersey, Massachusetts, Kansas, New Mexico, and California, with varying degrees of success.
4. See Medicaid and Chip Payment and Access Commission's (MACPAC) *Report to Congress, June 2015.*
5. Applications reviewed at http://www.health.ny.gov/health_care/medicaid/redesign/dsrip/pps_applications/, last accessed 10/29/15.
6. Each PPS must have signed master agreements with the participating partners obligating them to the requirements of the application responses.

7. Bruce Tuckman introduced the four stages of group development in the study of group dynamics. The theory was first published in 1965.
8. See, description in Section 2.0 of the Governance Section of the PPS application.
9. *Crain's Health Pulse,* April 22, 2015.
10. Attribution is defined as a formula used to determine how a population is assigned to a PPS responsible for the care of that population and done in such a manner that a beneficiary is assigned to only one PPS.
11. The writer acknowledges the existence of bargained-for agreements which include arbitration clauses.
12. See the Joint Commission's standard LD.02.04.01 where the hospital manages conflict between the leadership groups to protect the quality and safety of care.
13. See Applicants' responses to Process 6 in Section 2.2 Governance Processes.
14. See the 21st Century ADR Pledges at the Conflict Prevention and Resolution (CPR) website, http://www.cpradr.org.
15. The American Health Lawyers Association (AHLA) and the American Arbitration Association (AAA) are two such administrators that maintain panels of mediators as well as arbitrators.

Joan Hogarth is an attorney, arbitrator and mediator with a small law practice that focuses on Medicare/Medicaid regulatory, compliance and HIPAA issues. She sits on the American Health Lawyers (AHLA) and FINRA's panel of neutrals. Ms. Hogarth is a member of the NYSBA Dispute Resolution and Health Law sections; and edits the Federal Bar Association's (FBA) Alternative Dispute Resolution (ADR) magazine—*The Resolver.* She has mediated and arbitrated over 100 cases in the past 10 years.

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SECOND DEPARTMENT

Medicare Revalidations: Improvements and Cautions

By Carolyn Jacoby Gabbay, Lindsay Maleson, Kristen Marotta

New screening requirements under the Affordable Care Act (ACA) require all health care providers and suppliers to revalidate their Medicare enrollment information periodically so that the Centers for Medicare and Medicaid Services (CMS) has current and accurate information. If the required revalidation is not filed on time, Medicare enrollment may be deactivated and payments will cease.

All providers and suppliers need to revalidate their Medicare enrollment information under new screening requirements imposed by Section 6401(a) of the Affordable Care Act (ACA), as set forth in 42 CFR §424.515. This new revalidation requirement is in addition to the ongoing obligation for providers and suppliers to keep their enrollment information current by filing a "change of information" to reflect any changes in enrollment data, such as a change of ownership, final adverse action, change in practice location, etc.

In the revalidation process, each provider and supplier must revalidate their entire Medicare enrollment record so the Centers for Medicare and Medicaid Services (CMS) can assure that it has current information, including all active practice locations and current reassignments. If the required revalidation is not filed on time or is incomplete, Medicare enrollment may be deactivated and payments will cease. Deactivated providers and suppliers will have to file entirely new applications to reinstate their enrollment records and reestablish their right to bill Medicare.

CMS Addresses Revalidation Process Problems

Providers/suppliers have encountered various problems in complying with the revalidation requirements. For example, some providers/suppliers were told that they could not revalidate their enrollments until they received a revalidation notification letter from the Medicare Administrative Contractor (MAC). If they did not receive the letter due, for instance, to a faulty or outdated address, they could be disenrolled for failure to revalidate on time, resulting in a gap in payment until a new enrollment could be filed and processed. CMS's new process aims to address some of the logistical issues that providers/suppliers have encountered.

CMS has updated its website with information about the revalidation process and these improvements.[1] CMS also published a MedLearn Network article.[2] In addition, CMS held an Open Door Forum MLN call to discuss and explain the process and the changes. For later on-demand access, CMS posted the audio recording and written transcript after the call on the MLN Connects National Provider Calls and Events webpage.[3]

Specifics About CMS Guidance and Improvements to the Revalidation Process

Choosing PECOS or Paper

CMS encourages providers/suppliers to submit revalidations using the Internet-based PECOS website.[4] After completing their data input, providers/suppliers must sign the electronic revalidation application on PECOS. Supporting documentation can be uploaded via PECOS or can be mailed in hard copy format to the MAC along with a signed certification statement. The application fee ($554 for 2016) can also be paid online through PECOS.

Alternatively, providers/suppliers can print and complete the revalidation application in paper format using the applicable CMS-855 form. The signed application, supporting documentation, and appropriate fee can be submitted to the MAC via regular mail. The MAC will then enter the information into the PECOS system.

Although the PECOS system was challenging to use and overwhelmed by volume when it was first introduced several years ago, CMS advises that filing the revalidation through the PECOS system should now be the faster, more efficient option. Using PECOS avoids an extra step in the process of requiring the MAC to enter the data for the provider/supplier. The provider/supplier can perform its own quality control on data input, avoiding the risk that the MAC could make a data entry error.

The Revalidation Time Frame and Due Dates

Revalidations have been scheduled to take place in waves, with specific due dates that fall on the last day of the month assigned to each provider/supplier by which they need to submit their revalidations. The provider/supplier will continue to be subject to its assigned due date during future periodic revalidation cycles. DME suppliers need to revalidate about every 3 years, while all other providers/suppliers must meet the revalidation requirement approximately every 5 years.

CMS encourages filing applications up to 6 months before the assigned due date. However, any application that is submitted more than 6 months before the assigned due date will be deemed to be an "unsolicited" revalidation application and will be rejected and returned.

Beginning February 25, 2016, CMS will publish an online database of all currently enrolled providers/suppliers. The database can be accessed at https://data.cms.gov/revalidation. CMS plans to update this file periodically and provide a revalidation due date lookup tool with a data file that is downloadable in various formats.

This file will only list the revalidation due dates for the providers/suppliers that are due for upcoming revalidation within the next 6 months. All others will display "TBD" in the due date field and, for the time being, DME supplier information will not have due dates listed.

If an individual provider has reassigned payments to another organization, a crosswalk listing of reassignments will also be available at https://data.cms.gov/revalidation.

MACs will continue to send notices to providers/suppliers 2 to 3 months before the revalidation due date, reminding them that their filing due date is approaching and listing any organizations to which they currently reassign. These notices will be sent either via email or regular mail to a minimum of 2 addresses, based on information reported on past applications for correspondence purposes. To assure that they receive the MAC's notice on time, providers/suppliers should review their PECOS files online and update any information that is not current. If a provider/supplier does not receive the notice from the MAC and is within 2 months of the due date listed on the CMS online revalidation file, the provider/supplier should proceed to submit the revalidation application.

File on Time to Avoid Deactivation, Payment Holds, and Payment Gaps

To avoid a "hold" on Medicare payments and the possible deactivation of Medicare enrollment and billing privileges, a provider/supplier must submit a complete revalidation application and supporting documentation by the due date. The provider/supplier must also respond within 30 days to all requests by the MAC for additional information.

If the revalidation application is late, or the necessary additional information is submitted after the due date, the enrollment record may be deactivated. If this happens, payments will cease. While deactivated providers/suppliers will keep their original Provider Transaction Access Numbers (PTANs), they risk a gap in their enrollment and a loss of revenue. A deactivated provider/supplier will have to file an entirely new and complete application to reestablish its Medicare enrollment record and reinstate billing privileges. Retroactive billing will not be allowed for the period of deactivation. Reactivation will begin on the date the MAC receives the new—and complete—application.

Large Group Coordination

CMS defines "large groups" as those that have more than 200 members enrolled. These groups are to receive notices from their MAC listings indicating which of the providers in their groups are due for revalidation. On the revalidation application, providers/suppliers must report all groups to which they are reassigning. Since only one application for each provider/supplier can be submitted, CMS encourages groups to stay abreast of due dates for their practitioners so all materials are submitted in a timely fashion. MACs will have specialized staff to coordinate and facilitate the process for large groups.

Do Not Forget About Medicaid

Section 6401 of the ACA also requires Medicaid programs to revalidate enrollment information for all enrolled providers, regardless of provider type. Under this new enrollment screening criteria, revalidations must take place at least every 5 years for Medicaid as well. Individual states have implemented their own revalidation initiatives and providers/suppliers must comply with those program requirements if they want to continue in good standing with their state Medicaid programs.

Endnotes

1. https://www.cms.gov/medicare/provider-enrollment-and-certification/medicareprovidersupenroll/revalidations.html.
2. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1605.pdf.
3. https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2016-03-01-Enrollment.html?DLPage=10&DLSort=0&DLSortDir=descending.html.
4. https://pecos.cms.hhs.gov/pecos/login.do#headingLv1.

Carolyn Jacoby Gabbay, a partner in the Boston office of Nixon Peabody, LLP, represents health care providers before regulatory agencies and advises them in their business operations; Lindsay Maleson, a partner in the firm's Long Island office, represents academic medical centers, teaching hospitals, medical schools and hospital systems. Kristen Marotta, an associate in the firm's Long Island office, provides counsel to health care clients in regulatory and transactional matters.

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Let's Talk About Truvada, the HIV Preventative

By Cassandra Rivais

Ever since 2001 when the United Nations declared its commitment to find a cure for human immunodeficiency virus ("HIV"),[1] there has been increasing pressure to find one. President Obama created an Emergency Plan to combat AIDS in response to this pressure.[2] According to the United States Centers for Disease Control and Prevention ("CDC"), "[a]bout 50,000 people [in the United States] get infected with HIV each year."[3] By the close of 2010, "[a]bout 1.1 million people in the United States were living with HIV…[and of] those people, about 16% [did] not know they [were] infected."[4] Currently, more than 635,000 individuals have died of AIDS in the United States,[5] and there is no cure.[6]

There has also been a race to find a vaccine for the virus,[7] shifting the focus from treatment to prevention. Due to the mechanisms of vaccines, this solution has not been entirely successful.[8] HIV vaccines work using parts of the virus itself to trigger an immune reaction.[9] This method can be problematic because if unsuccessful it infects the person with HIV as a consequence. There have been over thirty vaccines tested and only one has progressed to Phase III in research trials.[10]

Another option, instead of a vaccine, is Truvada, used as a pre-exposure prophlyaxis ("PrEP").[11] Prophylaxis is defined as the "prevent[ing] or control[ing] the spread of an infection or disease."[12] Despite U.S. Food and Drug Administration ("FDA") approval in 2012,[13] Truvada is rarely prescribed. This is due to the social stigma attached to HIV and the drug itself, public criticism about the drug's effectiveness, and its impact such as the possibility of increasing risk compensation behaviors.[14] As one reporter wrote, about "two years into the PrEP era, Truvada is already in need of a rethink."[15] One solution could be mandating counseling about the drug as preventive treatment. The issue then becomes who should be counseled,[16] how to best communicate the information, and how to ensure it reaches those most at risk.

Part A of this article provides background information about the HIV/AIDS virus and the social stigma attached to the virus. It also provides information about PrEP and the reactions to Truvada as a prevention option. Part B discusses reasons why the simple solution of mandating the use of Truvada by high-risk populations may not be legal, and even if it is, it is impractical. It also discusses a plausible solution of implementing a mandate that physicians provide counseling about PrEP as a preventive option to patients. This section also discusses two methods of implementing this mandate through already established procedures: HIV contact tracing and/or coupled with an offer of an HIV test.

A. Background Information

1. HIV/AIDS virus

HIV is a retrovirus virus that attacks the immune system in humans.[17] The virus uses the human cell's DNA replication process to replicate itself; in a sense turning the human cell against itself. In simple terms, the DNA replication process in any cell works by translating ribonucleic acid ("RNA") to DNA, then using that information from DNA to make proteins. The HIV virus inserts its own RNA into a specific human cell[18] called the CD4 T lymphocyte,[19] or more commonly known as the T-cell. RNA is the template from which DNA is made, so the now infected human cell reads the virus's RNA and translates it into DNA.[20] The T-cell now has virus DNA in it instead of its own DNA. The infected cell then reads the virus DNA, and begins to make virus proteins, which will create more virus cells. This process results in a cascading effect[21] and causes the cell to use its own resources against itself. Once a new virus cell has formed inside the infected human cell, the new virus cell breaks out of the infected human cell through a process called budding, which destroys the human cell.[22] This process of replication is problematic for humans because the destroyed cells are a vital part of our immune system.[23] T-cells signal to the body when it is invaded by an outside substance and activate an immune response.[24] Without that signal and activation, the body does not fight back the infection.[25] In fact, the HIV virus is not the proximate cause of death from AIDS; it is the infections the infected person gets from a weak immune system.[26]

There are three stages of HIV/AIDS based on the T-cells count: HIV-1/ acute infection, HIV-2/clinical latency, and AIDS. A healthy range of T-cells would be from 500 cells/mm^3 to 1,200 cells/mm^3.[27] AIDS is the last stage of the virus and is diagnosed when the T-cell count falls below 200 cells/mm^3. The disease is contracted via exposure to certain bodily fluids of someone with the virus.[28] These fluids include blood, semen, pre-seminal fluid, breast milk, vaginal and rectal fluids.[29] Methods of contact that spread HIV infection include sexual contact, occupational exposure, injection drug use, blood transfusion, organ transplant, pregnancy, childbirth, and breast feeding.[30] In the United States, eighty percent of new HIV infections are caused by sexual exposure, but not all sexual conduct poses the same level of risk.[31] Unprotected anal sex has the highest risk of transmitting the virus.[32]

3. PreEP: Truvada

Truvada is a combination of two substances in one pill, Emtriva or emtricitabine, and Viread, or tenofovir disoproxil fumarate.[33] Manufactured by Gilead Sciences

Inc., it originally was prescribed for HIV-1 infected individuals as a method to prevent HIV from digressing into AIDS.[34] However, after FDA approval in 2012,[35] it is now also used for PrEP purposes.[36] The idea is that HIV negative individuals can take the drug "to help reduce the risk of getting HIV-1 infection…."[37] Common side effects of the drug are stomach pain, headache, and decreased weight.[38] More serious but rare side effects[39] of Truvada include: increase of lactic acid in the blood, liver problems, and worsening hepatitis B infection for those who are infected with hepatitis B.[40] Tenofvor, one of the PrEP components, was known to cause long-term harm to kidneys, but studies now show that it does not when it is coupled with emtricitabine.[41]

PrEP is not the same as a traditional vaccine.[42] This method of prevention treatment involves taking one pill, once a day, at the same time, every day for the rest of one's life, unlike a vaccine, which is a one-time injection that enables one's body to fight infection.[43] However, some organizations state that an individual would not need to take PrEP all the time, only when the person is at risk of getting HIV.[44] Truvada when used for PrEP does not involve injecting the body with parts of live or dead HIV like a vaccine; it works by blocking reverse transcriptase, which is an HIV protein needed in the HIV replication process.[45] This means that the HIV virus is unable to make copies of itself and eventually the virus will die without reproducing.[46] Truvada is only an HIV preventative, meaning it does not cure someone who already has AIDS.

4. Historical Social Stigma of HIV/AIDS

It is important to understand the history[47] behind this virus because it explains many of the reactions people are having to this new idea of treatment. In the past, people with HIV were discriminated against because of how most people contract the virus. Two main ways that HIV infection was originally spread were homosexual contact and injection drug use.[48]

The start of "the world's most deadly pandemic" within young homosexual men in Los Angeles forever stigmatized anyone with the virus.[49] In fact, it was first called GRID, "gay-related immune deficiency disease," by the media.[50] Unfortunately, the media has continued to paint HIV as a "gay disease" in recent years,[51] even though there are other methods for transmitting the virus. The virus also stigmatizes a person as promiscuous because the original sexual spread of the infection was based on the supposed promiscuous behavior of homosexuals,[52] particularly in bathhouses.[53] Many LGBT organizations have been fighting to "de-gay" this virus, in order to get more government assistance for medical care.[54] However, "de-gaying" the virus turned government assistance away from the homosexual population because the government prefers to assist children and women affected over homosexual males.[55]

Injection drug users ("IDUs") are prone to HIV infection because they may share the needles they use for injecting drugs.[56] Sharing of needles can result in blood contact, one of the methods of HIV transmission. Some drugs used by injection are heroin, other opiates, cocaine, and amphetamines.[57] Amphetamine-type stimulants tend to be used by younger populations, while heroin is an older generation drug.[58] Image and performance enhancing drugs are now being used via injection, and use of these drugs is increasing.[59] IDUs are also likely to get hepatitis B or C, due to the transmission of blood.[60] Users with hepatitis B may not want to take PrEP because one of the side effects is worsening the symptoms of hepatitis B.[61]

AIDS has also been labeled an African American disease since it predominantly affects African Americans[62] because they are high IDUs.[63] One study during 2004 – 2007 showed that "62.2% of IDUs with a new diagnosis of HIV infection were males, 57.5% were blacks or African Americans, [even though they only make up about 13% of the population][64] and 74.8% lived in urban areas at the time of their HIV diagnosis."[65] As the CDC states, "African Americans face the most severe burden of HIV and AIDS of any racial/ethnic group in the nation[.]"[66] One 1990 study found a majority of the United States expressed some animosity towards individuals with AIDS, despite efforts to end discrimination.[67] This stigma was found to be worse, when coupled with racial discrimination towards African Americans.[68] The same study expressed concern that this stigma impeded preventative treatment from reaching populations in need, particularly African Americans.[69]

This negative stigma has also been fueled by HIV-criminalization statutes,[70] which were encouraged by the 1987 Presidential Commission due to the spread of the disease.[71] These statutes imposed "criminal liability for HIV/AIDS transmission, exposure, or non-disclosure."[72] As of 2013, thirty-four states still have statutes on their books imposing criminal liability on those who fail to disclose they have HIV/AIDS and expose another to the disease, or transmit the virus to another individual.[73] The passage of the Ryan White Comprehensive AIDS Resources Emergency Act in 1990 was aimed at changing these statutes by offering HIV funding to those states that only criminalized intentional HIV exposure.[74] Some of these statutes have not been updated since knowledge about transmission has changed.[75] For example, Michigan criminalized nondisclosure after all sexual contact, including non-intercourse activities which carry no risk of transmitting HIV.[76] In a sense, "HIV-positive individuals have lost their right to have any sexual contact[,]" based on these laws.[77] Criminalizing HIV transmission has reinforced the stigma associated with HIV infections and has increased reluctance to have HIV testing.[78] HIV gained the label of a "deadly weapon" by courts as well.[79]

It took "innocent victims" like Ryan White, someone who contracted the virus from a blood transfusion, to motivate politicians to take action.[80] However, even when it became understood that HIV is not simply a sexually transmitted disease, the social stigma remained and even Ryan faced discrimination in his hometown.[81] Elton John wrote in his letter to Ryan White, "all victims are innocent."[82] Although efforts to remove the multiple layers of stigma associated with HIV have begun,[83] this stigma continues to hinder the HIV prevention effort.[84] As a *New York Post* reporter worded it, "[d]ecades into the AIDS era, HIV remains a disease of shame and secrecy…. nothing's ever been 'equal' about an HIV diagnosis."[85] He also suggested that "if all gay men are taking PrEP, many activists reckon, HIV status will eventually stop mattering."[86]

5. Preventive Treatment

Preventing HIV infection is cheaper in the long term than treating the disease and reduces human suffering.[87] There are two prevention methods: the medical model and the public health approach.[88] The medical model is individual-centered and "seeks to identify high-risk individuals and offer them individual protection, often by counseling[,]" although it ignores the larger picture.[89] This model runs the risk of targeting the wrong individuals.[90] The public health approach seeks to decrease the overall disease of the population through methods such as mass education.[91] Blending both of these models would be the ideal preventative approach.[92] For example, education about preventing diseases through methods such as counseling would embrace both models and have proven to be somewhat effective.[93]

"Both clinicians and lay people in [one] study found it difficult to make logical decisions about preventive treatment[,]"[94] because of the various concerns about the concept of preventative treatment. These same concerns are relevant to Truvada since it is a preventative treatment. One concern is that there is insufficient knowledge[95] about whether the treatment will be effective. Another concern is that giving a healthy person a medication may cause more medical problems. Doctors may be hesitant to prescribe drugs to generally healthy people.[96]

Preventive treatment also fails when there is a lack of commitment to promotion of the drug, or lack of resources.[97] Another concern about preventive treatment is the access to it and ability to pay for it.[98] Although PrEP is expensive, costing $8,000 to $14,000 per year,[99] it is covered by most insurance,[100] meaning cost is generally not a reason for avoiding this prevention method. Gilead, the company making Truvada, offers a patient assistance program to help cover the cost.[101] The cost of this drug is lower than the cost of treating AIDS for a particular person. However, the costs to society for implementing mandated use of PrEP for high-risk populations would likely be great, especially when there would issues concerning enforcement.

6. Negative Public Reactions to Truvada and Explanations for Lack of Use

Individuals may be afraid of the assumptions that can be drawn if they take Truvada.[102] For example, some doctors will assume an individual has HIV when Truvada is prescribed, even though an HIV-negative individual may take the drug as a prevention method.[103] Others might assume someone taking Truvada is promiscuous, a stigma that attaches to many who contract HIV.[104] In fact, phrases such as "Truvada whore"[105] and "HIV morning after pill"[106] have already developed.

This stigma is reinforced by the fear that those who seek the drug may be those who engage in risky sexual behaviors.[107] However, some studies have demonstrated there is no connection between PrEP and increased risky sexual behaviors.[108] Some of these potential risky behaviors are increased drug use, particularly in youth,[109] and decreased condom use. Some express fears that PrEP will counteract decades of promoting condom use,[110] which is still the most effective method to prevent sexually transmitted diseases ("STDs"). PrEP only prevents HIV transmission and does not protect against transmission of other STDs.[111] Some have described this method as "like offering insulin to the obese[,]"[112] meaning it does not address the real underlying problem.

Several AIDS organizations oppose PrEP because they fear the false sense of security it will give individuals, particularly the homosexual community, about contracting AIDS. Michael Weinstein, President of the AIDS Healthcare Foundation, has been an active opponent of PrEP, believing it will only lead to more infections because of the lack of adherence to the pill-taking schedule.[113] He also expressed concerns about the development of drug-resistant HIV strains if one does not take the drugs as prescribed.[114] One editor of a magazine designed for people with AIDS "called PrEP a 'profit-driven sex toy for rich Westerners.'"[115] Two British HIV associations also expressed concern about the lack of information about PrEP and about prescribing the drug on demand.[116]

7. Support for Truvada[117]

In November 2010, the CDC began research on the effectiveness of the drug on homosexual men and discovered it lowered the risk of getting HIV.[118] Shortly after, two milestone studies confirmed this November study, one conducted by the CDC and Botswana Ministry of Health and one conducted by the University of Washington and the Bill and Melinda Gates Foundation.[119] Several more studies about the effectiveness of PrEP followed these two, including a controversial study using female African prostitutes.[120] Studies about the effectiveness of Truvada continue to date.[121]

The CDC released guidelines for PrEP use of Truvada after the initial results from the November study.[122] The CDC Guidelines list eight studies as evidentiary support for its finding that Truvada is effective in reducing the

risk of HIV transmission. Three of the eight studies were not completed due to low adherence to the medication schedule, issues with sample size, and follow-up time.[123] Considering these studies as a whole, the studies prove that Truvada is effective in preventing HIV infection, which is a major breakthrough in the HIV crisis.

three trials that used them as research subjects had to be stopped. Researchers hypothesized that the women were failing to take their medication properly.[136] In addition, the CDC does not recommend Truvada to individuals who will have issues adhering to the daily schedule of taking the medication[137] or experience renal difficulties.[138]

CDC Studies[124]

Name of the Study	Target Group	Location	Total Participants[125]	Total Participants Taking the Drug (Experimental Group)[126]	Total Acquired HIV Infections in the Experimental Group[127]	Issues	CDC's View on the Quality of Evidence
iPrEx Trial	Men who have sex with men	Peru, Ecuador, Brazil, Thailand, South Africa, and U.S.	2,499	1,251	36/1,224 (3%)[128]	Adherence	High
US MSM Safety Trial	Men who have sex with men	San Francisco, Boston, and Atlanta	400	201	3[129]/201 (1%)	Minimal	High
Partners PrEP	Heterosexual men and women	Uganda and Kenya	4,758	3,172	30/3,140 (1%)	Minimal	High
TDF2	Heterosexual men and women	Botswana	1,219	611	9/601 (1%)	High Loss to follow-up, modest sample size	Moderate
FEM-PrEP	Heterosexual women	South Africa, Kenya, and Tanzania	2,120	1,062	33/1,024 (3%)	Stopped at interim analysis, limited follow-up time, low adherence	Low
West African Trial	Heterosexual women	Ghana, Cameroon, and Nigeria	936	496	2/427 (0%)	Stopped for operational concerns, limited follow-up time, small sample size	Low
VOICE	Heterosexual women	Eastern and southern Africa	3,019	2,010	113/1,978 (6%)	Stopped at interim analysis, low adherence	Low
BTS	Injection Drug Users	Bangkok, Thailand	2,411	1,204	17/1,204 (0%)	Minimal	High

The CDC has strongly recommended that high risk groups receive this drug to prevent contracting HIV.[130] These high risks groups include homosexuals, heterosexual sexually active men and women with a substantial risk of HIV acquisition, such as prostitutes,[131] and bisexuals, injection drug users, and HIV-discordant couples.[132] The guidelines focused on homosexuals,[133] heterosexually active adults at risk,[134] and injection drug users.[135] The guidelines do not focus on prostitutes because all

It also recommends adherence counseling for those who choose to take the drug.[139] The CDC recommends "patients…be encouraged…to use PrEP in conjunction with other effective prevention methods."[140] The organization also recommends that clinicians properly inform and educate their patients about Truvada and other prevention methods such as condoms.[141] Based on these CDC studies, Truvada appears to be highly effective.

The World Health Organization, ("WHO") has also expressed support for PrEP.[142] In July 2012, prior to the CDC's guidelines, the WHO published its own recommendation.[143] The WHO recommended PrEP for serodiscordant couples,[144] men and transgender women who have sex with men at high risk of having HIV infection.[145] WHO did not extend its recommendation to other populations,[146] such as IV drug users. WHO also recognized the potential for "[i]ssues of criminalization, stigma and discrimination, and violence [against those taking PrEP]… during implementation[.]"[147] WHO also recommended guidance and further research to "[d]evelop[ ] transition mechanisms for those who wish or need to stop taking PrEP" and "[g]athering additional information to facilitate decision-making about ethical issues in countries where drug supplies and resources are limited and universal access to treatment has not been achieved[.]"[148]

Some officials from New York have already expressed support for the drug.[149] In addition, there has been some positive support for extending the use of this drug in the media.[150] There have also been social media efforts to help properly educate individuals about PrEP.[151] One such project is called Project Inform, which is aimed at informing individuals about centers that provide PrEP.[152] Another public awareness effort is called PrEPwatch[153] that directs the browser to other relevant links such as the CDC's guidelines, Truvada's website, Global Advocacy for HIV Prevention's website,[154] and the WHO's guidance.[155]

B. Mandating Truvada to High Risk Populations

In the ideal society, mandating Truvada use for the CDC high risks groups would be the most effective method for prevention of HIV. However, this method may not be legal, because of the constitutionally protected right to refuse medical treatment. Practically, it may also be difficult to identify these groups when it comes to enforcing such a mandate.

Infringement on a Fundamental Right

Although states have the police power to protect public health,[156] mandating use of PrEP would violate a patient's right to refuse medical treatment.[157] When a constitutional right protected by the Due Process Clause of the Fourteenth Amendment is infringed by a state statute,[158] the statute would have to overcome strict scrutiny to be upheld.[159] However, in *Jacobson v. Massachusetts*, the Supreme Court held that where there is: 1) a public health necessity; 2) a reasonable means to pursue that necessity;[160] 3) a method to proportional apply the statute to everyone;[161] and 4) the statute avoids harm,[162] the statute would be upheld in the interests of public health. *Jacobson* can be distinguished from this analysis because PrEP is not the same as a vaccine;[163] therefore, an analysis about the public health interest is necessary.

The public health necessity would be to decrease the number of new HIV infections.[164] Decreasing HIV in the high risk populations would reduce HIV risk to society as a whole because of herd effects.[165] This mandate would not be a reasonable means because it would force a healthy person to take a medication. It also would not be reasonable because without the cooperation of these high risk populations, there would be no practical way to enforce the mandate, especially since these populations are traditionally considered "irresponsible." Although the benefit may be high for society as a whole, the risks of taking Truvada may be high for the particular individual, particularly IDUs.[166] It would become a balancing act between society's interests and the individuals. This method could not be proportionally applied to everyone because it would only apply to high risk populations. Physicians would have to make subjective judgments about who was at high risk, which may not be accurate. For example, a physician may decide to prescribe PrEP to all homosexuals, even those who do not engage in HIV risky behavior. In addition, mandating the medication would potentially cause physical harm to those who experience bad side effects as well as the physical and psychological harm to those who will have to be forced to take the treatment against their will. Therefore, this mandate would not be upheld as a necessity for public health because it is not a reasonable means for accomplishing the public health interest, and the mandate would be unconstitutional.

C. Counseling Mandate About Truvada

Mandating disclosure of information about Truvada as a preventive may be the best plausible solution for increasing its use. There already is social pressure for all homosexual men to take this drug, simply to fight the pandemic.[167] But as the media has worded it, "[d]o we really want to mass-medicate an entire generation of gay men? Until we know more, that has to be bad medicine and bad policy."[168] Counseling would help an individual make fully informed decisions about his/her health and such preventive health counseling is already covered by many insurance providers.[169] Indeed, the CDC's guidelines state that PrEP is the most effective with "medication education and adherence counseling."[170] Studies have already shown that such preventive counseling works to decrease HIV transmission.[171]

The type of counseling recommended in this article would be provided by a physician and include information about Truvada, effectiveness of PrEP, and the benefits and risks of the medication. The physician would only provide a recommendation for a prescription of the medication if the patient asks for one.

Methods for Disclosing Information About Truvada

There are two circumstances that could trigger this recommended counseling: the HIV contact tracing system

or coupled with counseling information already mandated with the offer of an HIV test. These circumstances arise in New York based on requirements in the New York State's Department of Health regulations. This article recommends that amendments to these regulations be made so counseling about PrEP can be implemented in New York State.

1. HIV Contact Tracing System

HIV contact tracing is a statutory system of identifying people who may have been exposed to HIV and providing them with information. The law governing HIV contact tracing requires that "[e]very municipal health commissioner or the department's district health officer, upon determination…[of a] reported [HIV] case or, any other known case of HIV infection [that] merits contact tracing in order to protect the public health, [to] personally or through their qualified representatives notify the known contacts of the protected individual."[172] A contact is defined as "an identified spouse or sex partner of the protected individual, a person identified as having shared hypodermic needles or syringes with the protected individual or a person who the protected individual may have exposed to HIV under circumstances that present a risk of transmission of HIV[.]"[173] Once a contact is identified, that contact must be informed of the following:

(a) the nature of HIV,

(b) the known routes of transmission of the virus,

(c) as circumstances may require, the risks of prenatal and perinatal transmission,

(d) actions he or she can take to limit further transmission of the virus,[174]

(e) other facilities or community based organizations which are accessible to the person that provide counseling, medical care and treatment, further information or other appropriate services for persons infected with HIV.[175]

There is even a referral system in place if the identified contact lives in another area, meaning this method of informing can effectively work between municipal boundaries.[176] Confidentiality of the HIV-positive person must still remain protected.[177] This confidentiality protection is a way to prevent medical discrimination.[178] The Department of Health also has the PartNer Assistance Program ("PNAP") or Contact Notification Assistance Program in New York City ("CNAP") to counsel HIV-positive about how to contact a person or will contact the person directly, protecting the identity of the HIV-positive individual.[179] The HIV contact tracing system has already been successful at identifying HIV infections.[180]

It would be simple to add a discussion of preventive treatment options such as PrEP to the information that must be disclosed to the identified contacts. The system has proven effective in identifying HIV infections, and therefore would be effective at identifying individuals who would likely need information about PrEP. The confidentiality of these individuals would also remain protected as required after receiveing PrEP information. One issue is that an HIV-positive individual is not penalized for not disclosing his/her sex partners, so this method of disclosure would rely on voluntary compliance.[181]

There have been ethical concerns about the HIV contact tracing system.[182] Some argue it violates "the right of confidentiality and privacy,"[183] stemming from the physician's fiduciary duty to the patient. The right of confidentiality and privacy may be violated when a doctor reports a patient's HIV status against the patient's wishes.[184] A patient may feel particularly harmed by this disclosure because a patient trusts the physician with sensitive, personal health information. Despite these concerns, the American Medical Association supports this reporting because of the overriding public health interest.[185]

There have been examples of doctors reporting HIV status without consent of the patient. One example of a physician reporting HIV status against a patient's wishes' was *Doe v. Roe* in 1992. The Workers' Compensation Board had subpoenaed the employee's medical records during the course of a workers' compensation proceeding and the doctor had provided the records.[186] The court found the Workers' Compensation Board had demonstrated a "compelling need" to have an employee's confidential HIV history disclosed to it;[187] therefore, the physician had not violated the patient's right of confidentiality.

2. Disclosure with Mandated Offer for HIV Test

In New York, a physician is required to disclose certain information prior to offering an HIV test and after performing an HIV test. The pre-test disclosure[188] is more analogous to the type of counseling this mandate would require while the post-test counseling is more extensive. N.Y. Public Health Law also requires that:

> [e]very individual between the ages of thirteen and sixty-four years…who receives health services as an inpatient or in the emergency department of a general hospital…or who receives primary care services in an outpatient department of such hospital or in a diagnostic and treatment center…or from a physician, physician assistant, nurse practitioner, or midwife providing primary care shall be offered an HIV related test [by a physician, physician assistant, nurse practitioner, or midwife providing primary care]….[189]

This is not a mandated test, just the offer of the test. The patient has the option to decline the test or take the HIV

test, after giving written informed consent.[190] If the patient does decide to take the test, the physician[191] is required to disclose the following information before the test:

(a) HIV causes AIDS and can be transmitted through sexual activities and needle-sharing, by pregnant women to their fetuses, and through breastfeeding infants;

(b) there is treatment for HIV that can help an individual stay healthy;

(c) individuals with HIV or AIDS can adopt safe practices to protect uninfected and infected people in their lives from becoming infected or multiply infected [people] with HIV;

(d) testing is voluntary and can be done anonymously at a public testing center;

(e) the law protects the confidentiality of HIV related test results;

(f) the law prohibits discrimination based on an individual's HIV status and services are available to help with such consequences; and

(g) the law allows an individual's informed consent for HIV related testing to be valid for such testing until such consent is revoked by the subject of the HIV related test.[192]

If the result is positive, the physician who performed the test must provide the patient:

> with counseling or referrals for counseling: [i] for coping with the emotional consequences of learning the result; [ii] regarding the discrimination problems that disclosure of the result could cause; [iii] for behavior change to prevent transmission or contraction of HIV infection; [iv] to inform such person of available medical treatments; and [v] regarding the need to notify his or her contacts….[193]

The regulations provide two opportunities for a physician to counsel the patient during the HIV testing process, before receiving the test and after if the results are positive. The Commissioner has the power to "promulgate rules and regulations concerning implementation of this article for health facilities, health care providers and other persons to whom this article is applicable."[194] However, the Commissioner has additional responsibility for developing model forms for informed consent which would be provided during the pre-test counseling session.[195]

A discussion about medical prevention options such as PrEP should be included in both of these counseling sessions. PrEP could arguably already be covered under "available medical treatments[,]" since it is used to prevent HIV from turning to AIDS; however, it is unclear whether or not the doctor would discuss that PrEP could also be used as a preventative. In addition, the Commissioner could also add information about PrEP within the standardized inform consent form for those who take an HIV test.

There would still be the problem of how to disclose this information to those individuals who turn down the HIV test. Some people are still too afraid to get an HIV test because they do not want to know if they have HIV since HIV infection is physically, economically, emotionally, and socially devastating. The physician could provide a pamphlet to the patient with information about HIV prevention whenever the physician offers the test. This would ensure the patient at least received the information, even if she/he did not agree to an HIV test. If patient asked for more information, then the physician could counsel the patient about PrEP.

However, there will still be a population of people who would not receive this information: those who do not regularly get medical services. This would include those who cannot afford medical services or do not think they need medical services. The poor population, especially undocumented immigrants, may need this information the most, but even if the poor received information about the drug, there still may be issues of getting access to the drug. One way to get information to these populations would be to use epidemiological information about what areas have high rates of HIV infections. Then, information about PrEP could be distributed to these areas. How this disclosure would be implemented is beyond the scope of this article.

D. Conclusion

Ideally, counseling about PrEP through HIV contact tracing, HIV testing, and offers of HIV testing should be easy to implement and effective in informing the public about the benefits of PrEP. This counseling increase the chances that those who need the information the most will receive it. These proposed amendments to already existing laws would not cause any undue cost or burden on government authorities or health care providers.

There is a need for New York State to step up and help educate the public about PrEP as a prevention method as part of the battle against HIV/AIDS. There is power in information and that information should be with the people. Simply bringing awareness to the citizens of New York about a proven medical alternative[196] may help decrease HIV infections, thereby reducing the social stigma attached to HIV. As one New York reporter wrote, "[e]nding the stigma around AIDS is a noble and vital goal. But teaching healthy folks to truly stay healthy is still the best prevention method available."[197] New York State should

teach its citizens about Truvada and its potential to stop the transmission of HIV/AIDS.

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125. These numbers are from Table 2. CDC Guidelines, *supra* note 16, at 21.

126. These numbers are from Table 2. CDC Guidelines, *supra* note 16, at 21.

127. These numbers are from Table 3. CDC Guidelines, *supra* note 16, at 22.

128. These percentages were calculated by the author using the two numbers in the chart.

129. There were two experimental groups: one that delayed taking the drug and one that did not. The three HIV cases were among the delayed group. CDC Guidelines, *supra* note 16, at 15, 22.

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132. *Id.* at 9. An HIV-discordant couple is when one partner has HIV while the other partner does not. *See id.*

133. The CDC Guidelines refer to homosexuals as "MSM" for men who have sex with men. Homosexuals at risk were those with an HIV-positive partner, recent bacterial STI, high number of sex partners, history of inconsistent or no condom use, or commercial sex work. CDC Guidelines, *supra* note 16, at 11, 12.

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135. Those at risk had an HIV-positive IDU partner, shared injection equipment, or had recent drug treatment but were still injecting. CDC Guidelines, *supra* note 16, at 11, 12.

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196. Studies about Truvada's effectiveness continue to date. See iPeEX OLE, STUDY MEDICATION THE PREP INITIATIVE COMMUNITY, http://www.iprexole.com/ (last visited Apr. 29, 2015) (study is still currently accepting research subjects). See also Gus Cairns, Overall PrEP effectiveness in iPrEx OLE study 50%, but 100% in those taking four or more doses a week, AIDSMAP (July 22, 2014) http://www.aidsmap.com/Overall-PrEP-effectiveness-in-iPrEx-OLE-study-50-but-100-in-those-taking-four-or-more-doses-a-week/page/2892435/.

197. *Kaufman*, *supra* note 15.

Cassandra Rivais is a Joint Degree Student, JD/MS in Bioethics, graduating in May 2016 from Albany Law School and Albany Medical College. She is the Executive Editor of the *Albany Government Law Review* as well as President of the Health Law Society. She will be a Clinical Bioethics Fellow at the Alden March Bioethics Institute at Albany Medical Center/College starting August 2016.

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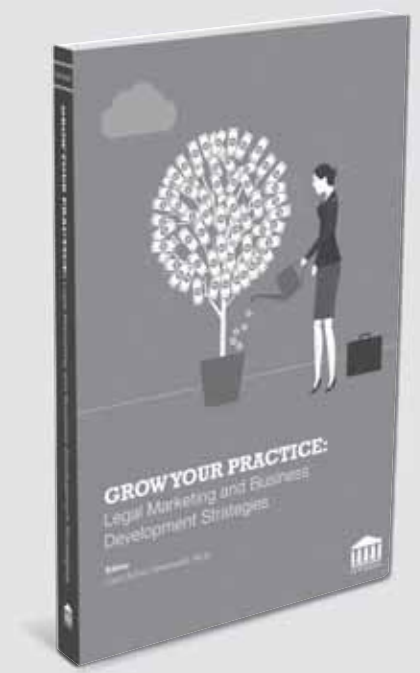

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New Section Officers

On June 1, the following persons will start their terms as Section Officers:

Chair: Raul A. Tabora, Jr. will become next Chair of the Health Law Section; his term begins June 1. Mr. Tabora is a Member of Bond Schoeneck & King, and practices from its Albany and NYC offices. He represents health and long term care providers in a broad range of health law matters, including compliance and reimbursement audits, investigations and litigation. His has extensive experience in health law issues affecting long term care providers and is General Counsel to long term care institutions.

Chair-Elect: Lawrence R. Faulkner, Director of Corporate Compliance and General Counsel to the ARC of Westchester.

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Secretary: Julia C. Goings-Perrot, Associate General Counsel, HealthQuest.

Treasurer: Hermes Fernandez, Bond Schoeneck & King (Albany NY).

Recent Events

- **Annual Meeting** The Section's Annual Meeting was held along with the NYSBA Annual Meeting at the New York Hilton on January 27 in NYC. The program, chaired by Margaret J. Davino of Fox Rothschild, LLP, surveyed key developments in health law, including legislative developments, DSRIP, employment law, the 60-day repayment window, behavioral health, and legal issues affecting startup companies. An attendance record was set for this program, and the program was well regarded
- **Brave New World: Exploring Today's Health Law Career Paths**. This program, held on March 10, 2016 at Brooklyn Law School, was sponsored Section's Health Law Membership and Diversity Committee and Brooklyn Law School's Center for Health, Science and Public Policy, and chaired by Karen Porter, J.D. A panel of health law practitioners discussed how the changing world of health care delivery is transforming their practice, and highlighted traditional and nontraditional areas of opportunity for students and lawyers wishing to practice health law. The panel included Salvatore Russo, Esq. Senior VP and General Counsel, NYC Health & Hospital Corporation; Ingrid Green Jones, Esq., Assistant General Counsel, Compliance, The College Board; Robert Swidler, Esq., VP Legal Services, St. Peter's Health Partners (Albany) and Danette Slevinski, Esq. SVP, Chief of Corporate, Compliance & HIPAA Privacy Officer, NYU Lutheran, Medical Center.
- **Senior Housing in New York State.** This CLE program was held on March 11, 2016 at the offices of Duane Morris on Broadway in NYC. It explored all types of senior housing options available in New York, including independent living, assisted living, skilled nursing, continuing care retirement communities and home healthcare. The program included a presentation on applicable regulatory trends in New York, including related health policy issues, by Assembly Health Committee chair Richard N. Gottfried, Esq.

Upcoming Event

- **Fall Meeting.** The Section's fall meeting will be held on Friday, October 28, 2016 at the NYSBA Bar Center in Albany New York. The program is under development. Check the NYSBA website for information.

Section Committees and Chairs

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

Continuing Legal Education
Robert P. Borsody
Robert P. Borsody, PC
666 Fifth Avenue, 29th Floor
New York, NY 10103
rborsody@phillipsnizer.com

Developmental Disabilities
Hermes Fernandez
Bond, Schoeneck & King, PLLC
22 Corporate Woods, Suite 501
Albany, NY 12211
hfernandez@bsk.com

E-Health and Information Systems
Daniel Meier
Benesch Friedlander Coplan & Aronoff
Continental Plaza II
411 Hackensack Avenue, 3rd Flr.
Hackensack, NJ 07601-6323
dmeier@beneschlaw.com

Charles C. Dunham IV
Epstein Becker & Green, P.C.
250 Park Avenue
New York, NY 10177
cdunham@ebglaw.com

Ethical Issues in the Provision of Health Care
Lawrence R. Faulkner
ARC of Westchester
265 Saw Mill River Road, 3rd Floor
Hawthorne, NY 10532
lfaulkner@westchesterarc.org

Health Care Providers and In House Counsel
Carolyn B. Levine
Memorial Sloan Kettering
1275 York Ave., 20th Floor
New York, NY 10065-6094
levinec@mskcc.org

Margaret J. Davino
Fox Rothschild LLP
101 Park Avenue
New York, NY 10271-1699
mdavino@foxrothschild.com

Anoush Koroghlian Scott
Whiteman Osterman & Hanna LLP
One Commerce Plaza
Albany, NY 12260
ascott@woh.com

Health Professionals
Laurie Tangora Cohen
Nixon Peabody
677 Broadway
Albany, NY 12207
lauriecohen@nixonpeabody.com

Jay B. Silverman
Ruskin Moscou & Faltischek PC
1425 RXR Plaza
East Tower, 15th Floor
Uniondale, NY 11556-1425
jsilverman@rmfpc.com

Legislative Issues
James W. Lytle
Manatt, Phelps & Phillips, LLP
30 S Pearl Street
Albany, NY 12207
jlytle@manatt.com

Long-Term Care
Jane Bello Burke
Hodgson Russ LLP
677 Broadway, Suite 301
Albany, NY 12207
jbburke@hodgsonruss.com

Managed Care and Insurance
Harold N. Iselin
Greenberg Traurig, LLP
54 State Street
Albany, NY 12207
iselinh@gtlaw.com

Ross P. Lanzafame
Harter Secrest & Emery LLP
1600 Bausch and Lomb Place
Rochester, NY 14604
rlanzafame@hselaw.com

Medical Research and Biotechnology
Alex C. Brownstein
BioScience Communications
250 Hudson Street, 9th Floor
New York, NY 10013
alex.brownstein@bioscicom.net

Samuel J. Servello
205 East 10th Street, #5D
New York, NY 10003
samservello.barmail@gmail.com

Membership
Karen L. I. Gallinari
NYC Health & Hospitals
160 Water Street, 9th Floor
New York, NY 10038
karen.gallinari@nychhc.org

Salvatore J. Russo
NYC Health and Hospitals Corporation
125 Worth St., Room 527
New York, NY 10013-4006
salvatore.russo@nychhc.org

Mental Health Law
Carolyn Reinach Wolf
Abrams, Fensterman, Fensterman, Eisman, Formato, Ferrara & Wolf, LLP
1111 Marcus Avenue, Suite 107
Lake Success, NY 11042
cwolf@abramslaw.com

Professional Discipline
Joseph L. DeMarzo
41 Hathaway Lane
White Plains, NY 10605-3609
jdemarzo@optonline.net

Carolyn Shearer
Bond, Schoeneck & King, PLLC
22 Corporate Woods Boulevard, Suite 501
Albany, NY 12211
cshearer@bsk.com

Public Health
Jason M. Brocks
Benecard
1200 Route 46 West
Clifton, NJ 07013
jbrocks@gmail.com

Reimbursement, Enforcement, and Compliance
Robert A. Hussar
Manatt, Phelps & Phillips, LLP
30 South Pearl Street
Albany, NY 12207
rhussar@manatt.com

Melissa M. Zambri
Barclay Damon LLP
80 State Street
Albany, NY 12207-2207
mzambri@hblaw.com

Young Lawyers
Nicole R. Ozminkowski
Harris Beach P LLC
99 Garnsey Road
Pittsford, NY 14534
nozminkowski@harrisbeach.com

Lara Glass
466 Prospect Ave.
Brooklyn, NY 11215
lara.glass@brooklaw.edu

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Editor
Robert N. Swidler
St. Peter's Health Partners
5 Cusack
315 S. Manning Blvd.
Albany, NY 12208
(518) 525-6099
robert.swidler@sphp.com

Section Officers

Chair
Kenneth R. Larywon
Martin Clearwater & Bell LLP
220 East 42nd St.
New York, NY 10017
larywk@mcblaw.com

Chair-Elect
Raul A. Tabora, Jr.
Bond, Schoeneck & King, PLLC
22 Corporate Woods, Suite 501
Albany, NY 12211
rtabora@bsk.com

Vice-Chair
Lawrence R. Faulkner
Dir. of Corp Compliance & Gen'l Counsel
ARC of Westchester
265 Saw Mill River Road, 3rd Floor
Hawthorne, NY 10532
faulkner@westchesterarc.org

Secretary
Robert A. Hussar
Manatt Phelps & Phillips LLP
30 South Pearl Street
Albany, NY 12207
rhussar@manatt.com

Treasurer
Julia C. Goings-Perrot
Associate General Counsel
HealthQuest
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Lagrangeville, NY 12540
jgoingsp@health-quest.org

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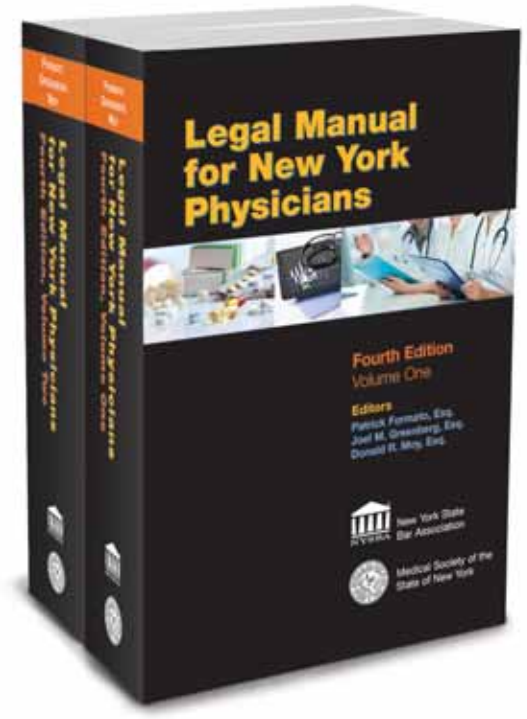

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