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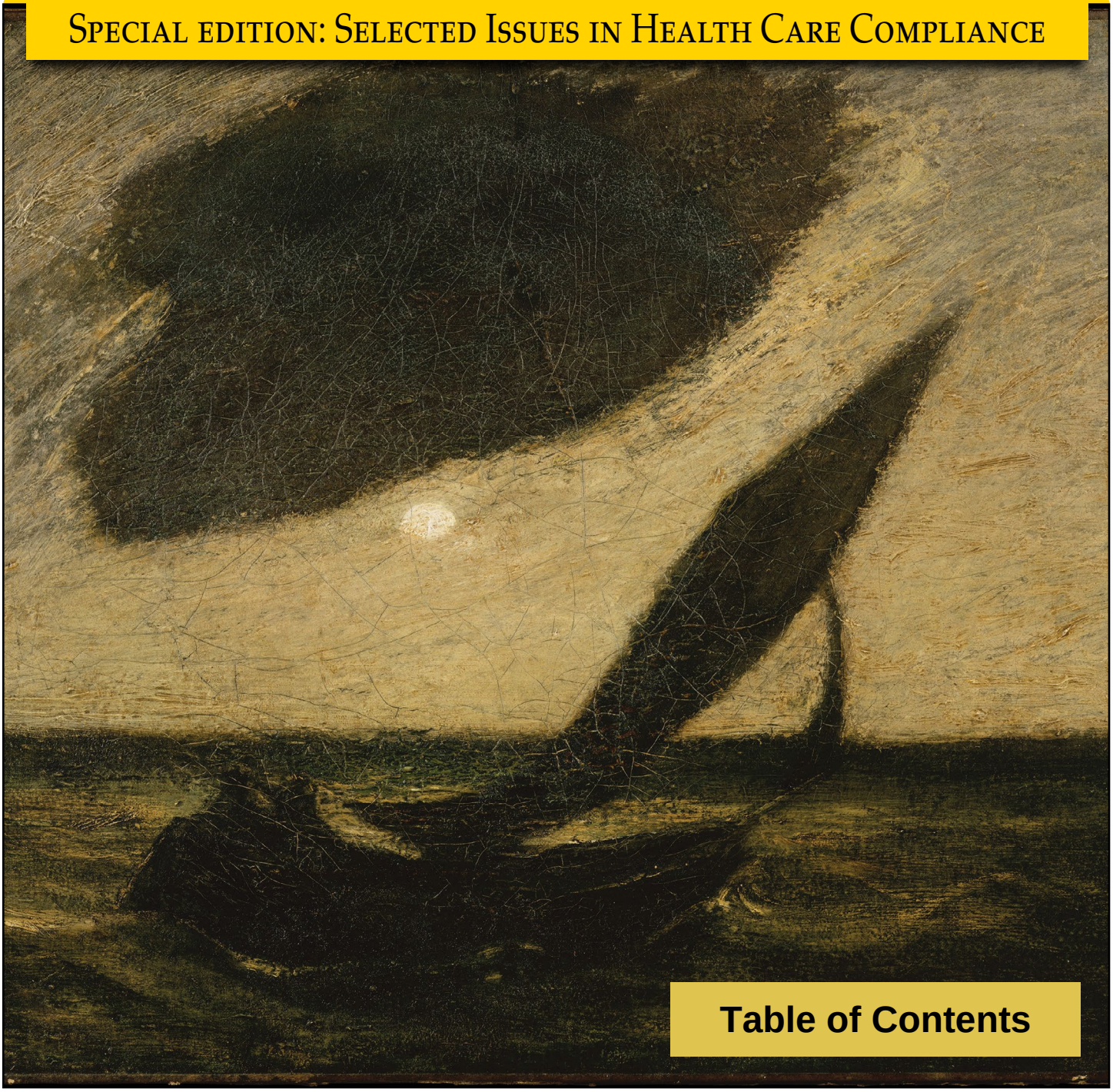
Special edition: Selected Issues in Health Care Compliance



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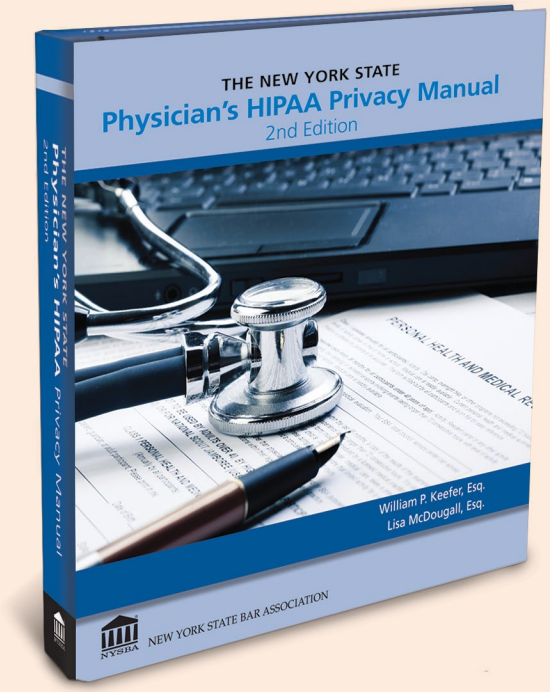
From the NYSBA Book Store

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.



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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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Cover artwork: *Under a Cloud* by Albert Pinkham Ryder, ca. 1900

* Robert A. Hussar, a partner in the Albany office of Barclay Damon, provides public and private clients with strategic advice and guidance on Medicare, Medicaid, and other payer regulatory, compliance, licensure and reimbursement issues.

Message from the Section Chair

"Integrity is the quality of being honest and having strong moral principles. . . .It is generally a personal choice to hold oneself to consistent moral and ethical standards." Thus says Wikipedia. As we face the threat of fraud, abuse and waste in the health care system, it is increasingly clear that despite all of the means and methods used to ensure compliance, integrity is the core attribute. New technologies may transform and disrupt the system yet technology is still a tool which can either be manipulated or unjustly enforced. Recently, the National Institute of Standards and Technology (NIST) held a workshop on September 26, 2016 entitled, "Use of Blockchain for Healthcare and Research." This workshop highlighted the winners of a competition which sought white papers on the uses of Blockchain technology in health care.

The Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) describes a Blockchain as a "data structure that can be timed-stamped and signed using a private key to prevent tampering." The concept uses a distributed ledger which is maintained on a peer-to-peer system of servers across an industry to ensure the accuracy of information and verification of transactions. The technology is part of the original platform for bitcoin currency developed in 2008. Its potential application to health information exchange, eligibility and reimbursement systems could be revolutionary. The HHS workshop provided a forum for discussion of these uses and follows HHS' recent campaign named the "Ideation Challenge." This challenge specifically called out the following potential uses for Blockchain in health care:

- Digitally sign information,
- Computable enforcement of policies and contracts (smart contracts),
- Management of Internet of Things devices,
- Distributed encrypted storage, and
- Distributed trust.

(See July, 2016 Federal Register announcement at: https://www.federalregister.gov/articles/2016/07/08/2016-16133/office-of-the-national-coordinator-for-health-information-technology-announcement-of-requirements.)

Winners were announced this past September and 15 winning papers are posted on the ONC website. As a sample, a paper submitted by the IBM Global Public Sector Team is entitled: "Blockchain: The Chain of Trust and Its Potential to Transform Healthcare—Our Point of View." The benefits to the health care system in terms of fraud prevention are noted as:

- Blockchain eliminates data silos and aggregates clinical data from EMRs. . .driving seamless interoperability between health care systems.
- Records are guaranteed to be cryptographically secure, with no possibility of bad actors threatening data integrity.
- Outside auditing is made easier.
- Outcomes research and precision medicine initiatives can be better supported; patients can control what data is shared with whom, achieving improved interoperability and increased anonymous data samples.

As we have all predicted and expected for decades, our actions (or inactions) will increasingly be indelibly fixed as evidence in a historical record—a record which is now to be created in real time. Will this drive perfection? Is perfection a desired outcome?

In the words of Mary Jo Bane, who was commissioner in charge of the Medicaid program during the early 1990s, "my job is to assure that the right person is paid for the right service provided to the right individual enrolled in the Medicaid program." She was responding to a pointed statement from Senator Joseph Holland that her "job" was to recover overpayments. (Testimony before NYS Senate Standing Committee on Health on agency's efforts to control fraud and abuse.). In the current fractured and multi-dimensional system of enforcement, the word "right" is a loaded concept.

We may be heading into a world in which the compliance officer will be a virtual and artificially intelligent robot. Yet, time and again consumers, providers, payers and regulators have found ways around the systems in place in order to attain results which are contrary to public policy.

While increased transparency and the certainty of "getting caught" will be a deterrent, there is no substitute for "integrity" in the people who receive, give, pay and regulate health care.

Raul A. Tabora

In the New York State Courts

By Leonard M. Rosenberg

Court of Appeals Holds That Mental Hygiene Law § 33.15 Does Not Limit the Availability of Common Law Writ of Habeas Corpus

People ex rel. DeLia v. Munsey, 26 N.Y.3d 124 (2015). A patient involuntarily admitted to Holliswood Hospital upon medical certifications that he was unable to care for himself and required mental health treatment, appealed from the Appellate Division's determination that he was not entitled to immediate release following the Hospital's failure to comply with the Mental Hygiene Law ("MHL"), absent a determination as to his mental fitness.

Pursuant to MHL Article 9, when a patient is involuntarily admitted, a facility may hold the patient for a limited period of time and, in the event further retention is required, must apply to the court for an order authorizing continued retention within 60 days of admission. The patient is entitled to a hearing upon request regarding the Hospital's application for a retention order. Section 9.33 of the MHL provides that, once an order retaining a patient has been obtained, if the facility believes retention beyond the provided time frame is required, the facility must apply for such extension during the period of retention authorized by the most recent court order.

Under Section 33.15 of the MHL ("§ 33.15"), one who is retained by a facility is entitled to a writ of habeas corpus to question the cause and legality of detention when he believes he has sufficiently recovered to be released. Under § 33.15, courts are required to consider the facts concerning the individual's mental disability and detention, and may only discharge the patient if they believe he is not mentally disabled and not in need of further inpatient treatment.

In March 2012, Appellant was involuntarily admitted to the Hospital. Two months later, the Hospital applied to the Supreme Court for authorization to continue his involuntary retention. Granting the Hospital's application, the Court extended Appellant's retention for a period not to exceed three months. At no point during this three-month period did the Hospital apply for court authorization for Appellant's continued retention, as required under MHL § 9.33. Nevertheless, the Hospital continued to retain Appellant.

Mental Hygiene Legal Services initiated a habeas corpus proceeding on Appellant's behalf, seeking his immediate release from the Hospital based upon his illegal detention. The proceeding was brought under article 70 of the CPLR, which governs special proceedings for a writ of habeas corpus. In response, the Hospital sought an order authorizing Appellant's continued involuntary retention for a period of six months under MHL § 9.33. Despite conceding that it had erroneously retained Appellant without a court order for approximately six weeks, the Hospital argued that Appellant could not be released without a hearing, and only if the court deemed him mentally fit for discharge.

The Hospital argued that § 33.15 should be construed as the sole habeas corpus provision available to article 9 patients because the more general habeas provisions of CPLR article 70 must yield to the specific mandate of § 33.15. The Hospital further argued that involuntary commitment is lawful so long as the patient is in need of treatment, without regard to whether the procedural directives of the MHL are followed.

The Court of Appeals rejected the Hospital's argument that § 33.15 governs all habeas proceedings brought by patients, as such an interpretation "abrogates the common law writ of habeas corpus for mentally ill patients and is not supported by our case law, the rules of statutory construction, or principles of due process."

The Court reasoned that nothing in the plain language of § 33.15 limits the availability of the common-law writ of habeas corpus in MHL proceedings. Emphasizing the fact that § 33.15 enhances the efficacy of the writ of habeas corpus, the Court held that § 33.15 and the provisions of CPLR article 70 should be read in tandem according to the rules of statutory construction. The Court noted that § 33.15 allows patients to seek a writ of habeas corpus where they believe they have sufficiently recovered from their mental illness such that continued retention is not warranted, while CPLR article 70 allows patients to seek the writ where their detention is otherwise unauthorized. Therefore, the Court held that if § 33.15 were deemed the exclusive habeas corpus avenue available to involuntarily retained patients, such decision would "permit the flagrant disregard—either deliberately or through laxity—of the due process protections provided throughout the MHL." As such, the Hospital's reading of § 33.15 would effectively eliminate the availability of habeas corpus for patients such as Appellant, wishing to challenge the procedural methods by which they were retained, and to obtain release from an unlawful detention. The Court held that, where a facility believes a patient requires further treatment notwithstanding having been granted a writ of habeas corpus under CPLR article 70, the facility must commence a new

proceeding in compliance with Article 9 of the MHL.

A vigorous dissent by Justice Abdus-Salaam challenged the entirety of the majority's reasoning. The dissent noted that the patient was schizophrenic, and during his six month admission, had assaulted staff members, patients, and his mother, had stabbed a staff member in the neck with a pen, and had choked his treating psychiatrist; yet the majority's ruling required his release with no consideration of his mental condition because the Hospital had inadvertently missed the deadline for filing a retention application.

Third Department Upholds Revocation of Physician-Lawyer's Medical License Following Conviction for Stealing Money From Clients' Escrow Accounts

Casamassima v. New York State Dept. of Health, Administrative Review Bd. for Professional Medical Conduct, 135 A.D.3d 1200 (3d Dep't 2016). Petitioner, a physician and an attorney, brought a CPLR Article 78 proceeding following a determination from the State Department of Health, Administrative Review Board for Professional Medical Conduct, revoking his medical license.

In 2010, Petitioner was arraigned on criminal charges for stealing funds from an escrow account while acting as an attorney. In 2011, on his application to the State Education Department seeking renewal of his medical license, Petitioner denied the existence of any criminal charges pending against him. In 2012, Petitioner pled guilty to both felony and misdemeanor charges of larceny, and was sentenced to five years of probation and ordered to pay restitution.

In response, the Bureau of Professional Medical Conduct charged Petitioner with practicing the profession fraudulently and being convicted of an act constituting a crime in New York. Finding Petitioner guilty of both charges, a Hearing Committee of the State Board for Professional Medical Conduct revoked his medical license. A subsequent administrative appeal by Petitioner resulted in Respondent affirming both the determination of misconduct and the revocation of Petitioner's license.

Petitioner objected to the Hearing Committee's preclusion of his wife from testifying regarding his motive for stealing funds from the escrow account. Petitioner also claimed that the proceeding was rushed to the extent that reversal was warranted.

The Appellate Division rejected Petitioner's assertion that the Hearing Committee's evidentiary rulings and hearing format deprived him of due process. Specifically, the Court held that the exclusion of cumulative testimony is not violative of due process, and that Petitioner was afforded ample opportunity to present evidence. The Court also held that the Hearing Committee's efforts to avoid extended testimony and submissions regarding peripheral matters did not infuse the proceeding with unfairness.

As to the revocation of Petitioner's license, the Court held that it would not reverse a penalty imposed by Respondent unless such penalty was so disproportionate to the offense so as to shock one's sense of fairness. Based on Petitioner's admission that he stole over $40,000 from his clients, to whom he owed a professional duty, the Court affirmed Respondent's determination that Petitioner had engaged in a pattern of misconduct by stealing the funds and then lying on his renewal application. Accordingly, the Court held that the penalty of license revocation as a consequence for these actions was not disproportionate.

Third Department Grants Hospital's Motion to Convert a Physician's Article 78 Proceeding into an Injunctive Action under Public Health Law §2801-c, and Upholds Suspension and Denial of Surgeon's Hospital Privileges

Fischer v. Nyack Hosp., 140 A.D.3d 1264, 32 N.Y.S.3d 714 (3d Dep't 2016). Pursuant to Public Health Law § 2801-b ("PHL"), Petitioner Eva Fischer, a surgeon, initiated an Article 78 proceeding seeking to annual Nyack Hospital's (the "Hospital") suspension and non-renewal of her medical staff privileges at the Hospital, following a ruling by The Public Health and Health Planning Council that the Hospital's reasons for terminating her privileges were "focused on patient care and welfare" and consistent with PHL § 2801-b. The Hospital moved to convert the proceeding into a plenary action and, once converted, for summary judgment dismissing the complaint. The trial court denied the Hospital's motion and transferred the proceeding to the Third Department pursuant to CPLR 7804 (g). The Third Department reversed.

Petitioner maintained medical staff privileges at the Hospital that were set to expire in mid-2012. While her application to renew was pending, the Hospital summarily suspended her privileges in May 2012 after learning that her privileges had recently been suspended at another hospital. Following Petitioner's suspension, she met with the Hospital's medical executive committee, which recommended that the suspension be upheld and her privileges not be renewed. After this recommendation was adopted by the Hospital, Petitioner requested a hearing, which ensued before a four-member panel of physicians. The panel issued a detailed written decision finding, among other things, that Petitioner had a pattern of inaccessibility to staff when on call, repeatedly did not respond promptly to the emergency department when on call, failed to obtain coverage when unavailable because of illness, left the operating room and could not be located while her patients were in surgery and failed to properly disclose her suspension at the other hospital as required by the Hospital's bylaws. Based on these and other findings, the panel recommended that Petitioner's application be denied. The Hospital's board of trustees accepted the panel's recommendation.

The Appellate Division held that the Hospital's motion to convert the proceeding into an action for

injunctive relief should have been granted. The Court explained that under common law, a private hospital had unfettered discretion to deny privileges; this was tempered by the enactment of PHL § 2801-b and c. Under § 2801-b, it is an improper practice for a hospital to deny privileges without giving a reason, or if the reason(s) are not related to "standards of patient care, patient welfare, the objectives of the institution, or the character or competence of the applicant." PHL § 2801-c provides a remedy of an action for injunctive relief. because Petitioner sought annulment of the Hospital's decision and an order directing reinstatement of her privileges at the Hospital, injunctive relief under PHL § 2801-c.

With regards to the Hospital's motion for summary judgment, the Court explained that its review was limited to "whether the purported grounds were reasonably related to the institutional concerns set forth in the statute, whether they were based on the apparent facts as reasonably perceived by the administrators, and whether they were assigned in good faith." Accordingly, the Court granted the Hospital's motion for summary judgment, reasoning that the record reflected that Petitioner received a fair hearing at which she was represented by counsel, who cross-examined the Hospital's witnesses and presented proof in support of her position. The Court further reasoned that the grounds found by the Hospital were reasonably related to institutional concerns and amply supported by proof, including, among other things, testimony of the Hospital personnel and physicians as well as Hospital records.

Court of Appeals Holds That Hospital and Treating Physician Violated Patient's Privacy Rights by Allowing Media to Record and Broadcast Patient's Treatment and Death Without His Prior Consent

Chanko v. American Broadcasting Companies, Inc., 27 N.Y.3d 46, 29 N.Y.S.3d 879 (March 31, 2016). Appellants, family members of a deceased hospital patient, brought an action against the hospital, treating physician, and the ABC television network for filming and broadcasting the patient's medical treatment and death without his prior consent. Reversing the decision of the Appellate Division, the Court of Appeals held that although Defendants' actions were not so extreme and outrageous as to support a cause of action for intentional infliction of emotional distress, the Complaint sufficiently stated a cause of action against the hospital and treating physician for breach of physician-patient confidentiality.

Mark Chanko (decedent) was brought into the hospital's emergency room after being struck by a vehicle. While decedent was being treated, an ABC news crew was in the hospital—with the hospital's knowledge and permission—filming a documentary series (*NY Med*) about medical trauma. Although decedent was alert when he first arrived at the hospital, no one informed decedent or any of his family members of the camera crew's presence. Without his family's knowledge, ABC filmed decedent's medical treatment, his declaration of death, and the moment his treating physician informed his family of his death. Over a year later, decedent's widow watched an episode of *NY Med* on her television at home, which aired the footage. Although decedent's image was blurred, she recognized the scene, heard decedent's voice asking about her, heard him moaning, and watched him die.

Decedent's family commenced this action against, among others, the hospital, decedent's treating physician, and ABC. The Defendants separately moved to dismiss, which the trial court granted in part, dismissing all causes of action except: (i) breach of physician-patient confidentiality against the hospital and treating physician; and (ii) intentional infliction of emotional distress against ABC, the hospital and the treating physician. On appeal, the Appellate Division granted the Defendants' motions in their entirety and dismissed the complaint. Finding that the complaint sufficiently stated a cause of action for breach of the physician-patient confidentiality, the Court of Appeals reversed and reinstated the complaint.

In rendering its decision, the Court of Appeals examined the scope of the physician-patient privilege and held that the privilege applies not only to information orally communicated by the patient, but generally covers all "information relating to the nature of the treatment rendered and the diagnosis made." With respect to emergency rooms specifically, the Court noted that "patients should not fear that merely by obtaining emergency medical care they may lose the confidentiality of their medical records and their physician's medical determinations." The Court further noted that the physician-patient privilege, with its concomitant duty of confidentiality, belongs to the patient and is not terminated by death alone.

The Court rejected Defendants' assertion that, to support such a cause of action, the disclosed medical information must be "embarrassing or something that patients would naturally wish to keep secret." The Court also rejected Defendants' argument that decedent's confidential information was not disclosed because decedent was not identifiable on the aired television program. The Court held that even if no one who actually viewed the televised program recognized the decedent, the complaint expressly alleged an improper disclosure of medical information to the ABC employees who filmed and edited the recording, in addition to the broadcast itself.

Finally, the Court concluded that Defendants' conduct, although reprehensible, is not so extreme and outrageous to satisfy the exceedingly high legal standard to set forth a cause of action for intentional infliction of emotional distress. This is especially true given that the footage aired was edited so that it did not include decedent's name, his image was blurred, and the aired episode included less

than three minutes devoted to decedent and his circumstances.

Court of Appeals Holds That in Medical Malpractice Action, Admission of OPMC Consent Order Is Sufficiently Prejudicial to Warrant New Trial

Mazella v. Beals, 27 N.Y.3d 694 (2016). Appellant, a psychiatrist who treated Respondent's deceased husband, appealed the Appellate Division's decision affirming that Appellant's negligence proximately caused the decedent's suicide.

Appellant began treating the decedent in 1993, diagnosing him with major depression, obsessive compulsive disorder, and generalized anxiety disorder. Between 1993 and 1994, Appellant prescribed medication for decedent, monitored his care, and ultimately tapered off his medication dosage. In 1998, decedent contacted Appellant following a depressive episode, after which Appellant monitored his medications for several weeks. Thereafter, for over 10 years, Appellant continued to refill decedent's Paxil prescription by telephone or facsimile without ever seeing or evaluating him. In 2009, decedent called Appellant complaining about anxiety, an increase in obsessive thoughts, and difficulty sleeping, and Appellant again prescribed medications over the telephone.

Several days later, in stable condition, decedent visited Appellant's office. Respondent alleged that Appellant spoke to decedent in a manner that adversely impacted his condition, including degrading and yelling at him. Appellant disputed these allegations, but corroborated the fact that the decedent was sobbing and suicidal. Following additional care from another physician and at the local psychiatric emergency program over a period of several weeks, decedent committed suicide.

Prior to trial of Respondent's claims alleging wrongful death and medical malpractice, Appellant filed a motion *in limine* to prevent admitting into evidence a Consent Order between Appellant and the Office of Professional Medical Conduct ("OPMC") concerning misconduct charges against him. Specifically, in 2012, OPMC brought charges alleging that Appellant had deviated from accepted standards of medical care by prescribing medications to 13 patients, including decedent, over several years without adequately monitoring and evaluating them, and often without in-person visits. By Consent Order finalized in February 2012, Appellant agreed not to contest charges of negligence based on the allegations involving his treatment for 12 of the 13 patients, specifically excluding decedent.

Appellant argued that the Consent Order was not probative evidence of his negligence regarding decedent, and was unduly prejudicial, as none of the uncontested charges involved decedent or addressed the proper treatment for a patient with a longstanding history of depression, anxiety and OCD. Despite Appellant's argument that the Consent Order's admission into evidence would serve only to unfavorably sway the jury, the Supreme Court denied his motion and determined that the Consent Order would be fully admissible regarding both the issues surrounding decedent's case, and also regarding habit and credibility.

On the day the trial was to begin, Appellant conceded that prescribing medication to decedent for a period of more than ten years without any face-to-face conduct was a deviation from acceptable medical practice, and renewed his motion to preclude the Consent Order, arguing that in light of his concession, the Order was no longer probative of any disputed issue. The Court denied his motion again. The Consent Order was admitted and, at trial, Respondent was permitted to question Appellant about its contents, over counsel's objection. The jury returned a verdict for Respondent, which the Appellate Division affirmed.

Reversing the Appellate Division's decision and ordering a new trial, the Court of Appeals held that the Consent Order was neither probative of Appellant's negligence, nor the question of proximate causation. In the Consent Order, Appellant agreed not to contest negligent treatment of certain patients, none of whom was decedent. Accordingly, the Court held that he preserved his objections to the factual allegations related to decedent, as well as any charges of misconduct in connection with such allegations.

Therefore, the Court held that, because the Consent Order did not establish facts concerning Appellant's treatment of the decedent, the Order was not probative as to that issue. The Court further held that, following Appellant's pre-trial concession that he did, indeed, deviate from accepted medical practice, the issue of negligent treatment no longer required resolution by the jury.

The Court also held that any possible relevance of the Consent Order's contents was outweighed "by the obvious undue prejudice of his repeated violations of accepted medical standards." Underscoring the rules of evidence, the Court held that the Order was "nothing more than evidence of unrelated bad acts, the type of propensity evidence that lacks probative value concerning any material factual issue, and has the potential to induce the jury to decide that case based on evidence of defendant's character."

In addition, the Court was not persuaded by Respondent's argument that the Consent Order was admissible for purposes of impeaching Appellant's credibility, holding that collateral matters pertaining solely to credibility are properly excluded because they distract the jury from central issues, and risk prejudicing the jury based upon character and reputation.

Supreme Court Grants Order Barring Husband's Presence in Delivery Room During Birth of Child

B.T. v. E.T., 2016 WL 4680918 (N.Y. Sup. Ct. Sept. 2, 2016). Plaintiff "Wife" commenced a divorce action before the Supreme Court of New

York, Richmond County. Then, by order to show cause, Plaintiff sought an order enjoining Defendant "Husband" from being present in the delivery room when she gives birth to the parties' child. Husband objected, arguing that his attorney received less than 24 hours' notice of the emergency application, and thus, Wife failed to comply with the notice requirements in 22 NYCRR 202.7(f).

First, the Court held that 24 hours' notice is not required; the regulation only requires that notice be sufficient to permit the party an opportunity to appear. As Wife was in labor and Husband acknowledged he was already aware of her objections to his presence in the delivery room, the Supreme Court held that a fax to Husband's counsel was sufficient notice.

On the merits, the Court held that Wife, as a patient, had a legal right to determine her medical treatment and receive privacy during the receipt of medical care. Her privacy rights included the sole decision to consent to non-medical spectators. The Court reasoned that under HIPAA, Husband had no right to access Wife's medical information without her consent, much less be physically present during the rendering of any such medical care. The Court also held that the right to determine her medical care, and attendant and privacy rights, are solely that of the Wife; thus, Husband lacked standing to challenge those rights or Wife's choices. Further, the Court noted that granting Husband access could potentially create an unsafe and volatile situation that might disrupt Wife's medical treatment and create an unsafe situation. Therefore, the Supreme Court granted the Wife's emergency application.

Appellate Division Rejects Justice Center's Interpretation of Protection of People with Special Needs Act

Matter of Anonymous v. Molik, 141 A.D.3d 162, 34 N.Y.S.3d 203 (3d Dep't 2016). Petitioner is a facility licensed by the Office of People With Developmental Disabilities ("OPWDD") to provide residential care for individuals who suffer from cognitive and physical disabilities. Respondent, Justice Center for the Protection of People With Special Needs ("Justice Center"), is an administrative agency established under the Protection of People With Special Needs Act ("Act"). The Justice Center is charged with, among other things, collecting, investigating, and responding to allegations of abuse and neglect of persons receiving treatment at facilities licensed, operated, or certified by six different state agencies, including the OPWDD.

Under the Act, the Justice Center must notify the director or operator of a facility and the applicable state oversight agency when an incident of abuse or neglect is reported. All such incidents must be investigated by the agency, the facility, the OPWDD, or the Justice Center, and found to be either "substantiated" or "unsubstantiated." When a report of abuse or neglect is substantiated, it must further be graded into one of four categories depending on the nature and severity of the conduct. The Act also allows for a "concurrent finding" that "a systemic problem caused or contributed to the occurrence of the incident." Findings by a facility or the OPWDD must be reviewed by the Justice Center, which may amend or adopt them before they are considered final. If a report is deemed substantiated, then the subject of the report can request an amendment of the report. Upon the denial, in whole or in part, of such a request, the subject is entitled to an administrative hearing and further review by the Director of the Justice Center's Administrative Hearing Unit before a final determination is made.

On June 13, 2013, one of Petitioner's male residents engaged in inappropriate sexual contact with one of its female residents after two staff members momentarily left the common living room. A report of neglect against the two staff members was made to the Justice Center, which conducted its own investigation and concluded that the allegations were unsubstantiated because there is no rule prohibiting staff from leaving a common living room while residents are present. However, the Justice Center found that a report of neglect against Petitioner was substantiated because the facility failed to provide a clear protocol for staff concerning supervision of residents in the common living room, and because it did not provide increased supervision to a patient who had engaged in similar behavior two prior times within the past six months.

The Justice Center denied Petitioner's request to amend the report to unsubstantiated and seal the report. Following an administrative hearing and final determination by the Director of the Justice Center's Administrative Hearings Unit, Petitioner brought an Article 78 proceeding in the Supreme Court, Schenectady County, which was then transferred to the Appellate Division, Third Department. Petitioner sought to annul the Justice Center's determination on the grounds that, *inter alia*, the agency lacked statutory authority to substantiate a finding of neglect against it.

The court began its analysis by noting that the issue presented was pure statutory interpretation and, as such, it did not need to afford any deference to the Justice Center's determination. The court then parsed the language of the Act and found that the Justice Center may only substantiate a finding of neglect against a facility where an incident occurred but the individual responsible cannot be identified. Because two staff members were implicated in the report, the court stated that such provision did not apply.

Although the Justice Center argued that it was authorized to substantiate an allegation of neglect as a "concurrent finding," the court held that such power is "expressly circumscribed by the statute" to the

determination of whether a systemic problem contributed to the occurrence of the incident. The court also noted that the Act requires that substantiated reports of abuse or neglect be assigned to one of four enumerated categories. Because the Act does not provide for the categorization of a "concurrent finding," the court held that it can neither constitute, nor be equated with, a finding of neglect.

Finally, the court recognized that the Legislature may not have contemplated a scenario in which the subject of the report is exonerated and the facility avoids liability despite having contributed to the reported incident. However, the court stated that it cannot override the plain language of the statute merely because it produces unfavorable results. Accordingly, the court granted the petition and annulled the Justice Center's determination.

New York City Board of Health Regulations That Mandate Influenza Vaccinations for Some Child Care Facilities and Schools, but Permit Opt-Out by Payment of a Fine, Are Invalid

Garcia v. New York City Dep't of Health & Mental Hygiene, 2016 WL 5819381 (1st Dep't Oct. 6, 2016). On December 11, 2013, the New York City Board of Health, a part of the New York City Department of Health and Mental Hygiene, used its regulatory authority to amend articles 43 and 47 of the New York City Health Code with respect to influenza ("flu") vaccines (the "amendments"). Although state law already required children of a certain age to receive enumerated vaccinations, the flu was not part of that mandated list.

Under the city agency's amendments, all children, between six and fifty-nine months, attending a child care or school-based program under Board of Health's jurisdiction must receive annual flu vaccines or otherwise qualify for a health or religious exemption. Child care providers or schools could, in effect, elect to opt-out and admit nonexempt, unvaccinated children, by paying a fine for each non-exempt, unvaccinated child in the program.

On November 15, 2015, five mothers brought suit on behalf of their children ("Petitioners") against the City Department of Health, its Commissioner, and Board of Health. The petition sought to permanently enjoin Respondents from enforcing the amendments or, in the alternative, to declare the amendments unconstitutional. By order to show cause, Petitioners moved for a preliminary and permanent injunction or, in the alternative, for the declaration sought in the petition, asserting that, *inter alia*, the amendments were preempted by New York Public Health Law and the City Board of Health had exceeded the scope of its regulatory authority. Respondents cross-moved for, *inter alia*, failure to state a cause of action.

On December 16, 2015, without reaching the issue of the City agency's authority, the Supreme Court held in favor of Petitioners, finding the amendments were preempted by state law. Respondents appealed.

The Appellate Division, First Department affirmed the Supreme Court's holding on different grounds. The Court began its analysis by explaining why preemption did not apply. The Court stated that the New York Court of Appeals only recognizes two scenarios in which state law may preempt local law: (1) field preemption, a doctrine applicable when the state has demonstrated its intent to assume full regulatory authority in an entire field, and (2) conflict preemption, a doctrine applicable when a local law directly conflicts with a state statute. Here, the Court held that the first doctrine did not apply because the state legislature has expressly delegated to local authorities various responsibilities in the field of disease control and vaccination. As for the second doctrine, the Court found that the New York Public Health Law did not address flu vaccinations, nor did it prohibit localities from requiring vaccinations in excess of those mandated by state law.

Nevertheless, the Court determined that the regulations were invalid because the City Board of Health exceeded its regulatory authority. As the Court explained, administrative agencies may promulgate regulations under legislative mandates, but they may not engage in legislative policy-making. To determine whether an agency has crossed that line, the Court of Appeals has set forth a four-part balancing test, which reviews for any use of value judgments, rule creation, policy consideration on topics where the legislature has unsuccessfully tried to reach an agreement, and special expertise. Applying that framework, the Court found that the City made value judgments by creating a regulatory scheme not grounded in promoting public health, given the opt-out provision. The Court also noted that the amendments applied unevenly, imposing a flu vaccination on less than twenty percent of the child care providers in the city.

Southern District Holds That Poor Performance Is a Non-Retaliatory Reason for Termination and a Complete Defense to Retaliation Claims under Labor Law Sections 740 and 741

Thompson v. Jamaica Hosp. Med. Ctr., No. 13 CIV. 1896, 2016 WL 4556905 (S.D.N.Y. Aug. 30, 2016). Plaintiff was employed as the director of Jamaica Hospital's Total Joint Replacement Program ("Program"). His salary was $250,000 annually, plus benefits. In its first 18 months, the Program did not generate enough revenue to cover Plaintiff's compensation. The Hospital notified Plaintiff that it was discontinuing the Program (and thus his employment) because the volume was insufficient to cover costs.

Plaintiff alleged that during the course of his employment, he ad-

vised Defendants about a number of patient health and quality of care issues dealing with cleanliness and sterility of the hospital. Plaintiff alleged that these issues included allegations of trash and flies in the operating room, mishandling culture swabs with dirty and unsterile gloves, delays resulting in prolonged anesthesia time and potential increases in infection rates, lack of sterile equipment for surgeries, and patients lying in their own feces. Plaintiff also alleged that a physician at the hospital told Plaintiff he was "a young snotnose surgeon who can't come here and demand changes."

Plaintiff sued the Hospital, alleging that termination of his employment was in retaliation for disclosing the above issues, in violation of New York Labor Law §§ 740 and 741. These statutes permit damages claims against an employer that takes adverse employment action in retaliation for an employee's disclosure or threatening to disclose violations of law that pose a danger to public health or safety or to the health of a specific patient. Defendants moved for summary judgment.

The court held that despite Plaintiff's allegations, it was undisputed that Plaintiff did not produce enough revenue to cover his salary and other related expenses, and his low volume of patients and revenue was a sufficient reason for termination. The court noted that both statutes provide an exception for any potentially retaliatory termination that was based on other grounds. Specifically, under § 740(4)(c), it is a complete defense to a retaliatory claim if "the personnel action was predicated upon grounds other than the employee's exercise of any rights protected by this section." Similarly, under § 741, "it shall be a defense that the personnel action was predicated upon grounds other than the employee's exercise of any rights protected by this section." Thus, the court held that Plaintiff's poor performance was a valid non-retaliatory reason for termination.

Additionally, the court held that Plaintiff's claim under Labor Law § 740 was time barred. Under § 740 a claim must be brought "within one year after the alleged retaliatory personnel action was taken." It was not disputed that the action was brought a year after the § 740 claim had accrued. Plaintiff, however, argued that because he brought his § 740 claim concurrently with a claim under § 741, a related statute with a two-year statute of limitations, that the two-year limitation should be applied to § 740. To support this argument Plaintiff cited to legislative history that the legislature meant to apply this two-year limitations period to cases bringing both claims concurrently since the purpose of the bill was to avoid significant risks to public health. The court rejected this argument and held that the § 740 claim was time barred.

Second Department Finds That Clinical Supervision of a Nurse by a Person Unauthorized to Do So Can Constitute a Substantial and Specific Danger to Public Health under New York Labor Law § 741

Fough v. Aug. Aichhorn Ctr. for Adolescent Residential Care, Inc., 139 A.D.3d 665, 30 N.Y.S.3d 677 (2d Dep't 2016). Plaintiff, a registered nurse, was discharged from her position as Head of Nursing with Defendant August Aichhorn Center for Adolescent Residential Care, Inc. ("AAC"). Plaintiff commenced an action against AAC and various other related entities asserting a cause of action for unlawful termination in violation of Labor Law § 740. Defendants moved to dismiss the complaint and the trial court dismissed. The Second Department reversed.

The court explained that Labor Law § 740 creates a cause of action in favor of an employee who has suffered a "retaliatory personnel action" as a consequence of "disclos[ing], or threaten[ing] to disclose to a supervisor or to a public body an activity, policy or practice of the employer that is in violation of law, rule or regulation which violation creates and presents a substantial and specific danger to the public health or safety," or as a consequence of "object[ing] to, or refus[ing] to participate in any such activity, policy or practice in violation of a law, rule or regulation." Plaintiff alleged that she was offered a promotion whereby she would have been placed under the supervision of a person who was not authorized to supervise a registered nurse concerning clinical activities. Plaintiff made the AAC aware of the impropriety and turned down the promotion. Plaintiff's employment was subsequently terminated.

The Second Department held that Plaintiff sufficiently alleged activities covered by Labor Law § 740 to state a cause of action sufficient to withstand a motion to dismiss at the pleading stage. It reasoned that the supervision of a nurse in clinical activities by an unauthorized person would, under the circumstances alleged, cause a substantial and specific danger to public health.

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.

2017 Health Care Legislative Preview

By James W. Lytle

With all of the attention on the Presidential election, you would be forgiven in not being focused on the State Legislature, where every seat is on the ballot every two years. While the outcome of the race for the White House may have been unexpected and surprising, the State Legislature election proved to be comparatively unexceptional. The Assembly, as expected, remains overwhelmingly under Democratic control and the much-anticipated battle for the State Senate leaves the Republicans still in the majority, presumably again aligned with the Independent Democratic Conference.

While the outcome of the state elections could have resulted in altering Albany's balance of power, the issues that will be debated during the coming session are likely to be largely the same, regardless of the election outcome. If one were to assemble a "top ten" list of issues that may emerge in the State Capitol during 2017, it might include the following:

ACA/New York State of Health issues: Assuming that the ACA remains alive post-election, the Legislature may devote some attention to the operations and policies underlying the New York State of Health exchange. For starters, perhaps the Legislature might actually put the exchange into state legislation: the exchange mechanism was first established by Executive Order to avoid the necessity of securing legislative support from the State Senate for "Obama-care." Concerns have arisen over the affordability of the coverage, the ease with which potential enrollees access coverage and whether the exchange is functioning well as the key enrollment portal for not only the individual and small group insurance market, but for Medicaid, as well. In addition, the Legislature may return to the issue of whether the Department of Financial Services devoted sufficient financial scrutiny to the insurers on the exchange—a concern illustrated by the collapse of Health Republic last year. While there does not seem to be sufficient support in both Houses for the establishment of a Health Insurance Guaranty Fund, the Legislature last year created authority for a state account to pay the unpaid claims of Health Republic, but did not yet appropriate any moneys to support it. Beginning next year, it may become more apparent how large a gap will remain between the liquidated assets of failed insurer and its liabilities to the health care industry.

Medicaid Redesign/Transformation Agenda: Over the past several years, the Legislature has taken a back seat to the Executive Branch on the Administration's efforts to undertake health care transformation through the Medicaid Redesign initiative and the Delivery System Reform Incentive Program (DSRIP). Whether the Legislature may begin to play a more active role in overseeing these transformation activities remains to be seen. A key element of the Medicaid reforms was the creation of a global Medicaid cap that limits growth in the State share of the Medicaid program. It has become increasingly challenging to restrain spending below the cap, causing the State to take certain expenditures—like those required to satisfy the increase to the minimum wage—outside of the cap.

Biomedical Research: As other States seek to compete with New York for federal and private research dollars and to lure leading researchers to their research centers, New York has been asked to step up its support for biomedical research. The Legislature will be asked to maintain and expand existing programs that fund particular research areas, including funding for stem cell research, spinal cord research, AIDS and Alzheimer's Disease, while also supporting the biomedical research enterprise more globally—as a means to spur economic development and to cure disease.

Telehealth: In 2015, legislation was enacted that provided for insurance and Medicaid reimbursement for telehealth services under certain circumstances. While the bill may have been a good step in the right direction, the legislation imposes some limitations on the manner in which telehealth might be utilized to enhance timely access to specialized services, to improve quality of care and to reduce costs. The Department of Health is preparing regulations that have raised similar concerns over restrictions on the use of telehealth and some effort may be undertaken to permit and to encourage more robust use of the technology.

HCRA: The Health Care Reform Act (HCRA), the massive state scheme put in place twenty years ago that both raises and spends billions of dollars of revenue for a host of health care purposes, expires next year. While the Administration has not signaled an interest to consider any significant reform of the HCRA regime, the necessity of extending the program provides the opportunity for the Legislature to either fundamentally rethink the approach or, more likely, to tweak the revenue-raising and/or spending components of HCRA. Given its longstanding role in funding approaches to paying for care provided to the uninsured and indigent, HCRA may be the mechanism that is identified to address the ongoing need to cover care provided to the uninsured (including undocumented aliens) and to offset the sig-

nificant scheduled reductions in Federal disproportionate share support.

Issues around death and dying: Increasing attention and support has been given to proposals that empower individuals to have a greater say in how they might die, including legislation that would permit physician-assisted aid in dying. Legislation was favorably considered in the Assembly Health Committee this year and a change in the makeup of the State Senate might improve its chances in that House. The issue was also front and center last year as patients unsuccessfully sought a ruling from the state's appellate courts that obtaining physician assistance in dying was constitutionally protected.

Medical Marijuana: A slow start to the state's medical marijuana program may prompt efforts by supporters to expand New York's somewhat cautious and limited program.

Opioid epidemic: A package of bills were enacted last year to address the heroin epidemic that dealt with insurance reimbursement, the availability of medication-assisted treatment and host of other issues. The issue remains front and center across the state and additional legislation might be considered to address opioid abuse and treatment, even as the initiatives from last year just begin to become effective.

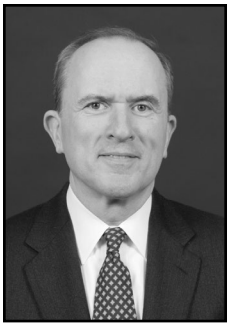
Pharmaceutical costs and pricing: The substantial increases in pharmaceutical costs—and some unsavory practices by some particularly bad apples—have prompted consideration of proposals that might curb the cost of prescription drugs. While the state's role in this area may be somewhat limited, the Administration has examined ways that New York might negotiate better prices for its government programs and has considered whether it might be able to undertake some collective action with other states to address these issues.

Healthcare planning: The still unresolved question of the future of healthcare in Brooklyn illustrates the ongoing challenges of what the state's role should be in restructuring the health care system to meet the public health and fiscal challenges of the 21st century. The growth of large hospital-based systems, the expanding role of multi-specialty medical groups, explosions in urgent care and retail health care, and consolidations of health plans may require a closer look at New York's health planning system, which was put in place more than a half century ago.

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

In the New York State Agencies

By Francis J. Serbaroli



Children's Camps

Notice of Adoption. The Department of Health amended 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. Filing date: June 1, 2016. Effective date: June 22, 2016. *See* N.Y. Register June 22, 2016.

Site Based Prevocational Services Certification and Physical Plant Requirements

Notice of Adoption. The Office of People with Developmental Disabilities amended section 635-7.5 of Title 14 NYCRR to apply existing physical plant and certification requirements in OPWDD regulations to site based prevocational services. Filing date: June 7, 2016. Effective date: September 1, 2016. *See* N.Y. Register June 22, 2016.

Zika Action Plan; Performance Standards

Notice of Emergency Rulemaking. The Department of Health added section 40-2.24 to Title 10 NYCRR to require local health departments to develop a Zika Action Plan as a condition of State Aid. Filing date: June 14, 2016. Effective date: June 14, 2016. *See* N.Y. Register June 29, 2016.

Cost Report Submission and Penalty Changes

Notice of Adoption. The Office of People with Developmental Disabilities amended section 635-4.4 of Title 14 NYCRR to amend requirements for submission of cost reports and penalties for failure to submit cost reports to OPWDD. Filing date: June 14, 2016. Effective date: July 1, 2016. *See* N.Y. Register June 29, 2016.

Reciprocal Emergency Medical Technician Certification Requirements

Notice of Adoption. The Department of Health amended section 800.12 of Title 10 NYCRR to replace the emergency medical technician-intermediate category with the advanced emergency medical technician category. Filing date: June 21, 2016. Effective date: July 6, 2016. *See* N.Y. Register July 6, 2016.

Protection Against Legionella

Notice of Adoption. The Department of Health added Part 4 to Title 10 NYCRR to protect the public from the immediate threat posed by Legionella. Filing date: June 21, 2016. Effective date: July 6, 2016. *See* N.Y. Register July 6, 2016.

Controlled Substances for EMS Agency Agent and Requirements for an Advanced Life Support System

Notice of Adoption. The Department of Health amended sections 80.136 and 800.5 of Title 10 NYCRR to amend the regulations regarding the EMS Agency Agent and the Requirements for an Advanced Life Support System. Filing date: June 30, 2016. Effective date: July 20, 2016. *See* N.Y. Register July 20, 2016.

General Program Standards; Qualified Health Professionals

Notice of Adoption. The Office of Alcohol and Substance Abuse Services amended Part 800 of Title 14 NYCRR to include all mental health practitioners as qualified health professionals (QHP). Filing date: July 7, 2016. Effective date: July 27, 2016. *See* N.Y. Register July 27, 2016.

General Facility Requirements

Notice of Adoption. The Office of Alcohol and Substance Abuse Services amended Part 814 of Title 14 NYCRR to update regulations relating to program facilities. Filing date: July 7, 2016. Effective date: July 27, 2016. *See* N.Y. Register July 27, 2016.

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

Notice of Adoption. The Office of Alcohol and Substance Abuse Services amended Part 836 of Title 14 NYCRR to clarify requirements for reporting patient deaths. Filing date: July 7, 2016. Effective date: July 27, 2016. *See* N.Y. Register July 27, 2016.

Requirements for Manufacturers and Distributors Regarding Controlled Substances

Notice of Adoption. The Department of Health amended section 80.11 of Title 10 NYCRR to clarify and use language consistent with current terminology used by the State Board of Pharmacy. Filing date: July 20, 2016. Effective date: August 10, 2016. *See* N.Y. Register August 10, 2016.

School Immunization Requirements

Notice of Adoption. The Department of Health amended Subpart 66-1 of Title 10 NYCRR to update school immunization and NYSIIS regulations. Filing date: August 2, 2016. Effective date: August 17, 2016. *See* N.Y. Register August 17, 2016.

Practice of Radiologic Technology

Notice of Revised Rulemaking. The Department of Health proposed to amend Part 89 of 10 NYCRR to update regulations related to the practice of radiologic technology. *See* N.Y. Register August 17, 2016.

Incident Management, Criminal History Record Checks, Operation of Psychiatric Inpatient Units General Hospitals, RTFs and CPEPs

Notice of Adoption. The Office of Mental Health amended Parts 524, 550, 580, 584 and 590 of Title 14 NYCRR to update statutory and regulatory citations and to conform to non-discretionary statutory provisions. Filing date: July 27, 2016. Effective date: August 17, 2016. *See* N.Y. Register August 17, 2016.

Repeal of Obsolete Rules; General Provisions; HIV-AIDS; Inpatient Programs; Funding for Services; Hearings; Authorizing MDs

Notice of Proposed Rulemaking. The Office of Alcohol and Substance Abuse Services proposed repealing Parts 309, 369, 829, 1000, 1034, 1050, 1070 and 1072 of Title 14 NYCRR to repeal obsolete rules of DSAS/DAAA and the Office. *See* N.Y. Register August 24, 2016.

Specialized Programs for Residents with Neurodegenerative Diseases

Notice of Revised Rulemaking. The Department of Health proposed adding section 415.41 of Title 10 NYCRR to establish nursing home specialty units for residents with Huntington's Disease (HD) and Amyotrophic Lateral Sclerosis (ALS). *See* N.Y. Register August 24, 2016.

Hospice Operational Rules

Notice of Adoption. The Department of Health amended Parts 700, 717, 793 and 794 of Title 10 NYCRR to implement hospice expansion. Filing date: August 10, 2016. Effective date: August 31, 2016. *See* N.Y. Register August 31, 2016.

Transgender-Related Care and Services

Notice of Adoption. The Department of Health amended section 505.2(1) of Title 18 NYCRR to revise and clarify the criteria for Medicaid coverage of transgender related care and services. Filing date: August 16, 2016. Effective date: August 31, 2016. *See* N.Y. Register August 31, 2016.

All Payer Database (APD)

Notice of Proposed Rulemaking. The Department of Health proposed adding Part 350 of Title 10 NYCRR to define the parameters for operating the APD regarding mandatory data submission by health care payers as well as data release. *See* N.Y. Register August 31, 2016.

Telepsychiatry Services

Notice of Adoption. The Office of Mental Health added Part 596 and repealed section 599.17 of Title 14 NYCRR to establish basic standards and to approve telepsychiatry in certain OMH-licensed programs and to repeal unnecessary existing provisions. Filing date: August 11, 2016. Effective date: August 31, 2016. *See* N.Y. Register August 31, 2016.

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

Notice of Emergency/Proposed Rulemaking. The Department of Financial Services proposed amending Part 52 (Regulation 62) of Title 11 NYCRR to allow blanket accident insurance policy issued in accordance with General Business Law, section 1015.11 to be excess to any plan. Filing date: August 18, 2016. Effective date: August 18, 2016. *See* N.Y. Register September 7, 2016.

Medical Use of Marihuana

Notice of Proposed Rulemaking. The Department of Health proposed amending section 1004.1(a)(2) of Title 10 NYCRR to authorize nurse practitioners to register with DOH in order to issue certifications to patients with qualifying conditions. *See* N.Y. Register September 14, 2016.

Lead Testing in School Drinking Water

Notice of Emergency Rulemaking. The Department of Health added Subpart 67-4 to Title 10 NYCRR to require lead testing and remediation of potable drinking water in schools. Filing date: September 6, 2016. Effective date: September 6, 2016. *See* N.Y. Register September 21, 2016.

Agency Name Change and Terminology Updates

Notice of Adoption. The Office for People with Developmental Disabilities amended Parts 602-606, 620-622, 633, 635, 643, 671, 676, 679-681, 686, 687 and 690 of Title 14 NYCRR to update the agency name and other terminology updates in the Title 14 NYCRR Part 600 series. Filing date: September 6, 2016. Effective date: September 21, 2016. *See* N.Y. Register September 21, 2016.

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

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 361 of Title 11 NYCRR to allow for the implementation of a market stabilization pool for the small group health insurance market. Filing date: September 9, 2016. Effective date: September 9, 2016. *See* N.Y. Register September 28, 2016.

Charges for Professional Health Services

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending section 68.6 (Regulation 83) of Title 11 NYCRR to limit reimbursement for no-fault health care services provided outside NYS to highest fees in fee schedule for services in NYS. *See* N.Y. Register September 28, 2016.

Zika Action Plan; Performance Standards

Notice of Emergency Rulemaking. The Department of Health added section 40-2.24 of Title 10 NYCRR to require local health departments to develop a Zika Action Plan as a condition of State Aid. Filing date: September 12, 2016. Effective date: September 12, 2016. *See* N.Y. Register September 28, 2016.

Non-Prescription Emergency Contraceptives Drugs

Notice of Proposed Rulemaking. The Department of Health proposed amending section 505.3 of Title 18 NYCRR to allow pharmacies to dispense non-prescription emergency contraceptive drugs for Medicaid female recipients without a written order. *See* N.Y. Register September 28, 2016.

Expanded Syringe Access Program

Notice of Proposed Rulemaking. The Department of Health proposed amending section 80.137 of Title 10 NYCRR to eliminate the word "demonstration." *See* N.Y. Register September 28, 2016.

Transgender Related Care and Services

Notice of Proposed Rulemaking. The Department of Health proposed amending section 505.2(l) of Title 19 NYCRR to amend provisions regarding Medicaid coverage of transition-related transgender care and services. *See* N.Y. Register October 5, 2016.

Residential Health Care Facility Quality Pool

Notice of Emergency/Proposed Rulemaking. The Department of Health proposed adding section 86-2.42 to Title 10 NYCRR to reward NYS facilities with the highest quality outcomes as determined by a methodology developed by this regulation. Filing date: September 21, 2016. Effective date: September 21, 2016. *See* N.Y. Register October 12, 2016.

Compounded Trend to Cost of Living Adjustments (COLAs) for Direct Care Workers

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 86-10 of 10 NYCRR to update the methodology to reflect a compounded cost-of-living adjustment and to remove a superfluous component. *See* N.Y. Register October 12, 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 and Edward J. Ohanian, both associates of Greenberg Traurig's Health and FDA Business Group, in compiling this summary is gratefully acknowledged.

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

There are no updates since the last edition.

NYS Attorney General Press Releases

Compiled by Joseph A. Murphy and Eric W. Dyer

Civil Settlement Agreement Requires Doctor to Pay Over $500k for Fraudulent Medicaid Billings—October 6, 2016—A Town of Gates doctor pled guilty to misdemeanor Falsification of Business Records for billing Medicaid for office visits that did not occur. In addition, the doctor's corporation pled guilty to felony Grand Larceny for improperly billing services between July 9, 2013 and May 6, 2016. The civil settlement agreement requires the doctor to pay more than $500,000 for claims involving overbilling, billing for services provided by ineligible staff, and improper billing of prescriptions. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-recovery-over-500k-local-doctors-fraudulent-medicaid.

Settlement with Nassau County Jail Health Services Company—October 5, 2016—The Company agreed to pay New York State $350,000 and to refrain from any contracts to provide jail health services in New York for three years. The agreement resolves charges against a Florida-based jail health services company alleging that it failed to perform various contractual duties, placing inmates' health in jeopardy. The agreement also provides for an independent monitor to oversee the company's compliance with its contractual obligations in Nassau County Jail for the remainder of the contract. From the settlement, $100,000 will be paid to the Office of Attorney General for penalties and $250,000 will go to Nassau County for reimbursement related to contractual obligations. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-lawsuit-against-jail-health-services-company.

Owner of Medical Equipment Store Pled Guilty to Defrauding Medicaid for $2 Million—September 30, 2016—The owner of a durable medical equipment and supply store and her corporation pled guilty to Grand Larceny for submitting thousands of false claims to Medicaid for over $2 million. The owner admitted to using Medicaid identification numbers of customers to fraudulently bill for items that were never purchased or delivered and to falsifying customer records, physician orders, and other books and records. The owner is expected to receive two to six years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-owner-suffolk-county-medical-equipment-store.

Herbal Supplement Maker Agrees to Increased Disclosure of Ingredients—September 28, 2016—A Long Island manufacturer of herbal supplements for Walgreens and Walmart reached an agreement with the Attorney General's Office to phase in DNA barcoding on ingredients within two years and test for allergens such as peanuts, milk, eggs and soy. The agreement also requires the manufacturer to double the number of on-site audits of major ingredient suppliers and receive third-party accreditation for active ingredients that are exempt by the FDA. In the first year, the manufacturer must invest at least $250,000 in herbal authenticity genetic research. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-major-nationwide-agreement-nbty-herbal-supplement-maker.

Settlement with Transportation Provider to Resolve Allegations of Falsely Billing Medicaid—September 26, 2016—A transportation company entered into a settlement agreement to resolve allegations that it billed Medicaid for transportation services provided by unqualified drivers and without required documentation. The company billed Medicaid for transportation services when drivers providing services were unqualified under Article 19-A of the Vehicle and Traffic Law, and the company failed to maintain contemporaneous records demonstrating the right to receive payments between June 1, 2007 and September 24, 2009. The company will pay New York State $173,650.83 in restitution and damages. The lawsuit was filed by a whistleblower pursuant to a qui tam action. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-173k-settlement-wny-transportation-provider-resolve.

Attorney General's Office Sues Opioid Addiction Drug Maker for Anticompetitive Practices—September 22, 2016—The Attorney General's Office, along with 34 other states and the District of Columbia, is suing the pharmaceutical company Indivior, which makes Suboxone, a drug used to treat opioid-addicted patients. The lawsuit claims the company has engaged in anticompetitive business practices by introducing a dissolvable oral strip to stop the entry of generic versions of Suboxone and maintain its monopoly on Suboxone. http://www.ag.ny.gov/press-release/ag-schneiderman-sues-manufacturer-opioid-addiction-drug-illegally-blocking-competition.

Three Arrested for Allegedly Filing False Medicaid Timesheets—September 16, 2016—Three individuals were arrested and charged with submitting false timesheets for care that was not actually provided to a Medicaid recipient. The alleged scheme to defraud Medicaid consisted of a mother who hired her daughter and a family friend to provide services for her other daughter who is a Medicaid recipient. The mother allegedly signed timesheets submitted by her daughter and family friend for care that was not provided. The mother and daughter were charged with Falsifying Business Records, and the mother and family friend were charged with Grand Larceny and Offering a False Instrument for Filing. The mother faces up to seven years in prison, and the daughter and the family friend face up to four years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-charges-against-3-individuals-allegedly-filing-false

Four Aides Arrested for Allegedly Taking Photos and Videos of Nursing Home Residents—September 15, 2016—In two separate cases, aides providing care to elderly and disabled residents were arrested for taking inappropriate photos and videos of residents. In one case, two aides allegedly took photographs of a resident in undignified positions, including pictures with the defendants in bed with the resident. In the other case, the aides allegedly filmed a video of themselves verbally and physically tormenting a resident, which allegedly caused emotional trauma and physical harm to the resident, as the resident lashed out in a violent manner to stop the abuse. The aides in both cases were charged with Endangering the Welfare of an Incompetent or Physically Disabled Person and Willful Violation of the Public Health Law. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-4-aides-who-allegedly-took-photos-and-videos-nursing.

Former Certified Nursing Assistant Sentenced to Jail for Sexually Abusing One Nursing Home Resident and Exposing Himself to Another—September 15, 2016—After pleading guilty to Sexual Abuse in the 1st Degree and Endangering the Welfare of a nursing home resident, a former certified nursing assistant was sentenced to four months of jail on weekends and 10 years' probation. The former Wayne County certified nursing assistant victimized a 99-year-old resident by placing her in the bathroom facing the wall while he sexually abused her daughter. He also exposed himself to an 84 year-old female resident while making lewd comments. The former assistant is required to be registered as a sex offender based on this conviction. http://www.ag.ny.gov/press-release/former-wayne-county-nursing-home-cna-sentenced-jail-sexually-abusing-one-victim.

Settlement with Optician Who Billed Medicaid in Violation of Medicaid Billing Rules—September 15, 2016—An optician has entered into a settlement agreement to resolve allegations that he violated the New York False Claims Act for causing Medicaid to pay for eyeglasses that Medicare should have covered. The optician also caused Medicaid to pay for the cost of eyeglasses that were never dispensed to Medicaid recipients. The settlement requires the optician to pay New York State $24,000 in restitution and damages. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-24k-settlement-optician-who-billed-medicaid-eyewear.

Man Arrested for Allegedly Defrauding Medicaid by Falsely Reporting Aide Services—September 8, 2016—A man in charge of the administration of aide care to his relative was arrested for allegedly submitting false time sheets to a health care provider in order to receive payments from Medicaid. The man allegedly hired his girlfriend to provide home care services for his relative for 502 hours, but during those hours the girlfriend was at work or the relative was in an adult day care program. The man and his girlfriend allegedly received $5,020 for work that was not performed, and the provider allegedly billed Medicaid $9,036 based on the false time sheets. The man was charged with Grand Larceny, Falsifying Business Records, and Offering a False Instrument for Filing. He faces a maximum of two to four years in prison. http://www.ag.ny.gov/press-release/ag-schneidmeran-announces-arrest-rochester-man-who-allegedly-defrauded-medicaid.

Attorney General Issues Legal Opinion that New York State's Criminal Law Does Not Interfere with Reproductive Health Rights—September 8, 2016—The Attorney General released a formal legal opinion clarifying that abortion rights under *Roe v. Wade* and later Supreme Court decisions are not limited by the New York Penal Law. The opinion was issued at the request of the Office of the New York State Comptroller to aid in its auditing over state payments to healthcare providers. The opinion stated that Penal Law Section 125.05(3), which places certain limitations on the timing and conditions for obtaining an abortion, must be read to contain an exception allowing abortion to preserve the mother's health and an exception to allow a doctor to determine viability of the fetus after 24 weeks of pregnancy. http://www.ag.ny.gov/press-release/ag-schneiderman-issues-legal-opinion-clarifying-new-york-states-criminal-law-does-not.

Former Group Home Worker Arrested for Abusing Disabled Resident—September 7, 2016—A former direct support assistant at a state-run group home in Long Island was arrested for allegedly tying an intellectually and physically disabled resident to her bed with bed sheets. The worker also allegedly failed to check on the resident during the night shift, in violation of requirements that he check on the resident every fifteen minutes. The worker was charged with Endangering the Welfare of an Incompetent or Physically Disabled Person and faces up to one and one-third to four years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-

former-long-island-group-home-worker-alleged-abuse.

***EpiPen Manufacturer Investigated for Anticompetitive School Contracts*—September 6, 2016—**The Attorney General's Office has launched an investigation into Mylan Pharmaceuticals Inc., the company that makes EpiPens. The investigation was prompted after a review of the company's sales contracts with multiple school systems revealed potentially anticompetitive terms. http://www.ag.ny.gov/press-release/ag-schneiderman-launches-antitrust-investigation-mylan-pharmaceuticals-inc-maker.

Multiple Hospitals Enter into a Joint State and Federal Settlement Agreement for False Claims Act Violations—August 24, 2016—In a $2.95 million settlement with three hospitals from the Mount Sinai Health System, New York State is receiving over $1.7 million to resolve allegations that the hospitals kept over $844,000 in Medicaid overpayments for more than sixty days, in violation of the state and federal False Claims Acts. As part of the settlement, the hospitals admitted that a software compatibility issue caused a coding error, which caused the hospitals to wrongfully bill Medicaid as a secondary payor. The improper billing was brought to the hospitals' attention by an employee who was later fired and became the whistleblower for this case. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-joint-state-and-federal-295-million-settlement-hospitals.

Nurse Aide Pleads Guilty for Striking and Shoving a Nursing Home Resident—August 23, 2016—A nurse aide pled guilty to Endangering the Welfare of an Incompetent or Physically Disabled Person in connection with an incident in October 2015 when the nurse aide struck a nursing home resident in the face and pushed him. The resident tripped and fell into a piece of furniture, causing injuries to his shoulder. The nurse faces up to four years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-nurse-aide-who-struck-and-shoved-nursing-home.

Settlement with Non-Profit Health Care Service Corporation for Wrongful Denial of Outpatient Mental Health Treatment Relating to Psychotherapy and Nutritional Counseling—August 22, 2016—A Buffalo-based non-profit that provides health care coverage to over 500,000 New Yorkers will pay its members for wrongfully denying claims for outpatient psychotherapy and nutritional counseling for eating disorders. In addition, as part of the settlement, the corporation will revise its policies, eliminate a company policy that required all psychotherapy claims to be reviewed after a member's 20th visit, and pay $60,000 as a civil penalty. An investigation found there were more than $1.6 million in wrongfully denied claims. Under New York and Federal laws, plans must ensure mental health conditions receive comparable coverage to other health conditions in the plan. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-healthnow-new-york-over-wrongful-denial-16.

Former Private Duty Nurse Sentenced for Stealing from Medicaid—August 19, 2016—A licensed practical nurse in Rochester was sentenced to three years of probation and required to make restitution for falsifying timesheets that resulted in $19,000 of Medicaid payments. She had been charged with billing 269 hours for services that were either not provided or not performed by this nurse. She pleaded guilty to Petit Larceny and will be required to pay restitution in the amount of $7,564.02. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-former-private-duty-nurse-sentenced-stealing-over.

Medical Equipment Store and Majority Shareholder Indicted for Allegedly Defrauding Medicaid of $2 Million—August 12, 2016—A medical equipment store and its majority shareholder were indicted on 50 counts for allegedly submitting thousands of false claims to Medicaid. The shareholder allegedly used customers' Medicaid identification numbers to bill for durable medical equipment and supplies that were never actually purchased or delivered to the customers. The company was the highest biller of at least thirteen durable medical equipment procedure codes in the state. The majority shareholder allegedly falsified customer files to make it look like providers ordered the supplies for the patients and falsified books and records. The charges allege that Medicaid paid more than $2 million in false claims. The shareholder and company were charged with Grand Larceny, Offering a False Instrument for Filing, Criminal Possession of a Forged Instrument, and Falsifying Business Records. The shareholder faces between eight and one-third to twenty-five years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-indictment-suffolk-county-medical-equipment-store-allegedly.

Tanning Salon Chain Settles Charges of Making Misleading Health Claims—August 10, 2016—A tanning salon chain, with 25 locations in upstate New York, has entered into a settlement agreement resolving claims that its website and employees downplayed risks of indoor tanning and it failed to provide free protective eyewear. The chain agreed to pay $5,000 per day for any future health misrepresentations and $500 for each future violation of New York tanning laws. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-agreement-barring-tanning-salon-chain-making-misleading.

Pharmacist Convicted of Illegally Selling Black Market HIV Medications—August 9, 2016—A pharmacist and his shell company were found guilty after trial for their role in a scheme that distributed diverted HIV medications. The pharmacist and three others were charged with distributing HIV prescription medication obtained on the black market through a

high-volume, online pharmacy located in Melville with satellite offices in Manhattan, Brooklyn and other states. The pharmacy and its parent company then dispensed the medication to Medicaid recipients and billed the New York State Medicaid program. The medications had unknown origins and potency and were mislabeled and potentially expired. As a result of the scheme, Medicaid was illegally billed $274 million and the pharmacist's profit was $25 million. The pharmacist was found guilty of Grand Larceny, Criminal Diversion of Prescription Medications and Prescriptions, Conspiracy, Attempted Grand Larceny, Attempted Criminal Diversion of Prescription Medications and Prescriptions, Money Laundering and Commercial Bribing. The shell corporation was found guilty on three counts of Money Laundering and Commercial Bribing. The pharmacist faces a sentence of up to eight and one-third to twenty-five years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-trial-conviction-pharmacist-who-illegally-sold-black-market.

Drug Company That Impeded Competition of Generic Prescription Makers Settles for $125 Million— August 4, 2016—As part of a 48-state, $125 million settlement with drug manufacturer Cephalon, New York State will receive over $10 million. The settlement comes after Cephalon was alleged to have engaged in anticompetitive practices that prevented generic competition of the drug Provigil. An investigation found that Cephalon delayed the generic competition through filing patent infringement lawsuits and intentionally defrauding the Patent and Trademark office. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-125-million-settlement-drug-company-impeded-competition.

Attorney General's Office Issues Cease and Desist Letters to Companies Falsely Advertising "Zika-Preventive" Products— August 3, 2016—The Attorney General's office issued letters to seven companies demanding that they stop falsely advertising Zika virus prevention and protection products that are known to be ineffective. The companies were advertising either ultrasonic devices or botanical oil-based products that do not contain one of the five CDC-recommended active ingredients to repel mosquitos. As an alternative, the Attorney General's office recommended that consumers purchase EPA-registered insect repellants that contain one of the CDC's recommended ingredients. http://www.ag.ny.gov/press-release/ag-schneiderman-issues-cease-and-desist-letters-demanding-companies-stop-falsely.

Four Nursing Home Staffers Arrested for Alleged Failure to Provide Care to a 94 Year-Old Resident—August 2, 2016—Two licensed practical nurses and two certified nurse assistants were arrested for allegedly failing to provide care to a nursing home resident during Memorial Day weekend. Video from the facility camera showed that the 94 year-old resident was left in a recliner for over 41 hours and failed to receive proper care. During this time, the nurses allegedly changed the resident's briefs once, delivered one meal, and provided one round of medications. The resident was later diagnosed with pressure sores. Three defendants were arrested on felony charges, including Falsifying Business Records, Endangering the Welfare of an Incompetent or Physically Disabled Person in the First Degree, and a misdemeanor charge of Willful Violation of Health Laws. The fourth defendant was charged with the misdemeanor of Willful Violation of Health Laws. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-four-nursing-home-staffers-alleged-failure-provide.

Syracuse Hospital to Pay $3.2 Million Settlement for Improperly Billing Medicaid for Mental Health Services—August 1, 2016—A Syracuse hospital will pay $3.2 million to resolve allegations that it violated the federal and New York False Claims Act by presenting false claims for payment to the state Medicaid program for mental health services rendered by unqualified staff. The settlements resolve allegations that the hospital knowingly presented false claims for payment to Medicaid for mobile-crisis outreach services rendered from January 1, 2007 through February 29, 2016 by personnel who failed to satisfy staffing requirements for its Comprehensive Psychiatric Emergency Program. This investigation was triggered by a whistleblower lawsuit filed under the qui tam provisions of the federal and New York False Claims Acts. http://www.ag.ny.gov/press-release/ag-schneiderman-and-us-attorney-hartunian-announce-32m-settlement-st-josephs-hospital.

Former Nursing Home Counselor Arrested for Alleged Sexual Abuse of Residents with Traumatic Brain Injures—July 28, 2016—A former "Neighborhood Counselor" responsible for overseeing the social environment at a rehabilitation center that treats individuals suffering from traumatic brain injuries was arrested for sexually abusing two of the facility's residents. The former counselor was suspended and then terminated from the Lake Katrine facility. The charges include two counts of Criminal Sexual Act in the First Degree, five counts of Sexual Abuse in the First Degree, and related charges. The former counselor was arraigned in Ulster Town Court and faces up to 25 years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-former-nursing-home-counselor-alleged-sexual-abuse.

New York Joins Department of Justice and Ten Other States in Complaint to Stop Anthem Merger with Cigna—July 21, 2016—New York joined a federal/state complaint that alleges the merger between Anthem and Cigna would be anticompetitive and should be stopped. The complaint alleges that the merger would reduce competition for large-group employer plans and drive down reimbursement rates for providers, which would result in a

negative impact to the access and quality of health care services for New Yorkers. The lawsuit was filed in federal court in Washington, D.C. by the Department of Justice, New York, ten other states, and the District of Columbia, and seeks a court order halting the merger between the two companies. http://www.ag.ny.gov/press-release/ag-schneiderman-joins-justice-department-and-ten-states-seeking-stop-anticompetitive.

Non-Profit Executives Indicted for Tax-Fraud and Filing False Tax Returns—July 18, 2016—A former Chief Executive Officer of a not-for-profit organization that serves the developmentally disabled community in New York City and Long Island was indicted, along with the Chief Executive Officer of a management services company, for a related tax fraud and embezzlement scheme. The two executives allegedly failed to pay taxes on money that they embezzled through the non-profit by directing the organization to pay hundreds of thousands of dollars in consulting fees to the management services company. Findings from the investigation allege that one non-profit CEO used the funds for personal credit card debt, cosmetic surgery, and family vacations, among other personal expenses. She is charged with Criminal Tax Fraud in the Third Degree, Criminal Tax Fraud in the Fourth Degree and Offering a False Instrument for Filing in the First Degree. Similarly, the management company CEO was indicted on counts of Criminal Tax Fraud in the Third Degree and Offering a False Instrument for Filing in the First Degree. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-indictment-non-profit-executives-charged-criminal-tax-fraud.

Home Health Care Agency Owner Pleads Guilty to Wage Theft—July 14, 2016—The owner of a Home Health Care Agency based in Peekskill pleaded guilty to numerous Class E felonies in connection with the owner's failure to pay wages to at least 67 employees. From December 2012 to June 2015, the owner hired workers to provide home health care services to patients but failed to pay them. The workers quit and the owner hired new workers who were also not paid. The owner pleaded guilty to charges of Scheme to Defraud, Falsifying Business Records in the First Degree, Offering a False Instrument for Filing in the First Degree, Failure to Pay Wages, and Willful Failure to Pay a Contribution to the Unemployment Insurance Fund. The owner is scheduled for sentencing on December 8, 2016 and was ordered to pay $135,000 in back wages to the employees and $66,000 to the state Unemployment Insurance Fund. http://www.ag.ny.gov/press-release/ag-schneiderman-obtains-guilty-plea-peekskill-home-health-care-agency-owner-over-wage.

Nurse Aide Pleads Guilty to Stealing from Nursing Home Resident—July 13, 2016—A certified nurse aide pled guilty in Cortland County Court to Criminal Possession of Stolen Property in the Fourth Degree for using the debit/credit card of a nursing home resident to steal $5,229.14 of merchandise and cash. The certified nurse aide and a co-defendant obtained personal information from the resident to activate the card and check the balances. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-nurse-aide-who-stole-nursing-home-resident.

Nurse Aide Arrested for Allegedly Punching Nursing Home Resident—July 8, 2016—A certified nurse aide working in a Utica-based nursing home was arrested for allegedly punching an 87 year-old resident in the face, causing multiple fractures. The aide also allegedly omitted her part in causing the injuries in facility reports. The charges against the aide include Endangering the Welfare of a Vulnerable Elderly Person or an Incompetent or Physically Disabled Person in the Second Degree and Falsifying Business Records in the First Degree, punishable by up to four years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-aide-allegedly-punching-nursing-home-resident.

Civil Settlement with Long Island-based Nursing Home and Its Owners—June 22, 2016—New York State has entered into a settlement with a Long Island nursing home and its owners for $28 million in connection with claims of criminal conduct by employees, staffing cuts, and diversion of Medicaid funds to the owners and their controlled entities. The settlement requires, among other things, that $10 million be returned to the Medicaid program, and that the remaining funds be controlled by an Independent Financial Monitor who will use the funds to improve the nursing home's delivery of care and services. Separately, the corporation was also sentenced and fined $10,000, after a guilty plea to Attempted Falsifying Business Records in the First Degree for an administrator's cover up of a patient's death in 2012. Previously, three nurses, two respiratory therapists, and a former administrator were convicted and sentenced in connection with the cover-up. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-landmark-civil-settlement-long-island-nursing-home-and-its.

Nurse Charged With Injuring 91 Year-Old Nursing Home Resident—June 21, 2016—A licensed practical nurse working at a Saratoga County nursing home was arrested on charges that he endangered the welfare of a 91 year-old resident by showering her despite her refusal. The resident, who suffered from dementia, allegedly fell onto the shower floor under the nurse's care, and he failed to report the fall to a supervisor to ensure that the resident was properly assessed for injury. It was later discovered that the resident sustained a fracture to her leg and significant bruising to her chest and bottom. The nurse was charged with endangering the Welfare of an Incompetent or Physically Disabled Person and Willful Violation of Health Laws. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-charged-connection-injury-91-year-old-nursing.

Bronx Clinic Owner Arrested on Charges of $5 Million Medicaid Fraud—June 20, 2016—The owner of a not-for-profit organization in the Bronx allegedly offered affordable housing to low-income individuals under the condition they surrender their personal health care information and submit to unnecessary medical tests. In addition, the not-for-profit is alleged to have directed prospective residents to see doctors and counselors connected with the not-for-profit organization, who then submitted false claims to Medicaid. In an eight-month period, the organization allegedly submitted over 125,000 claims for services allegedly rendered for which Medicaid reimbursed over $5 million. The doctors then paid millions of these dollars to the owner. According to the allegations, the doctors saw hundreds of patients a day, gave each patient the same medical diagnosis, practiced outside their field of specialty, and delivered treatment they were not qualified to provide. The owner was charged with Grand Larceny, Health Care Fraud and Insurance Fraud and faces maximum sentences of between 8 1/3 to 25 years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-bronx-clinic-owner-alleged-five-million-dollar.

Former Nursing Home Employee Sentenced to Jail for Stealing Patient Funds—June 20, 2016—A 28 year-old former nursing home receptionist at a Columbia County nursing home, who had pled guilty to knowingly possessing and cashing multiple forged checks drawn on a nursing home's Patient Funds Account, was convicted of one count of Criminal Possession of a Forged Instrument in the Second Degree, a class D felony and sentenced to imprisonment for six months and five years' probation. The former receptionist was responsible for submitting check requests for residents that requested funds from the Patient Funds Account. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-jail-time-former-nursing-home-employee-who-stole-patient.

Certified Nurse Aide Arrested for Patient Abuse—June 17, 2016—A certified nurse aide was arrested for allegedly tying the ankles of an elderly Long Island nursing home resident with a plastic bag to keep the resident from getting out of bed. After initially admitting the conduct, during an investigation by the nursing home the certified nurse aide later denied any involvement. The certified nurse aide was charged with two Class E felonies, Endangering the Welfare of an Incompetent or Physically Disabled Person in The First Degree, and Falsifying Business Records in the First Degree. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-suffolk-county-certified-nurse-aide-accused-patient.

Nurse Aide Arrested for Allegedly Slapping Nursing Home Resident—June 14, 2016—A certified nurse aide in Buffalo was arrested for slapping an 88 year-old nursing home resident on the head with an open palm and then again in the face. The resident was incapable of caring for himself as he suffered from Alzheimer's disease and acute kidney failure. The nurse aide was charged with Endangering the Welfare of an Incompetent or Physically Disabled Person in the Second Degree, Willful Violation of Health Laws, and Harassment in the Second Degree. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-aide-allegedly-slapping-nursing-home-resident.

NYS Office of the Medicaid Inspector General Update

Compiled by Margaret Surowka Rossi

MIG Rosen Presents at Health Care Association's Annual Corporate Compliance Symposium — October 7, 2016 — https://www.omig.ny.gov/latest-news/984-rosen-presents-at-hca-s-annual-corporate-compliance-symposium

Pharmacist Sentenced to Prison for Health Care Fraud, Filing False Tax Returns —September 16, 2016 — https://www.omig.ny.gov/latest-news/977-pharmacist-sentenced-to-prison-for-health-care-fraud-filing-false-tax-returns

Home Care Scheme Leads to Arrest of Rochester Man — September 16, 2016 — https://www.omig.ny.gov/latest-news/976-home-care-scheme-leads-to-arrest-of-rochester-man

OMIG Posts Compliance Guidance: Certifying Official for Compliance Program Certifications — September 15, 2016 — OMIG Compliance Guidance 2016-01 is available at: http://on.ny.gov/2c3OTUS. https://www.omig.ny.gov/latest-news/975-omig-posts-compliance-guidance-certifying-official-for-compliance-program-certifications

OMIG's investigative efforts help take down major fraud scheme — August 8, 2016 — For more information on this story, see: http://on.ny.gov/2b30Jio; https://www.omig.ny.gov/latest-news/971-omig-s-investigative-efforts-help-take-down-major-fraud-scheme

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In the Law Journals

By Mishka Woodley

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A Shameful Practice: Despite Enactment of the Emergency Medical Treatment & Active Labor Act in 1986, Violations of Patient Dumping Continue to Represent a Serious Hazard in the City of Los Angeles, Will Jay Pirkey, 39 Los Angeles Lawyer 20 (2016).

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Mishka Woodley, an associate at Shenker Russo Clark LLP in Albany, recently received her J.D. from Albany Law School and an M.S. in Bioethics from Clarkson University / Icahn School of Medicine at Mt. Sinai.

For Your Information

By Claudia O. Torrey

Since the current issue of the *Health Law Journal* is compliance focused, this author will give a brief "nod" to a couple of hot topics in a vast category that is a necessary component to every facet of the health care industry; to paraphrase a Persian Proverb, s/he who wants a rose must respect the thorn! Thus, compliance is **that** thorn:

- As this column was being prepared, the Centers for Medicare & Medicaid Services came out with the Final Rule (with comment period; 42 CFR Parts 414 and 495) on October 14, 2016 regarding the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 11410 enacted April16, 2015), which amended Title XVIII of the Social Security Act: to reauthorize the Children's Health Insurance Program, to strengthen Medicare access by creating a closer tie to healthcare quality/value and physician/clinician payments, and to repeal the Medicare Sustainable Growth Rate. Effective January 1, 2017, the Rule will require physician compliance with one of two newly designed payment models that utilize performance and quality metrics. The two payment options are the Merit-Based Incentive Payment System and the Advanced Alternative Payment Models (such as an accountable care organization or patient-centered medical home), collectively known as the Quality Payment Program; penalty implementations will start in 2019.
- In September 2016, two non-profit organizations produced a 2016 Compliance Effectiveness Survey (2016-compliance-effectiveness-survey-report.pdf)—The Society of Corporate Compliance & Ethics, and The Health Care Compliance Association. One of the key results included 86% of healthcare compliance professionals reported compliance training/emphasis in the workplace prevented incidents, whereas 81% of non-healthcare compliance professionals reported such incident prevention.

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

Limitations on Damages and Penalties for False Claims Act Violations Related to the Retention of Overpayments

By Roger A. Cohen

There has been considerable focus on the circumstances that will give rise to liability for the failure to timely return a Medicare and Medicaid overpayment, including in the Center for Medicare & Medicaid Services' Final Rule on Reporting and Returning Overpayments and in a number of decisions in False Claims Act ("FCA") cases. Generally, the Final Rule and early FCA decisions expansively interpret the obligation to report and return overpayments. This has caused concern among health care providers. That concern has only been exacerbated by the recent doubling of FCA civil penalties.

In light of the cause for concern about potential liability for the failure to timely report and return an overpayment, this article examines the application of the FCA's damages and civil penalty provisions in cases related to the retention of overpayments. As set forth below, in many cases, damages and penalties should be limited in a number of important respects.

First, damages for an FCA violation must be causally related to the violation. As a result, in cases where the overpayment is returned after the statutory deadline but before the defendant receives notice of the FCA action, the economic loss that will be subject to trebling should be the interest due on the overpayment for the period between the date the overpayment should have been returned and the date it was actually returned. The overpayment itself should not be part of the damages calculation in such cases.

Second, because the FCA provides for a single civil penalty for each violation of the statute, only a single penalty should be imposed in many cases.

Third, the Excessive Fines Clause of the United States Constitution and due process prohibit penalties that are grossly disproportional to the gravity of a defendant's offense. These limitations should serve to limit penalties both where the damages are limited to the interest due on the overpayment and in cases involving a large number of claims with low reimbursement.

The Statutory Limitations on Damages

In at least a subset of FCA cases arising out the retention of overpayments, damages should be limited to three times the interest due on the overpayment from the date the overpayment should have been returned through the date of repayment. Specifically, in some FCA cases involving overpayments, the defendant will repay all or a portion of the overpayment after the 60-day statutory deadline,[1] but prior to its receipt of notice of the action. In these cases, any portion of the overpayment that has been returned prior to the defendant's receipt of notice of the action should not be included in the "damages" that are subject to trebling. Instead, the amount that is trebled is the time value of the funds that should have been returned within 60 days of identification of the overpayment.

The limitation on damages in the "late repayment" cases described above is compelled by the plain language of the FCA which provides that a person who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for . . . 3 times the amount of damages which the Government sustains *because of the act of that person*."[2] The damages sustained by the Government in a case involving a late repayment are the time value of the money during the period of delay, not the payment itself.

United States v. Hibbs, 568 F.2d 347, 349 (3d Cir. 1977) illustrates this point. The defendant in *Hibbs* submitted certifications to the Federal Housing Administration ("FHA") stating that the plumbing, electrical, and heating systems of six houses met standards established by the Department of Housing and Urban Development.[3] These representations were false, and there were plumbing, electrical and heating deficiencies that cost approximately $3,500 to repair.[4] FHA insured the mortgages and was required to pay approximately $60,000 to cover losses after the borrowers defaulted for reasons unrelated to the issues with the plumbing, electrical, and heating systems.[5]

The version of the FCA in effect at the time provided for "double the amount of damages which the United States may have sustained by reason of the doing or committing such act."[6] In rejecting damages of double the $60,000 required to cover the default on the mortgages, the court explained that the "[t]he statutory limitation, 'by reason of' the commission of the unlawful act" requires a "relationship between the unlawful act and the injury ultimately sustained."[7] Because the $60,000 due as a result of the defaults on the mortgages was not "caused by or related to" the false certifications concerning the plumbing, electrical, and heating systems, the Court held that there was no basis to award double the $60,000 as damages.[8]

Just as the FCA did not support damages based on the full amount of the default in *Hibbs*, so too, in an FCA case involving late repayment, damages based on the amount of the overpayment itself are not warranted. Indeed, while to government argued that it would not have insured the

mortgages but for the false certification of compliance concerning the plumbing, electrical and heating systems of the houses in *Hibbs*,[9] there can be no similar claim of attenuated "but for" causation in a case involving the late return of overpayments. Thus, the only loss that can be causally linked to the late return of an overpayment is the time value of the overpayment during the period of delay.

While the FCA was amended after *Hibbs*,[10] that amendment did not eliminate the requirement for a causal relationship between the violation of the FCA and damages. Rather, the provision for damages caused "by reason of" the FCA violation was replaced with similar language providing for damages sustained "because of" the violation.[11] Damages cannot be sustained "because of" an FCA violation absent at least some causal connection between the violation and the alleged loss.

"Excluding amounts refunded before the defendant learns of an FCA case is also in accord with the 'net trebling' approach to damages adopted by a majority of circuit courts."

Excluding amounts refunded before the defendant learns of an FCA case is also in accord with the "net trebling" approach to damages adopted by a majority of circuit courts.[12] Under this approach, damages are measured using a "benefit of the bargain" calculation of the difference between what the government received and what it paid, and then trebling that amount.[13] For example, in *United States v. Anchor Mortgage Corp.*, the defendant made false certifications to obtain federal mortgage guarantees.[14] After the borrowers defaulted, the government had to pay the lenders under the guarantees.[15] While the government argued that the amounts realized from the sale of the properties should be deducted only after trebling the amount it had to pay under the guarantees, the Seventh Circuit rejected this "gross trebling" approach.[16] The court noted that calculating damages based on net loss is the norm in civil litigation, and the FCA does not signal a departure from the norm.[17] Failing to account for repayments by the defendant in an FCA case related to the retention of overpayments would be akin to calculating damages using the "gross trebling" approach that was rejected in *Anchor Mortgage*.

The Statutory Limitation on the Number of Penalties

In more straightforward FCA cases involving the submission of a false claim for payment, the defendant will be subject to a single penalty for each false claim. It does not follow, however, that the defendants in an FCA case related to the retention of overpayments will be subject to one penalty for each overpaid claim. To the contrary, it is well established that the number of FCA penalties imposed on a defendant does not follow such a rote formula, and depends instead on careful parsing of the nature of the FCA violation at issue in light of the statutory language. For example, *United States v. Bornstein*, 423 U.S. 303 (1976) rejected the imposition of 35 penalties on a defendant subcontractor who caused the submission of 35 false claims by a prime contractor. The Court explained that while the prime contractor may have submitted 35 false claims, the FCA violation at issue involved *causing* the submission of false claims.[18] Thus, the Court explained:

> If [the defendant] had committed one act which caused [the prime contractor] to file a false claim, it would clearly be liable for a single forfeiture. If, as a result of the same act [by the defendant], [the prime contractor] had filed three false claims, [the defendant] would still have committed only one act that caused the filing of false claims, and thus, under the language of the statute, would again be liable for only one forfeiture.[19]

The rationale of *Bornstein* precludes imposition of penalties based on the number of individual overpayments in FCA cases related to the retention of overpayments. Specifically, in such a case, the FCA provision at issue states that a person who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable . . . for a civil penalty of not less than [$10,781.40] and not more than [$21,562.80]."[20] As such, just as *Bornstein* determined the number of penalties based on the number of acts causing the submission of false claims, the number of penalties in an overpayment case should correspond to the number of acts through which the defendant conceals, avoids, or decreases an obligation.

The government and relators are likely to argue that a defendant should be subject to one penalty for each overpayment because every overpayment that is not reported and returned within 60 days of its identification gives rise to a separate obligation, and by concealing, avoiding or decreasing multiple overpayments, a defendant commits numerous FCA violations. That logic, however, is at odds with *Bornstein* since, in *Bornstein*, the statutory violation

was causing the submission of false claims.[21] Although the defendant in *Bornstein* caused the submission of 35 false claims, the Court still looked to the number of acts causing the submission of false claims, not the resulting number of false claims.[22] As such, in the context of overpayments, the analysis should focus on the number of acts through which the defendant concealed, avoided or decreased an obligation, not the number of overpayments or obligations.

The Limitations of the Excessive Fines Clause and Due Process

Even if the courts determine that a defendant in an FCA case related to the retention of overpayments may be subject to a civil penalty for each overpaid claim (which they should not), the Excessive Fines Clause and due process should limit the amount of the civil penalty that may be imposed.

A punitive forfeiture violates the Excessive Fines Clause if it is "grossly disproportional to the gravity of a defendant's offense."[23] Numerous circuit courts have held that civil penalties under the FCA are punitive and therefore subject to the Excessive Fines Clause.[24] Courts have considered various factors in determining whether penalties are impermissibly excessive, including: (1) the reprehensibility of the defendant's conduct; (2) the extent and nature of the harm caused; (3) the comparison to penalties for similar conduct; (4) the statutory maximum; and (5) fairness.[25]

FCA defendants have prevailed in a number of cases challenging the imposition of civil penalties as a violation of the Excessive Fines Clause. For example, in *United States ex rel. Stearns v. Lane*, No. 2:08-CV-175, 2010 WL 3702538, at *4 (D. Vt. Sept. 15, 2010), after balancing the government's harm against the size of the potential penalty, the court concluded that an FCA civil penalty that "represent[ed] between 82 and 162 times the government's actual damages" would constitute an excessive fine under the Eighth Amendment. Similarly, in *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 242 (D.P.R. 2000), the court declined to impose any civil penalty where the defendants were subject to approximately $1.4 million in treble damages for 455 false claims, holding that a penalty of $5,000–$10,000 per claim would be excessive. In *United States v. Advance Tool Co.*, 902 F. Supp. 1011, 1018 (W.D. Mo. 1995), *aff'd*, 86 F.3d 1159 (8th Cir. 1996), the court held that and award of $3.4 million in civil penalties would be unconstitutionally excessive under the Eighth Amendment given, among other things, the lack of proof of actual damages and the defendant's low level of scienter. Finally, in *United States ex rel. Smith v. Gilbert Realty Co.*, 840 F. Supp. 71, 75 (E.D. Mich. 1993) the court found that the imposition of $290,000 in civil penalties for 58 false certifications would violate the Eighth Amendment where the actual damages were $1,630. Instead, the court imposed seven penalties for seven certifications where the defendant acted with a high level of scienter.[26] These cases illustrate that courts will refuse to impose or limit penalties under the FCA, particularly where actual damages are limited as compared to the penalty and the defendant acts recklessly, not with actual knowledge or specific intent.

A recent FCA decision, *United States ex. rel. Drakeford v. Tuomey*, 792 F.3d 364, 387-90 (4th Cir. 2015), considered whether civil penalties under the FCA comport with due process.[27] *Tuomey* relied heavily on *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003) in its due process analysis. In *State Farm*, the Supreme Court noted that a penalty award of four times the amount of compensatory damages would be "close to the line of constitutional impropriety," and penalty awards exceeding a single-digit ratio are generally unconstitutional.[28] While the Court noted that greater ratios may comport with due process where "a particularly egregious act has resulted in only a small amount of economic damages[,]" it also observed that the converse is true: "when compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee."[29]

The Excessive Fines and due process limitations discussed above have important implications in at least two categories of overpayment FCA cases. First, in late repayment cases (where the defendant returns the overpayment after the statutory deadline but before receipt of notice of the FCA action), penalties should be limited because, as noted above, damages will be limited to interest. While egregious conduct resulting in limited economic damages may justify a higher ratio of penalties to damages, cases where overpayments are returned, albeit belatedly, should not meet any test of egregiousness.

Second, the limitations of the Excessive Fines Clause and due process should also limit penalties in cases involving a large number of claims with relatively low reimbursement. Indeed, setting aside the relator's share (which will be covered by the treble damages award), the current minimum civil penalty of $10,781 will result in a penalty ratio of greater than 10:1 for all cases involving an average overpayment of less than $1,078 per claim. That ratio should give rise to a presumptive violation of the Excessive Fines Clause and due process.

Conclusion

While there has been no litigation to date considering damages and penalties in an FCA case related to the retention of overpayments, a review of the statutory language and the case law concerning damages and penalties under the FCA indicates that in many cases, and particularly in more marginal cases, there will be important limitations on damages and penalties. In particular, these limitations

include: (1) a limitation on damages in cases where the defendant returns an overpayment after the statutory deadline but before receiving notice of the FCA action; (2) a limit of one civil penalty in many cases; and (3) a presumptive maximum ratio of 10:1 between penalties and actual damages.

Endnotes

1. *See* 42 U.S.C. § 1320a-7k(d); 42 C.F.R. § 401.305.
2. 31 U.S.C. § 3729(a)(1) (emphasis added).
3. 568 F.2d at 349.
4. *Id*.
5. *Id*.
6. Rev. Stat. § 3490.
7. *Id*. at 351.
8. *Id*.
9. *Id*.
10. *See* P.L. 99-562, 100 Stat. 3153 (1986).
11. See 31 U.S.C. § 3729(a)(1).
12. *See United States v. Anchor Mortgage Corp.*, 711 F.3d 745 (7th Cir. 2013); *United States ex rel. Feldman v. Gorp*, 697 F.3d 78, 87-88 (2d Cir. 2012); *United States v. United Technologies Corp.*, 626 F.3d 313, 321-22 (6th Cir. 2010); *United States v. Science Applications International Corp.*, 626 F.3d 1257, 1279, (D.C. Cir. 2010); *Commercial Contractors, Inc. v. United States*, 154 F.3d 1357, 1372 (Fed. Cir. 1998).
13. *Id*.
14. 711 F.3d at 747.
15. *Id*. at 748-49.
16. *Id*. at 749-51.
17. *Id*. at 749.
18. 423 U.S. at 312.
19. *Id*.
20. 31 U.S.C. § 3729(a)(1)(G); 28 C.F.R. § 85.3(a)(9).
21. *Id*.
22. *Id*. at 313.
23. *United States v. Bajakajian*, 524 U.S. 321, 334 (1998).
24. *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 408 (4th Cir. 2013); *United States v. Bourseau*, 531 F.3d 1159, 1173 (9th Cir. 2008); *Hays v. Hoffman*, 325 F.3d 982, 992 (8th Cir. 2003); *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001).
25. *See e.g.*, *United States v. Mackby*, 339 F.3d at 1016.
26. *Id*.
27. *See United States ex. Rel. Drakeford v. Tuomey*, 792 F.3d 364, 387-90 (4th Cir. 2015).
28. 538 U.S. at 425.
29. *Id*.

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No Skin in the Game: MFCU and OMIG Audits and Investigations of Medicaid Managed Care Service Providers

By David R. Ross

Introduction

The New York State Attorney General's Medicaid Fraud Control Unit (MFCU) and the New York State Office of the Medicaid Inspector General (OMIG) functions include detecting and preventing fraud, waste, and abuse in the State's Medicaid program. In New York, where the total cost of Medicaid is estimated at $62 billion from federal, state and local sources for the fiscal year 2016,[1] Medicaid is one of the State's most costly programs. As the Medicaid program shifts away from the fee-for-service model to Managed Care, Medicaid Managed Care Organizations (Medicaid MCOs) are contracting with the State to be responsible for, and to coordinate, health care for Medicaid recipients. Medicaid dollars related to that responsibility are paid, via a capitated payment, to the Medicaid MCOs who subsequently use that money to pay the health care providers who render the services. Despite the Medicaid MCO being the direct recipient of the Medicaid funds, the MFCU and the OMIG have been attempting to recover funds directly from MCO-contracted providers. This article will posit that such recoveries are inappropriate and beyond the scope of the legal authority vested in the MFCU and the OMIG.

Medicaid MCOs and Their Service Providers

The Medicaid MCO is paid a monthly capitated rate designed to compensate the Medicaid MCO for managing the risk of, and meeting, the needs of each Medicaid recipient enrolled in its plan. This capitated rate payment to the Medicaid MCO remains the same whether the Medicaid recipient is provided health care services that cost the Medicaid MCO $100,000 or whether the Medicaid recipient is provided no health care services at all. The Medicaid MCO manages the risk of the health care needs of each of its insureds and is tasked with providing a network of service providers to meet these needs. In order for a Medicaid MCO to accomplish these tasks, since it is an insurance company and not a direct health care services provider, it contracts with various providers who directly serve their enrolled members.

It is beyond dispute that governmental agencies serve an important role in regulating and ensuring the proper use of Medicaid funds. When Medicaid program payments, made in the form of a capitated rate, are paid directly to Medicaid MCOs, of course the Medicaid MCOs are subject to audit and investigation. The Medicaid program will only pay one capitated payment per month for each recipient. When Medicaid MCOs have received multiple payments for the same recipient, recoupment of overpayments is completely legitimate and legally authorized. Such payments should be recouped because Medicaid MCOs are not receiving payment for any additional risk they are assuming but instead are being paid multiple times for the same risk for the same person.

However, in the instances where the MFCU and the OMIG are attempting to recover alleged overpayments directly from providers who are paid by the Medicaid MCOs for providing services to recipients, the situation is entirely different. Most Medicaid MCOs pay the majority of their service providers on a per-claim, fee-for-service basis. This form of payment incentivizes the Medicaid MCOs to monitor its provider-network billing for fraud, waste, and abuse, in the same way that the OMIG and the MFCU monitor fee-for-service billing in the Medicaid program. Of course, the Medicaid MCO has a strong self-interest in monitoring its service providers for fraud, waste, and abuse since it is paying these providers for the services that they render (or claim to have rendered). Moreover, Medicaid MCOs are legally required to report instances of fraud by its service providers to the New York State Department of Financial Services. Obviously, the Medicaid MCOs can police their own providers themselves, and already possess the provider billing and recipient information to do so. The MFCU and the OMIG, however, do not have any of this information, as the transactions between the Medicaid MCO and service provider occur outside of the Medicaid payment system. Limiting the audit/investigative functions to the Medicaid MCO would be a more efficient allocation of such resources, particularly given the fact that the MFCU and the OMIG are already insufficiently staffed to comprehensively police the non-Medicaid Managed Care aspects of the Medicaid program. Furthermore, if the MFCU, the OMIG, and the Medicaid MCO are all empowered to audit and recoup directly from the provider, there is a significant risk of confusion and inconsistent standards being applied as to what is an overpayment or how an overpayment is calculated.

In the instance where Medicaid MCOs are properly being paid their capitated amount, the MFCU and the OMIG should not be permitted to audit and recoup from the direct service provider. Medicaid is not paying any

more money as a result of the actions of the direct service provider, because it will have to pay the same capitated amount to the MCO regardless of the number of services furnished by the provider. Accordingly, without having any skin in the game, the MFCU and the OMIG cannot properly claim the legal right to recover "overpayments" from direct service providers who do not bill the Medicaid program directly but, instead, bill only the Medicaid MCO. Since there is no cost to the state's Medicaid program beyond the capitated rate payment, neither oversight agency can fairly claim that it is recovering misspent Medicaid program dollars.

Expansion of Oversight by the MFCU and the OMIG

Despite the considerations discussed above, government agencies in general are expanding their oversight and enforcement of Medicaid Managed Care fraud.[2] The MFCU and the OMIG have each increased their enforcement efforts against Medicaid fraud, waste, and abuse as a result of the expansion of Medicaid Managed Care enrollment and the resulting spending increase by the State. Expansion of oversight has been justified by the federal Government Accountability Office (GAO) which has stated "[g]rowth of managed care and states exploration of new models of health care delivery systems . . . will further heighten the need for program oversight."[3]

The oversight agencies will likely claim that they are merely "following the Medicaid dollar" but that rationale does not support the expansion of their audit and recovery efforts. The Medicaid dollar, once paid to the Medicaid MCO, is no longer a Medicaid dollar but rather a dollar that may be paid by the Medicaid MCO to whomever it wishes, including a service provider. The Medicaid dollar they "follow" should be the dollar paid to the MCO, not the downstream service providers.

The OMIG's Legal Authority

New York Public Health Law § 32 provides the OMIG with authority to "pursue civil and administrative enforcement actions against any individual or entity that engages in fraud, abuse, or illegal or improper acts or unacceptable practices perpetrated within the medical assistance program."[4] Further, the OMIG may initiate and maintain "actions for civil recovery and, where authorized by law, seizure of property or other assets connected with improper payments; and entering into civil settlements."[5] While this law provides the OMIG with the authority to seek enforcement, it does not lay out the limitations of such enforcement actions.

On its face, NY PHL Section 32 can be read to permit the OMIG recovery proceedings against the downstream providers, due to the broad concept of any activity "connected with improper payments." Further, the language of Section 32—"perpetrated within the medical assistance program [Medicaid]"—does not define when funds are no longer considered to be "within the medical assistance program."

While not part of the discussion regarding the OMIG's authority to seek recoupment of overpayments, it is important to note that the OMIG has clearly interpreted New York State's mandatory compliance program law[6] to apply to Medicaid MCO-contracted providers.[7] This legal requirement applies to "all persons, providers, or affiliates who provide care, services or supplies under the Medicaid program, or who submit claims for care, services or supplies for or on behalf of another person for which Medicaid is, or should reasonably be expected by the provider to be a substantial portion of their business operations."[8] A *substantial portion of business operations* is defined by regulation as occurring "when a person, provider or affiliate receives or has received, or should be reasonably expected to receive at least five hundred thousand dollars in any consecutive 12-month period directly or indirectly from the medical assistance program."[9] As a result, the OMIG views Medicaid MCO dollars as indirect payment of Medicaid program funds.

The MFCU's Legal Authority

The MFCU derives its legal authority from federal law. The MFCU's functions include "conducting a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with [ ] any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan."[10] Where the MFCU discovers "overpayments have been made to a health care facility or other provider of medical assistance under the State Medicaid plan, the unit will either attempt to collect such overpayment or refer the matter to an appropriate State agency for collection."[11]

The Code of Federal Regulations provides the MFCU with broad authority to recover funds, as the language "in connection with any aspect of the provision of medical assistance" and "the activities of providers of such assistance under the State plan" is very broad. This does not mean, however, that such authority extends recovering funds paid by Medicaid MCOs to service providers.

Medicaid MCO Money Post-MFCU/OMIG

A useful comparison may be made here to audits of the State Medicaid programs conducted by the United States Department of Health and Human Services Office of the Inspector General (OIG). After these audits are completed, a report is issued and the results are referred by the OIG to the State for appropriate action and recov-

ery. The OIG recovers funds only from the State, not from the actual service providers, even though there is a federal share involved. The pattern of New York State with respect to payments made by MCOs to service providers should be no different than that of the federal government to payments made by the State to the Medicaid service providers—it is the responsibility of the State, and by analogy, the Medicaid MCO, to audit and recoup, as the party injured by the claimed overpayment.

Assuming *arguendo* that the MFCU and the OMIG have the legal authority to recover money directly from the service provider, whether or not they are legally required to return the money to the Medicaid MCO who paid it out originally is a consideration that must be addressed. The so-called "cost recoveries" claimed by these oversight agencies are truly misnomers since the State never paid for these services in the first place. If the cost was never incurred by the Medicaid program (remember the capitated payments are "sunk costs" and remain the same regardless of recipient need), then neither the MFCU nor the OMIG may properly claim that it is recovering Medicaid costs. Merely recovering the costs incurred by the Medicaid MCO and keeping the money is an untenable result.

Conclusion

The broad language of the legal authorities behind the MFCU's and the OMIG's ability to recover funds due to Medicaid fraud, waste, and abuse may or may not support their activities with respect to MCO-contracted service providers when seeking repayment of funds that were allegedly improperly paid by the Medicaid MCO. However, until that is conclusively determined by the Legislature and/or courts of law, it can be argued that without having any skin in the game, the MFCU and OMIG cannot properly claim the legal right to recover so-called "overpayments" from health care service providers who do not bill the Medicaid program, or even increase the costs to the Medicaid program, but, instead, bill only the Medicaid MCO.

Since there is no cost to the State's Medicaid program, neither the MFCU nor the OMIG may properly claim that it is "recovering" misspent Medicaid program dollars. Guidance and clarification are needed in order to limit the scope of their ability to recover funds, which are too attenuated from the Medicaid program. Lastly, until this issue is resolved, the money that is recovered should be returned to the entity that has truly lost out, the Medicaid MCOs themselves.

Endnotes

1. https://www.osc.state.ny.us/audits/15d1.pdf.
2. *See generally,* Jacqueline C. Baratian, Alston & Bird LLP, Washington, DC and Melissa J. Hulke, Berkeley Research Group, Phoenix, AZ, BEWARE: The Road Signals Are Showing a Green Light for Increased Future Oversight and Enforcement of Medicaid Managed Care Fraud, 2016 AHLA Connections July.
3. http://www.gao.gov/assets/680/671761.pdf page 67 (internal quotations omitted).
4. NY Pub. Health Law § 32(6).
5. NY Pub. Health Law § 32(6)(e).
6. NY Social Services Law § 363-d; 18 N.Y.C.R.R. Part 521.
7. New York State Office of the Medicaid Inspector General, Frequently Asked Questions (FAQs)—NYS Mandatory Compliance Programs (Revised: 12/1/2015), pages 2–3.
8. NY Social Services Law § 363-d(4); 18 N.Y.C.R.R. § 521.1(c).
9. 18 N.Y.C.R.R. § 521.2(b)(2).
10. 42 USC § 1396(q)(3).
11. 42 CFR § 1007.11(c).

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Compliance-Focused Services: Risk Areas Identified in the Substance Abuse Treatment Industry

By Eric Dyer and Linda J. Clark

I. Introduction

Like all health care providers, substance abuse treatment providers are increasingly vulnerable to regulatory review and scrutiny of claims submitted to commercial and governmental payors. With the passage of the Affordable Care Act (ACA) (including new mandates supporting increased spending for substance abuse treatment by Medicaid and commercial payors) providers must focus increasingly on compliance resources to manage the escalating civil and even criminal risks associated with Federal audits and investigations.[1] At the same time, State governments, such as New York, are increasing spending on substance abuse treatment in order to combat the opiate epidemic, calling even more attention to compliance-based reviews of provider spending from state regulators.[2] Significant increases in penalties for non-compliance have caught the attention of the provider community as well as regulators and even prosecutorial entities. Understanding that compliance is paramount in health care today can help providers navigate what is likely to be a period of intense regulatory scrutiny and industry change.

This article will address some of the key areas that are likely to be a focus of audits and investigations in the growing substance abuse industry.

II. Kickbacks and False Claims

Regulators and prosecutors have used the Federal Anti-Kickback Statute (AKS)[3] and False Claims Act (FCA)[4] to attempt to make claims against those in the industry. Both laws also have New York State counterparts and thus can be investigated on a Federal or State level, with agencies often working together in a coordinated fashion. In New York, the anti-kickback[5] and false claims statutes[6] largely track the Federal statutes which are the focus of this discussion.

As an initial matter, the AKS and FCA apply generally to Federal health care programs involving the expenditure of Federal health care dollars (e.g., Medicare, Medicaid).[7] Under the AKS, a violation of the law occurs when anyone:

> [K]nowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.[8]

A violation of this statute may result in a felony conviction of up to five years in prison, a $25,000 fine, exclusion from Medicaid and Medicare, and civil monetary penalties.[9]

Liability arises under FCA when any person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[10] Significantly, in a recent United States Supreme Court decision, it was held that providers could be liable under the FCA under the implied certification theory[11] even when the failure to disclose certain violations of legal requirements were not express conditions of payment.[12] The penalties for violating the FCA include treble damages and civil penalties of $10,781-$21,562 for each false or fraudulent claim presented for payment.[13]

State prosecutors and regulators have begun to vigorously apply this standard in new and novel contexts, both criminal and civil. One example of a recent area of focus has been subsidized housing offered in connection with substance abuse services.

For example, a New York City-based, non-profit substance abuse provider that serviced thousands of New Yorkers faced numerous allegations alleging receipt of $27 million in inappropriate Medicaid payments. Key executives from the entity were indicted on numerous criminal charges. Central to the government's case was the allegation that the provider furnished low cost housing in "three-quarter homes" to induce residents to enroll in the provider's outpatient programs; and paid operators of three-quarter homes in exchange for referring residents to the provider's outpatient programs and enforcing attendance.[14]

In another example, two three-quarter house operators in New York City were indicted for various alleged

violations involving kickbacks and false claims. Prosecutors alleged that the two operators were receiving monthly payments in exchange for forcing their residents to attend certain drug treatment programs, as well as receiving improper payments for medically unnecessary services. In total, the kickbacks were alleged to be around $600,000.[15]

Other states like California have also aggressively pursued action against providers of substance use services. Managers and counselors for a Long Beach-based substance abuse treatment provider were indicted for allegedly participating in a scheme that was purported to have submitted over $50 million in fraudulent bills to a California state program that provided alcohol and drug treatment services for high school and middle school students. According to the Department of Justice, the alleged decade-long scam included claims that were purportedly false and fraudulent, as the provider allegedly:

- Billed for services provided to students who did not have substance abuse disorders or addictions and therefore did not qualify to receive the Medi-Cal services;
- Billed for counseling sessions that were not conducted at all;
- Billed for counseling services that were not conducted in accordance with Medi-Cal regulations regarding length, number of students, content and setting;
- Had personnel that falsified documents, including treatment plans, group counseling sign-in sheets, progress notes and update logs (which listed the dates and times of counseling sessions); and
- Had personnel that forged student signatures on documents.[16]

The treatment program was closed and the penalties for the defendants could possibly include significant time in prison.

In Tennessee, a substance abuse treatment provider agreed to pay the Federal government and the State of Tennessee $9.25 million to settle allegations involving false claims. The allegations claimed that the provider was billing "for substance abuse therapy services that were not provided or were provided by therapists that were not properly licensed." Additionally, the allegations included claims that the provider, in violation of State regulations, failed to make licensed psychiatrists available to patients; failed to maintain appropriate patient-staffing ratios; and billed while the facility was over patient capacity. Lastly, the allegations stated that the provider double-billed for substance abuse prescriptions.[17]

These are just a few examples of the long reach of the AKS and FCA. Substance abuse providers should be aware of how prosecutors and regulatory entities use these statutes to regulate industry conduct.

III. New York Medicaid Providers: Technical Noncompliance with Billing and Record Keeping Requirements

Although a FCA charge requires that the claim be made *knowingly*, providers are nonetheless accountable to and can still be penalized for improper billing and poor recordkeeping practices through recovery of overpayments. Medicaid compliance is a frequent area of concern especially given the large amount of Medicaid spending on substance abuse services. Under the Medicaid program, inappropriate record keeping and improper billing can lead to recoupment of payments[18] and provider sanctions.[19]

Billing requirements for substance abuse providers certified by the Office of Alcoholism and Substance Abuse Services (OASAS) are governed by Chapter 21 of Title 14 of the New York State Department of Mental Hygiene Regulations.[20] These regulations set forth billing standards for all types of substance abuse providers in New York State (e.g., inpatient, outpatient). In addition to these regulations, substance abuse providers should be familiar with the New York State Department of Health (DOH) Regulations under Title 10,[21] the Medicaid regulations under Title 18,[22] the Medicaid Management Information System,[23] and eMedNY Provider Manual.

The Medicaid provider agreement provides generally that Providers must "submit claims on officially authorized claim forms in the manner specified by the department in conformance with the standards and procedures for claims submission."[24] This standard is often touted by regulators as a basic premise of payment under the Medicaid program that could render any departure or omission a possible basis for recoupment. Providers and regulators often debate as to whether or not this stringent standard should cause a complete recoupment for services properly ordered and received by the recipient where the violation or error is minor and immaterial.[25] In addition, providers often defend alleged violations of unclear or inconsistently applied standards that were intended to be a best practice standard rather than a claiming or billing requirement.[26]

In most cases, claims are reviewed through an audit or investigation initiated by State or Federal regulators or their contractors. At the State level, "Providers shall be subject to audit by the department and with respect to such audits will be required . . . to reimburse the department for overpayments discovered by audits."[27] Notably, there is a six-year statute of limitations for OMIG au-

dits.[28] Consequently, when a provider submits claims to Medicaid, there is always an inherent risk of audit from OMIG.[29] With this in mind, providers must maintain a focus on compliance, understanding the audit process and most importantly the risk areas that are inherently present in this segment of the industry to avoid costly audits, investigations and paybacks.[30]

One possible strategy that providers can use proactively to test their compliance procedures is a self-audit or internal compliance review. Inpatient substance abuse provider self-audits can include a review of the following:[31]

- Missing patient records, including comprehensive evaluations and treatment plans;
- Missing physician, patient, and clinical staff member signatures on treatment plans;
- Missing progress notes;
- Certified beds exceeding capacity; and
- Improper billing for the length of stay.[32]

Likewise, outpatient substance abuse providers must be aware of these errors, as well as missing records of attendance,[33] excessive preadmission visits, and missing documentation of the duration of the visit.[34] Specifically, in the area of outpatient treatment, a key audit finding area has been exceeding the group counseling patient limit.[35] The rule, per OASAS regulations, is that group counseling sessions cannot exceed 15 patients.[36] However, OASAS' website explains a noteworthy exception to this rule, "Unanticipated staff illness or emergency absences." According to OASAS, this may occur when, "[t]wo simultaneous evening sessions have been scheduled, the patients are at the program site, and one of the counselors is unexpectedly unable to run their scheduled session."[37] Under such circumstances, OASAS regulations allow for deviation from the standard "if it is within the best interest of the patients to merge the two sessions, or should one of the sessions be canceled and rescheduled" and if certain other criteria are met.[38]

Further, prior audit results identify further risk areas for those in the substance use industry:

- Missing discharge summaries and plans, and an instance of billing the incorrect code;[39]
- Missing/late individual treatment plans;[40] and
- Claims submitted over 90 days from the date of service and missing signatures on treatment plans.[41]

Although these audit examples only involved a few errors, the overpayments requested by OMIG were significant, as OMIG may extrapolate or project the error rate over the entire audit period, which has the effect of magnifying the individual audit findings, although it sometimes exercises discretion in not extrapolating certain errors.

IV. Alleged "Patient Brokering"

Another form of kickback is patient brokering, usually involving the referral of a patient for gain. A recent *New York Times* story focused on drug treatment centers on Staten Island that were being contacted on a daily basis by marketers that offered thousands of dollars to refer one of their patients, with good insurance, to treatment centers in Arizona, California, Florida, and other parts of New York.[42] This practice is known as patient brokering.

"Specifically, in the area of outpatient treatment, a key audit finding area has been exceeding the group counseling patient limit."

It occurs when providers pay "marketers" for each patient (i.e., substance user/abuser) they bring to their program. Taken at its face, this practice is improper under the AKS (as well as other Federal laws and some State laws)[43] when Medicaid/Medicare dollars are involved; however, in many states, the issue still persists when private insurance is being used. Nevertheless, for New York providers, this practice may equate to misconduct under numerous regulations. For instance, one definition of professional misconduct for physicians, physician's assistants and specialist's assistants is:

> Directly or indirectly offering, giving, soliciting, or receiving or agreeing to receive, any fee or other consideration to or from a third party for the referral of a patient or in connection with the performance of professional services.[44]

Similarly, under a nearly identical regulation, misconduct for various addiction professionals is in part defined as:

> Directly or indirectly offering, giving, soliciting or receiving, or agreeing to receive, any fee, or other consideration to or from a third party for the referral of a patient or service recipient in connection with the performance of chemical dependence counseling services or alcohol and

substance use, abuse and dependence prevention services.[45]

Accordingly, despite the AKS' (and the New York kickback statute) inability to reach "patient brokering" when it does not involve Medicare or Medicaid dollars, other rules within New York can penalize professionals for such conduct.

V. Patient Rights Violations

Under the OASAS regulations, patients have a comprehensive list of "patient rights."[46] These rights include, among other things, the right to:

- Receive services in a therapeutic environment that is safe, sanitary, and free from the presence of alcohol or other addictive substances;
- Be free from any staff or patient coercion, undue influence, intimate relationships and personal financial transactions;
- Have a reasonable degree of privacy in living quarters and a reasonable amount of safe personal storage space;[47]
- Receive services that are responsive to individual needs in accord with an individualized treatment/recovery plan, which the patient helps develop and periodically update; and
- Be informed of and be able to understand the standards that apply to his or her conduct, to receive timely warnings for conduct that could lead to discharge and to receive incremental interventions for non-compliance with treatment/recovery plans.

Patient rights are paramount in health care and specifically in the addiction services industry. Possible examples of patients' rights violations include poorly maintained facilities, such as a facility that is unhygienic or where there is inappropriate crowding in the sleeping areas.[48] Likewise, concerns have been raised when patients are allegedly coerced into treatments, such as situations where patients are allegedly evicted from sober living without any process for failing to attend treatment.[49]

VI. Professional Misconduct, Unprofessional Conduct and Unacceptable Practices

Where providers hold a license to practice, concerns of unprofessional conduct or professional misconduct become a focus. In addition, in New York, providers can be sanctioned under the Medicaid program for unacceptable practices,[50] such as kickbacks, false claims, and unacceptable recordkeeping.[51] Providers must ensure that all staff are not excluded from Medicaid or Medicare; such checks are required to be performed on a monthly basis.[52]

Furthermore, addiction treatment providers should also ensure that their professionals have the appropriate credentials, such as Credentialed Alcoholism and Substance Abuse Counselor (CASAC) licenses, and that their licenses have not been revoked or otherwise suspended. Instances of reasons for CASAC license revocations include individuals testing positive for drugs when interviewing for employment for an OASAS provider, engaging in a relationship with a current or former patient, and selling a patient a pair of shoes to exploit him or her financially.[53]

VII. Ethics

While perhaps not traditionally compliance issues, in the substance abuse treatment world, practices not deemed illegal can, in some States, be considered "questionable practices." These practices should be avoided, even if technically permissible. According to a special report on addiction treatment centers, "questionable practices," can include:

- Using call centers to share patient prospect information with and between treatment providers;
- Paying bounties for referrals;
- Giving large gifts to interventionists with whom a program works;
- Claiming to take a patient's insurance, when in fact the anticipated reimbursement is very low and the client will be billed a large balance.
- Paying kickbacks to labs that are overcharging insurance companies for drug tests performed on a facility's patients;
- Promising a cure;
- Using nutrient supplements that are proprietary to the provider and billing the patient;
- Using brain scans and other unproven treatments and billing the patient; and
- Internet marketing scams.[54]

In support of opposing these "questionable practices," the National Association of Addiction Treatment Providers published a Code of Ethics, which all of its members accept as a condition of joining the association.[55] Within the Code, there is a strict prohibition against patient brokering, as well as other forms of arrangements that entail financial rewards in exchange for patient referrals. The Code also forbids deceptive and misleading marketing practices.[56] As mentioned previously, many of these "questionable practices" within New York State would be deemed illegal (e.g., paying bounties for referrals).[57]

VIII. Recommendations

Given the complexity of the area, the numerous laws and regulations and the increased focus, it is imperative that providers invest time and resources into their compliance programs,[58] as this will reduce, if not eliminate, costly compliance errors.[59] By focusing on these risk areas, providers ultimately conserve money and improve quality through preventing costly compliance lapses. Key components of an effective program include a code of conduct (written), a compliance officer, education and training (for all), periodic auditing, reporting procedures and investigations, response and prevention, and enforcement and discipline.

It should be noted that merely having a compliance program with these components is insufficient. An overly broad program with inadequate resources and training is unlikely to improve compliance, as is a program that is static and is not continually implemented. Finally, a lack of commitment by management undercuts an organization's compliance functions and can lead to an ineffective compliance program.

IX. Conclusion

The substance abuse industry in New York is in a growth period, at a time of increasing scrutiny of providers. Thus, it is essential that substance abuse treatment providers implement adequate compliance programs to address risk areas as present now and as they evolve. Embracing compliance measures is a provider's best chance at avoiding costly audits and investigations, paybacks and penalties. While it is impossible to prevent every error or to eliminate the possibility of audit or investigation, an effective compliance program addressing risk areas in the industry goes a long way toward decreasing errors and responding to regulators and prosecutors.

Endnotes

1. Medicaid coverage has expanded and insurers are required to cover substance use disorder services, 42 U.S.C.S. § 18022 & 42 U.S.C.S. § 1396a; *see* Christine Vestal, "States Gear Up to Help Medicaid Enrollees Beat Addictions" (Jan. 13, 2015), http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/1/13/states-gear-up-to-help-medicaid-enrollees-beat-addictions ("Of the estimated 18 million adults potentially eligible for Medicaid in all 50 states, at least 2.5 million have substance use disorders. Of the 19 million uninsured adults with slightly higher incomes who are eligible for subsidized exchange insurance, an estimated 2.8 million struggle with substance abuse."); *see also* Christine Stapleton, "More scams in drug treatment industry: Lying to get Obamacare" (Dec. 30, 2015), http://www.mypalmbeachpost.com/news/news/crime-law/more-scams-in-drug-treatment-industry-lying-to-get/nptZ6/.
2. *See* New York State Governor's Office, "Governor Cuomo Signs Legislation to Combat the Heroin and Opioid Crisis" (June 22, 2016), https://www.governor.ny.gov/news/governor-cuomo-signs-legislation-combat-heroin-and-opioid-crisis ("The FY 2017 Budget invests nearly $200 million through the New York State Office of Alcoholism and Substance Abuse Services to combat the heroin and opioid epidemic—an 82 percent increase in state spending since 2011. This investment includes $66 million for residential treatment beds, including counseling and support services for roughly 8,000 individuals; $38 million to fund medication-assisted treatment programs that serve approximately 12,000 clients in residential or outpatient settings; $25 million in funding for state-operated Addiction Treatment Centers; $24 million for outpatient services that provide group and individual counseling; and $8 million for crisis/detox programs to manage and treat withdrawal from heroin and opioids."); *see also*, Susan Benz & Melissa Zambri, "New State Opioid Abuse Law: Compliance Implications for Providers" (Aug. 4, 2016), http://barclaydamon.com/blog/health-care/new-york-state-opioid-abuse-law-compliance-implications-for-providers/ (discussing New York's law on combating opiate addiction).
3. 42 U.S.C.S. § 1320a-7b(b).
4. 31 U.S.C.S. § 3729.
5. N.Y. Soc. Serv. Law. § 366-d.
6. State Finance Law § 188.
7. There are, however, other laws addressing kickbacks and false claims that apply even when a Federal Health Care program is not involved. *See e.g.*, Education Law § 6530 (stating that it is professional misconduct to receive a fee from a third party for a referral) & N.Y. Penal Law § 177.05 (criminal law regarding health care fraud).
8. 42 U.S.C.S. § 1320a-7b(b).
9. Civil Monetary Penalties permit the Office of Inspector General to commence administrative proceedings to impose civil monetary penalties and assessment of damages for improperly filed claims for payments to induce the reduction or limitations of services, and other abuses. These penalties can range up to $50,000 for each improper act. 42 U.S.C.S. § 1320a-7a; 42 C.F.R. Part 1003. Examples of offenses subject to Civil Monetary Penalties include upcoding, violating the AKS, beneficiary inducements, and many others.
10. 31 U.S.C.S. § 3729.
11. This theory dictates that when a provider submits a claim, it is impliedly certifying compliance with all conditions of payments, University Health Services, Inc. v. U.S. et. al. ex rel. Escobar, et al., 579 U.S. ___ (6/16/16).
12. *Id.*; *see* Susan Benz & Linda Clark, "Supreme Court Provides Murky Guidance on Standard for Implied False Claims Liability" (June 17, 2016), http://barclaydamon.com/alerts/Supreme-Court-Provides-Murky-Guidance-on-Standard-For-Implied-False-Claims-Liability (discussing the *Escobar* case).
13. These were recently doubled from $5,500–$11,000, Federal Register, Vol. 81, No. 126 (June 30, 2016); *see* Susan Benz, "Doubling Down on False Claims Penalties Creates Even Higher Stakes for Providers," (July 1, 2016), http://barclaydamon.com/blog/health-care/doubling-down-on-false-claims-penalties-creates-even-higher-stakes-for-providers (discussing the increase in False Claims liability).
14. United States v. Narco Freedom, Inc., 95 F. Supp. 3d 747 (S.D.N.Y. 2015). A claim was also made that the chief executive received $13,000 a month in personal kickbacks for basing some of the organization's facilities in the buildings of a particular developer. *Id.*
15. "A.G. Schneiderman Announces Arrest Of Three-Quarter House Operators Yury And Rimma Baumblit On Charges Of Medicaid Fraud And Money Laundering" (April 14, 2016), http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-three-quarter-house-operators-yury-and-rimma-baumblit.
16. "Eight Indicted in Fraud Case That Alleges $50 Million in Bogus Claims for Student Substance Abuse Counseling" (Sept. 2, 2015), https://www.justice.gov/opa/pr/eight-indicted-fraud-

case-alleges-50-million-bogus-claims-student-substance-abuse-counseling.

17. "Tennessee Substance Abuse Treatment Facility Agrees to Resolve False Claims Act Allegations for $9.25 Million" (April 16, 2014), https://www.justice.gov/opa/pr/tennessee-substance-abuse-treatment-facility-agrees-resolve-false-claims-act-allegations-925.
18. N.Y. Comp. Codes R. & Regs. tit. 18, § 518.3.
19. N.Y. Comp. Codes R. & Regs. tit. 18, § 515.2.
20. N.Y. Comp. Codes R. & Regs. tit. 14, § 800.1.
21. N.Y. Comp. Codes R. & Regs. tit. 10.
22. N.Y. Comp. Codes R. & Regs. tit. 18.
23. "Medicaid regulations require that claims for payment of medical care, services, or supplies to eligible beneficiaries be initially submitted within *90 days of the date of service* to be valid and enforceable, unless the claim is delayed due to circumstances outside the control of the provider." Medicaid Management Information System, "New York State Medicaid Program: Information for all providers, General Billing" (Oct. 1, 2014), p. 2.
24. N.Y. Comp. Codes R. & Regs. tit. 18, § 504.3.
25. In a DOH hearing involving an ambulette services provider, an Administrative Law Judge denied an attempt by the Office of Medicaid Inspector General (OMIG) to exclude the provider and collect $2 million in restitution for overpayments. The Judge found that the provider did not engage in "unacceptable practices . . . motivated by dishonesty or corner-cutting," and further, "[i]n 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 [Providers] were able to document were provided and billed in the appropriate amount." Accordingly, this decision marked a victory for the provider community and signaled a shift towards a more reasonable standard. *See* Statewide Ambulette Services, Inc. v. NYS Office of the Medicaid Inspector General, Hearing #13-4-2317 (Oct. 28, 2015) ; *See also* Linda J. Clark, "A Rule of Reason Emerging From OMIG?" http://barclaydamon.com/alerts/A-Rule-of-Reason-Emerging-From-OMIG-11-25-2015 (Nov. 25, 2015).
26. *See supra* p. 32 and accompanying footnotes 11 and 12.
27. N.Y. Comp. Codes R. & Regs. tit. 18, § 504.8.
28. N.Y. Comp. Codes R. & Regs. tit. 18, § 517.3.
29. The OMIG's duties include the "prevention, detection and investigation of fraud and abuse within the [Medicaid program]." NY PHL § 31.
30. N.Y. Comp. Codes R. & Regs. tit. 18, § 518.3.
31. OMIG Audit Protocol—OASAS Inpatient Chemical Dependence Rehabilitation Services (May 9, 2013).
32. In computing days, the day of admission counts, but the day of discharge does not.
33. This includes the date and type of visit. N.Y. Comp. Codes R. & Regs. tit. 14, § 822.11.
34. OMIG Audit Protocol—OASAS Outpatient Chemical Dependence Services (May 9, 2013).
35. *Id.*
36. N.Y. Comp. Codes R. & Regs. tit. 14, § 822-4.2.
37. OASAS FAQ's, https://oasas.ny.gov/FAQs/getFAQ.cfm?id=422&criteria=group%20size&org_code=2 (visited Sept. 14, 2016).
38. "If the program determines that merging the two groups is clinically appropriate and does not violate patient confidentiality, then the two sessions may be merged. The session notes must fully document the reason for the merged sessions and be available in the event of a Medicaid audit or OASAS site review. It is further recommended that in anticipation of such emergency situations, the programs establish and document policies and procedures to address when it is appropriate to merge two sessions and what documentation should be maintained." *Id.*
39. OMIG, Final Audit Report, Audit #15-2808, Dec. 14, 2015.
40. OMIG, Final Audit Report, Audit #14-6394, July. 10, 2014.
41. OMIG, Final Audit Report, Audit #09-5588, Nov. 17, 2010.
42. Megan Jula, "How Staten Island's Drug Problem Made It a Target for Poaching Patients," New York Times (Aug. 23, 2016), http://www.nytimes.com/2016/08/24/nyregion/how-staten-islands-drug-problem-made-it-a-target-for-poaching-patients.html?_r=0.
43. Florida recently enacted a patient brokering statute to prohibit the practice, Fla. Stat. Ann. § 817.505.
44. Education Law § 6530.
45. N.Y. Comp. Codes R. & Regs. tit. 14, § 853.20.
46. N.Y. Comp. Codes R. & Regs. tit. 14, § 815.5.
47. Applicable when the patient is in an inpatient/residential setting.
48. N.Y. Comp. Codes R. & Regs. tit. 14, § 814.4.
49. Narco Freedom, 95 F. Supp. at 759.
50. N.Y. Comp. Codes R. & Regs. tit. 18, § 515.7; N.Y. Comp. Codes R. & Regs. tit. 18, § 515.2.
51. N.Y. Comp. Codes R. & Regs. tit. 18, § 515.2.
52. N.Y. Comp. Codes R. & Regs. tit. 18, § 515.5; 42 C.F.R. § 1001.1901.
53. OASAS, "Addictions Professionals Misconduct Enforcement," https://www.oasas.ny.gov/credentialingVerification/verification/revoked.cfm (visited Sept. 14, 2016).
54. Alison Knopf, "Special Report: Addiction treatment at an ethics crossroads" (March 12, 2013), http://www.addictionpro.com/article/special-report-addiction-treatment-ethics-crossroads.
55. The National Association of Addiction Treatment Providers has over 500 members, The National Association of Addiction Treatment Providers, "Addiction Industry Directory," https://www.naatp.org/resources/addiction-industry-directory (visited Sept. 15, 2016).
56. National Association of Addiction Treatment Provider, "Code of Ethics," https://www.naatp.org/resources/addiction-treatment-provider-ethics/code-ethics (visited 9/14/16) (the Code also suggests that certain deceptive marketing practices may fall under Federal Trade Commission Violations, 15 U.S.C.S. § 45).
57. *See supra* Part V.
58. Certain providers billing Medicaid may be required to have a compliance program, N.Y. Comp. Codes R. & Regs. tit. 18, § 521.1.
59. A compliance program should also reduce exposure under the United States Sentencing Guidelines Manual and the risk of *qui tam* actions, as well as help directors comply with their duty of care.

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Statistical Sampling and Extrapolation—Extrapolating Its Benefits and Concerns to the Commercial Sector

By Danielle E. Holley and Jeffrey J. Sherrin

In the context of audits and recovery of overpayments, the use or attempted use of statistical sampling and extrapolation techniques has become commonplace. Most of these cases have involved government payor audits, or actions under the False Claims Act. Due to the evidentiary advantages offered by sampling and extrapolation, however, private payors and private litigants are increasingly seeking to use statistical sampling and extrapolation methods to prove liability and/or damages in commercial sector cases. This article will examine some of the considerations in allowing this form of evidence to prove liability or damages in such private sector cases.

Background and Current Use

Proper statistical sampling and extrapolation is a scientific method whereby a representative sample of items, often claims, is identified and used to draw conclusions that are then applied to the universe of such items. Fundamental to any proposed use of statistical sampling is the understanding that the methodology is a science and not a mere mathematical "plug in the numbers." It must meet certain scientific rigors, including that the methodology be valid, replicable and reliable. The goal is to reach a result that has sufficient precision that the trier of fact can rely upon it as replicating the result that would be reached if a 100% case review were conducted. Oftentimes this is expressed as there being a 95% (or other percentage) probability or confidence level that the actual overpayment, if a 100% case review were conducted, would fall within the calculated range between a low and a high confidence interval. The midpoint in proper statistical sampling and extrapolation is not the "correct" overpayment. It is just the point at which it is equally likely that the correct overpayment would fall above or below that number.

Acceptable methods of sampling and extrapolation can vary based on the universe size and characteristics of the items in the universe. Different sampling techniques and sample designs need to be considered to arrive at a result that enjoys a sufficiently high level of confidence and is representative of what a 100% case review would yield.

The use of statistical sampling and extrapolation in governmental healthcare audits, whether by federal regulators or by New York State agencies, has been firmly accepted.[1] Sampling and extrapolation is even codified in statute and regulation for governmental audits for both New York State and federal government audits.[2] In fact, for the Department of Health and Human Services, the use of statistical sampling has been codified for the purpose of assessing civil monetary penalties, so long as it is "based upon an appropriate sample and computed by valid statistical methods."[3]

The routine use of statistical sampling and extrapolation in government audits, unlike in private sector cases, has its own unique policy considerations that courts weigh in balancing the due process interests of the litigants and the government. Courts strongly recognize "the government interest in minimizing administrative burdens," which policy consideration may be of lesser significance in the private sector.[4] Courts also routinely recognize the cost-effectiveness of using sampling and extrapolation.

Sampling and extrapolation is also favored where there is a low risk of error in its use, such as when the results of the sampling and extrapolation are considered, not as the final finding of fact, but rather as just one of many factors to be considered in the exercise of administrative discretion. Thus, while regulations authorize HHS to use statistical sampling and extrapolation in determining what civil monetary penalties are to be imposed, that is only one of many factors that are evaluated in determining the ultimate penalty.[5]

The use of statistical sampling and extrapolation is well accepted in federal cases under *Daubert* and FRE 702, particularly in mass tort litigation and even in discrimination cases.[6] It was also recently upheld to establish liability and damages in an overtime class action suit under the Fair Labor Standards Act in *Tyson Foods, Inc. v. Bouaphakeo*, 136 S.Ct. 1036 (March 22, 2016). In *Tyson,* the Court acknowledged that statistical sampling may be the only practical way to collect and present evidence, but that its use "will depend on the purpose for which the evidence is being introduced and on 'the elements of the underlying cause of action.'"[7]

In general, statistical sampling and extrapolation has been accepted when the cases in the sample are representative of the class as a whole, when it is the most practical method for litigants to proceed with, and the samples do not have individual components that could unfairly prejudice a litigant's due process rights.[8] This might involve, for example, showing that a condition exists in sufficient numbers in a universe as to allow for proper inferences

to be drawn. In such cases, the method might be more appropriate for establishing liability than for assessing precise damages. In the False Claims Act arena, however, cases have gone both ways on its admissibility.[9] As such, even though statistical sampling and extrapolation is codified and routinely accepted in governmental audits and even in these other contexts, this does not mean that any sampling and extrapolation is acceptable; it still has to meet scientific rigor.

Considerations for Use in the Commercial Sector

In non-governmental payor and commercial litigation cases, the need for scientific rigor in the methodology employed is arguably heightened, since the underlying policy rationale supporting its use in government audits may not be present. One must examine the purpose for which the evidence is being offered and the practicality and overall fairness to the parties. Given these interests, parties desiring to use statistical sampling and extrapolation or to oppose its use in private audits or litigation need to be sensitive to certain factors in addition to these different policy considerations.

individualized determinations such as those needed to prove clinical judgment, intent, or good (bad) faith, and not simply the existence or non-existence of a fact, the use of statistical sampling and extrapolation is less likely to be accepted as an appropriate method of proof. Determinations of clinical judgment, intent or good faith, all require proof of states of mind, which makes it less likely that a sample can be extrapolated over a large universe. Issues in recordkeeping, however, are more apt to be amenable to sampling and extrapolation, if the issue can be consistently validated over the universe. Thus, the degree of subjectivity, rather than objectivity of the individual assessment of each claim, affects the appropriateness of statistical sampling and extrapolation.

Another issue regarding the admissibility and reliability of the methodology is the confidence interval, or margin of error. As we stated above, the purpose of sampling and extrapolation is to reduce the time and expense needed to reach a calculation that enjoys a certain level of confidence as what would be achieved by a 100% case review. Unlike a 100% case review, however, sampling and extrapolation cannot tell you with precision what

"In New York, the use of statistical sampling and extrapolation will be evaluated based on the 'general acceptance' test for reliability and admissibility of expert testimony under Frye*."*

In New York, the use of statistical sampling and extrapolation will be evaluated based on the "general acceptance" test for reliability and admissibility of expert testimony under *Frye*.[10] The *Frye* analysis requires the court to assess whether the scientific method is (1) novel, (2) generally accepted in the scientific community and (3) reliable and acceptable.[11] Ultimately, unless an unusual methodology is used or its use is novel under the unique facts of the case, it is generally accepted for conducting audits.[12] Statistical sampling has even been used to prove common law fraud in one case in New York.[13] The issue then becomes, after the first two elements of the *Fyre* test are met, whether the method of statistical sampling and extrapolation employed is reliable and acceptable.

Reliability and acceptability factors speak to the rigor that must be met for the particular sampling and extrapolation methodology to be seen as a scientific method, and not just math. The first factor to be considered for reliability and acceptability of the sample and the extrapolation method is whether the "nature of the claim requires an individualized determination."[14] This question goes to the purpose and underlying elements of the claim as noted in *Tyson.* If the claim universe involves the exact number is. It can only give you a range, and the likelihood that a 100% case review would fall within that range. The expert who tests the hypothesis might say, therefore, that he or she is 95% confident that a 100% case review would be found in the range provided between the low and the high confidence level.

Under the *Fyre* standard, therefore, the margin of error from the methodology employed must be evaluated for its reliability and replicability. If it is a proper method that is used, the results should be able to be reproduced. The higher the error, for example, one that exceeds ±10 percentage points, the lower the confidence level that the methodology employed produces a reliable result. Generally, to reduce the error rate and to increase the confidence level, or, in other words, to produce a result with greater precision, a larger sample size may be needed.[15] Another technique involves stratification of the sample.

For example, in *MBIA Ins. Corp v. Countrywide Home Loans, Inc.*, the expert proposed a sample of 400 loans per population, and with the selected extrapolation method stated that the sample would provide a "confidence level of approximately 95% with a 5% margin of error."[16] The court in *MBIA Ins. Corp.* found that the methodology was

scientifically accepted, valid and reliable under *Frye* at the pre-trial stage.[17] In a similar case, statistical sampling and extrapolation was allowed despite the fact that the margin of error was ±10 percentage points, when "the typical margin of error in the litigation context…[for] mortgage-backed securities actions have employed a ± 5 percentage point margin of error."[18] There, it was demonstrated that the sample size would have to be quadrupled to decrease the margin of error to ±5 points and as such, the smaller sample struck the appropriate balance of judicious use of resources within an acceptable scientific range.[19] In these circumstances, however, what courts may overlook, or parties fail to argue, is that with less precision, the only scientifically reliable calculation of damages is the number arrived at with the lower confidence interval. In *Mass Mutual,* the court found that the increase in the margin of error spoke to its persuasiveness to the jury, not to its admissibility.[20]

Other factors to consider in determining reliability is whether the sample of claims was random and an accurate representation of the larger claim pool. Considerations here include composition of the universe, determination of sample size, and sample design. Sample design requires a determination of whether the proper methodology should be systematic sampling, stratification, cluster, random number or some other combination. Assessments will also have to be made regarding the overall sample size and whether all records are available. In *Tyson*, one reason that statistical sampling and extrapolation was allowed was that the FLSA allows for gap filling when reliable records were not kept by the employer.[21] Where records are in fact available, the party wanting to use statistical sampling and extrapolation will have to demonstrate why it is needed. Factors in support may include cost effectiveness and resources but this should not be at the expense of scientific rigor and reproducibility.

Another consideration is the purpose for which statistical sampling and extrapolation is being offered. One such consideration is whether it is being used to meet the burden of proof for liability or damages. By its very nature, statistical sampling and extrapolation often shifts the burden of proof, or at least the burden of going forward, to the party opposing its use to disprove the reliability of the sampling and extrapolation methodology. This can be achieved by the more "'traditional' devices of 'vigorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof.'"[22] Other strategies can include the use of adversary experts to debunk the methodology employed by the proponent of sampling and extrapolation, and even to offer a different methodology that is testified to as more precise. Or, a party could show that a 100% claim review is practical and, therefore, reliance on a short-hand method is misleading and unnecessary. Actually conducting the 100% case review is an excellent option, if that is feasible. Different counter-measures can be tried and the results tested before they are offered, if the stakes are sufficiently large.

The important point to remember is that two private litigants should be on equal footing before the court; neither should be entitled to an easy way out to prove its case. They should not enjoy some of the latitude that government agencies do for policy considerations in overpayment audits.

A final factor to be considered in choosing to use, or challenge evidence based upon sampling and extrapolations, is that decisions regarding how the universe and sample are designed can be driven by results the party offering it may want to achieve. Decisions over what universe to draw from, sampling technique, sample size, and use of the low, mean and high point estimates, among other factors, can affect the ultimate calculation and therefore can be tailored to reach a higher or lower number, as the litigants may desire. Government in payor audits should have less interest in reaching a litigation-favored outcome, but rather in using a consistent and fair method. Private litigants, on the other hand, have a tendency to adopt a methodology that will produce a desired higher or lower result. Whether it is Medicare or Medicaid, the appropriate audit agency should adopt a methodology that is statistically valid, fair, impartial and consistently applied. Private litigants have no such incentive.

Conclusion

Each of the above considerations is important when parties are assessing the use of statistical sampling and extrapolation in the commercial context. The policy rationales present in government cases to promote administrative efficiency, reduce cost and protect the integrity of the program at issue, and which have statutory or regulatory backing, are not present in commercial cases, at least to the same extent. Rather, concerns regarding the purpose, overall fairness, judicial economy and due process should control the ultimate admissibility of such evidence in private sector disputes. As the attempted use of statistical sampling and extrapolation in commercial payor and other private contexts increases, parties have to be vigilant regarding the purpose for which it is offered, and to ensure that the required scientific rigor of the methodology is being met.

Endnotes

1. 45 C.F.R. § 160.536; *Mercy Hosp. of Watertown v. NYS Dep't of Social Services*, 79 N.Y.2d 197 (N.Y. 1992); *Chaves County Home Health Servs. v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991); *Ratanasen v. California, Dep't of Health Servs.*, 11 F.3d 1467 (9th Cir. 1993); *Yorktown Medical Lab., Inc. v. Perales,* 948 F.2d 84 (2d Cir. 1991).

2. 18 N.Y.C.R.R. § 519.18(g); *see Medicare Program Integrity Manual, Ch. 8—Administrative Actions and Statistical Sampling for Overpayment Estimates*, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c08.pdf.
3. 45 C.F.R. § 160.536.
4. *Yorktown Medical Laboratory, Inc.*, 948 F.2d at 90.
5. 45 C.F.R. § 160.408 (the Secretary will also look to the nature and extent of the violation itself, the harm resulting from the violation, the history of prior compliance, the financial condition and such other matters as justice may require).
6. *See BCBS of N.J., Inc. v. Philip Morris, Inc.*, 133 F. Supp. 2d 162 (E.D.N.Y. 2001); *see Ottaviani v. State University of New York*, 875 F.2d 365 (2d Cir. N.Y. 1989).
7. *Tyson Foods, Inc. v. Bouaphakeo*, 136 S.Ct. 1036, *20 (March 22, 2016).
8. *See BCBS of N.J, supra* note 6*; see MBIA Ins. Corp. v. Countrywide Home Loans, Inc.*, 30 Misc. 3d 1201(a) (N.Y. Sup. Ct. Dec. 22, 2010); *see also Zippo Mfg. Co. v. Rogers Imps., Inc.*, 216 F. Supp. 670, 684 (S.D.N.Y. 1963) (relying on sampling methodology to conduct a consumer study as a practical approach to determine the state of mind of the smoking population).
9. *U.S. ex rel Loughren v. UnumProvident Corp.*, 604 F.Supp.2d 259 (D. Mass 2009); *U.S. ex rel. Martin et al., v. Life Care Centers of Am. Inc.*, Case No. 1-08-cv-251 (E.D. Tenn. Sept 2014); *U.S. ex rel. Michaels v. Agape Senior Community, Inc. et al.*, 15-2145 (4th Cir. 2016); *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 U.S. Dist. LEXIS 80160 (N.D. Tex. June 20, 2016).
10. *MBIA Ins. Corp., supra* note 8.
11. *Id*.
12. *Mercy Hosp. of Watertown, supra* note 1; *MBIA Ins. Corp. supra* note 8.
13. *BCBS of N.J., supra* note 6 (holding that statistical proof can be used for common law fraud).
14. *Vista Hospice Care, Inc., supra* note 9.
15. *Mass Mutual Life Ins. Co. v. Residential Funding Co., LLC*, 989 F. Supp. 2d 165 (D. Mass. 2013).
16. *MBIA*, 2010 N.Y. Misc. LEXIS 6182 at *13.
17. *Id*.
18. *Mass Mutual Life Ins. Co.*, 989 F. Supp. 2d at 174.
19. *Id*.
20. *Id*.
21. *Tyson*, *supra* note 7.
22. *BCBS of N.J., Inc., supra* note 6.

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Current Trends Involving Statistical Sampling in Health Care FCA Litigation

By Marta Alfonso

In 1863, the False Claims Act ("FCA" or "the Act") was originally enacted as a result of Congressional actions to stop army contractors involved in the Civil War from defrauding the U.S. government. Under the Act, as amended, a person who knowingly submits or causes others to submit false claims to the U.S. government is liable for such conduct equivalent to treble damages and a per claim penalty that ranges between $10,781 to $21,562.[1] The FCA also permits private individuals to make claims of statutory violations as a Relator in "Qui Tam" action on behalf of the U.S. Government.[2] Civil litigation against health care companies for alleged FCA violations has become one of the federal government's most effective legal tools in recovering damages and penalties from individual and corporate health care defendants. For the fourth consecutive year, the Department of Justice (DOJ) reported that in fiscal year ended September 30, 2015, it collected more than $3.5 billion in settlements and judgments from civil litigation involving fraud and false claims, with total cumulative recoveries exceeding $26.4 billion. In 2015, 54% or $1.9 billion of DOJ's collections came from health care industry defendants (individuals and companies) arising from FCA claims relating to "unnecessary or inadequate care, paying kickbacks to health care providers to induce the use of certain goods and services, or overcharging for goods and services paid for by Medicare, Medicaid, and other federal health care programs." The DOJ also noted that additional recoveries were made for state Medicaid programs and individuals.[3] The economic impact to a health care defendant in FCA cases can be consequential given the U.S. government's continued trend in bringing or supporting FCA claims, the potential for a defendant's liability, the magnitude of a defendant's potential economic damages and penalties, and the costs of defense.

In reviewing recent FCA claims brought in various Federal District Courts, FCA defendants are actively challenging the application of statistical sampling techniques employed by Qui Tam plaintiffs and the federal government to prove liability and to calculate damages. This article discusses key trends involving defense challenges and considerations involving statistical sampling in an FCA claim against health care defendants.

Historically, the federal government proffered damage calculations in FCA claims based on statistical sampling and extrapolation.[4] As explained in *United States v. Fadul*, a 2013 health care fraud case that alleged fraudulent billing practices by a licensed cardiologist, the District Court of Maryland found that "Courts have routinely endorsed sampling and extrapolation as a viable method of proving damages in cases involving Medicare and Medicaid overpayments where a claim-by-claim review is not practical."[5] In a recent FCA claim against a corporation that owns skilled nursing facilities, *USA ex rel. Martin v. Life Care Centers of America, Inc*., the District Court found that FCA did not specifically preclude the use of statistical sampling and permitted the federal government to prove FCA liability by using statistical sampling.[6] The District Court of Eastern Tennessee in *Life Care* case determined that even though the federal government could provide individualized proof of specific claims made or false statements, such individualized proof would require a level of effort by the federal government that was regarded by the District Court as impractical. The District Court also disagreed with Life Care's claim that unique patient factors and medical determinations should preclude the use of statistical sampling. Instead, the District Court of Eastern Tennessee opined that Life Care could challenge the weight that a fact-finder would place on conclusions drawn from a statistical sample through cross-examination and alternate witnesses to demonstrate the disparity between the parties' sampling and testing methods and conclusions.[7] In other FCA litigation, the District Courts have applied policy considerations and found that limiting statistical sampling would reduce FCA enforcement because having to perform claim-by-claim reviews would deter the number of prosecuted claims.[8] In a 2015 FCA case, *U.S. ex rel. Rukh v. Genoa Healthcare, LLC* the District Court of the Middle District of Florida applied similar justifications to those in used *Life Care*, to allow statistical sampling in FCA litigation where the federal government alleged that fifty-three medical facilities overbilled patient charges. The District Court determined that "(c)onsidering a large universe of allegedly false claims in the instant case, it would be impracticable for the Court to review each claim individually … it would consume an unacceptable portion of the Court's limited resources."[9] Thus, recent FCA litigation has shown that District Courts have permitted the use of statistical samples to prove liability based on Congressional intent and statutory interpretation of the Act, FCA enforcement policy considerations, and concerns relating to efficiency in evaluating the government's claims where there are large volumes of evidence to consider.

Although District Courts have expanded the use of statistical sampling to prove liability in FCA claims involving health care defendants, these federal court deci-

sions do not suggest that statistical sampling has been given blanket approval. In *United States v. Friedman*, the District Court of Massachusetts allowed the introduction of statistical sampling as evidence in claims against a defendant that allegedly overbilled Medicare and found that the defendant had violated the FCA. However, the District Court in *Friedman* denied the use of a sample to extrapolate and calculate damages. Since the District Court was faced with only 676 claims, it preferred the review of each individual claim in order to reach its determination of damages.[10] Thus, the size of the total population relative to the claims or damages may be a factor for consideration by the District Court in determining whether sampling is appropriate.

The reasonableness of statistical sampling methods may also be considered by the District Court in its determinations of whether samples should be admitted as evidence to prove FCA liability or damages. In *United States ex rel. Trim v. J.D. McKean*, the District Court of the Western District of Delaware found that certain proffered audits performed by Medicare, Medicaid, and other benefit programs were invalid statistical samples since the Court found that the proffered audits did not accurately represent all relevant claims at issue. Some of the *McKean* audit deficiencies identified by the District Court included, among others, the inclusion of atypical claims in the audit, the failure to establish the auditor's reliability or the reliability of the audit methods applied, the relatively small audit sample sizes, the varying scope of years in each audit, and finally, the judgmental nature of coding determinations. The Court also found that some of the *McKean* audit evidence was illegible and in a foreign language. Even though the District Court found the *McKean* audits were not reliable as statistical samples, it still held that the audits provided evidence that supported the conclusion that McKean had violated the FCA.[11] In a 2015 federal court opinion involving FCA claims, *United States of America ex rel. Brianna Michaels* and *Amy Whitesides v. Agape Senior Community, Inc. et al.*, the District Court of South Carolina denied the federal government's use of statistical sampling to prove that certain of Agape's nursing homes had violated the FCA. The District Court determined that Agape's medical charts remained available for review and were not under threat of being destroyed. In addition, the District Court found the government's claims to be fact-intensive, including medical testimony to determine whether nursing home patient services provided had been medically necessary. The Agape defendants also asserted that there would be no cost savings to the plaintiffs in using a sample to determine liability since each sampled item would be subjected to a lengthy cross-examination.[12] In a 2016 case, *United States of America ex rel. Misty Wall v. Vista Hospice Care, Inc. et al.*, the federal government alleged that a hospice care facility had violated the FCA based on a sample of 291 patient files from a total population of 12,000 patients and calculated economic damages.[13] The District Court for the Northern District of Texas found that the statistical sampling performed to establish Vista's FCA liability and damages was "inherently subjective, patient-specific, and dependent on the judgment of involved physicians… extrapolation is not always appropriate."[14] The District Court relied on a Supreme Court decision, *Tyson Foods, Inc. v. Bouaphakeo*, 136 S.Ct. 1036, 1046 (2016), where the Supreme Court held that "(t)he permissibility of statistical sampling turns on 'the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.'" The Court also distinguished the *Vista* case from *Life Care* by finding that while *Life Care* involved the clinical condition of individual patients, *Vista* involved the "subjective clinical judgment of a number of certifying physicians applying the 'uncertain… science' in predicting an individual's life expectancy."[15] The District Court also stated that "no circuit has resolved whether statistical sampling and extrapolation can be used to establish liability in an FCA case where falsity depends on individual physicians' judgments regarding individual patients."[16] In *Agape,* although there was a sizeable sample, the Court noted that there would be no efficiencies gained in cross-examination by sampling and was one of the factors the District Court considered in finding that the entire population of medical charts must be considered by the government in proving its claims. By highlighting the similarities between the *Agape* and *Vista* claims, the District Court for the Northern District of Texas noted that in *Agape*, "'each and every claim at issue' was 'fact-dependent and wholly unrelated to each and every other claim,' and determining eligibility for 'each of the patients involved a highly fact-intensive inquiry involving medical testimony after a thorough review of a detailed medical chart of each individual patient,'…the case was not 'suited for statistical sampling.'"[17] The District Court in *Vista* also found that conclusions made by one physician on a patient's condition could not be extrapolated to draw conclusions about the conduct of another physician.[18] In summary, District Courts have declined the use of statistical sampling in smaller cases where individual claims can be evaluated, where sampling methods are not determined by the Court to be appropriate or that produce unreliable results, or where the Court finds that there are individual fact intensive claims that involve subjective medical judgment on an individual's condition which cannot be extrapolated to other patients or physicians.

Federal courts have held defendants responsible for challenging the methods and approaches used by the federal government and its experts in selecting statistical samples, testing the sample population, and providing conclusions on the testing. In *Life Care,* the District

Court concluded that "statistical sampling is permitted to prove FCA claims brought by the federal government; however, the Court cannot control the weight that a fact finder may accord to the extrapolated evidence."[19] As defined, sampling involves the selection and testing of less than one hundred percent of items in order to draw conclusions about the characteristics or amounts of a particular population.[20] Extrapolation has been viewed as "a statistical method in which a sample of data is used to draw inferences about a larger population."[21] In *Life Care*, the District Court discussed various aspects of statistical sampling in a federal case involving various FCA claims of overbilling, false claims and false statements concerning skilled nursing facility payments where statistical sampling methods were challenged. The Court explained that,

> "the general purpose of statistical sampling is to 'provide a means of determining the likelihood that a large sample shares characteristics of a smaller sample…In order to 'draw reliable conclusions' about the sample universe, the statistical sample must be of a sufficient size to support the conclusions…statisticians account for any discrepancies by calculating a margin of error."[22]

The District Court relied on the *Reference Manual on Scientific Evidence* to set forth the elements of a reliable sample, including "when a sample method 'defines an appropriate population, uses a probability method for selecting the sample, has a high response rate, and gathers accurate information on the sample units.'"[23] As noted by the District Court, reliable conclusions drawn in statistical sampling are a direct result from selecting an appropriately sized sample from a defined population. All the factors regarding the method of sampling should be documented by the federal government's expert in a sampling plan that is scrutinized by defendant's counsel and experts.

Beyond the sampling plan, the defense must perform a thorough and careful evaluation of the statistical sample's testing approach and conclusions. In *Ruckh*, the District Court noted that statistical sampling evidence could be excludable if there were "defects in method, among other evidentiary defects."[24] Through analysis and testimony proffered by the defense, a fact finder may conclude that a statistical sample was improperly selected or improperly tested, a statistical sample was not truly representative of the population, or the conclusions related to the extrapolated results were inappropriate through an alternative analysis of the findings or application of relevant medical standards. In their Health Law & Policy Blog, James Segroves and Kelly Carroll effectively summarize key strategies for defense counsel to consider in challenging the government's use of statistical sampling:

"• *Challenge the Need for Statistical Sampling*: Consider whether other reasonable options exist for analyzing the claims at issue that would eliminate the need for statistical sampling.

- *Challenge the Validity of the Sampling Technique:* Highlight defects in the sampling methodology, including small sample sizes, unrepresentative samples, sample selection biases and randomness of the sample.
- *Challenge the Extrapolation Method and Conclusions*: Scrutinize the estimation method employed and extrapolation conclusions reached, paying close attention to the confidence (degree of certainty) and precision (range of accuracy) levels.
- *Challenge the Admission of Statistical Sampling Evidence*: ….In *Daubert* proceedings, a court determines the admissibility of expert testimony or scientific evidence under Federal Rule of Evidence 702 by analyzing whether the evidence is both relevant and reliable.
- *Challenge the Findings*: Closely review the factual findings and examination processes used regarding the sample claims, conducting an independent examination of the sample claims as appropriate. This is a critical step, as allowing incorrect or questionable determinations about sample claims to go unchallenged has significant ramifications when multiplied exponentially as a result of extrapolation. Providers may also demonstrate uncertainty by challenging the credentials or the findings of the reviewers or by providing evidence of the subjectivity of the medical decisions underlying the submitted payment claims."[25]

"Beyond the sampling plan, the defense must perform a thorough and careful evaluation of the statistical sample's testing approach and conclusions."

The Memorandum Opinion and Order by the District Court in the Northern District of Texas in *Vista* provide

valuable insight into the benefits of thorough diligence in evaluating the plaintiff's sampling plan, sample selection, and methodology that can result in successful exclusion of an expert on a pre-trial motion in District Court rather than relying on fact-finder opinions in trial.

The District Court found that the federal government's expert used against the defendants in *Vista* had acknowledged errors in the sample selection, including having selected duplicate items, permitted random exclusions of patients from the total population, performed misclassifications of patient groups, failed to differentiate across geographies, physicians, and disease type, and failed to appropriately stratify the population. Although the government's expert claimed the errors were corrected, the Ph.D. did not provide corroborating evidence of the corrections, and precluded evaluation of the corrections by opposing counsel. The expert's sampling errors and failure to account for relevant sampling variables caused the District Court to lose confidence in the expert's extrapolation opinions, and ultimately, the Court found that the government expert's conclusions were unreliable, which precluded the extrapolation of his results to the total patient population.[26] Through health care defense counsel insights and examining a recent District Court decision on the exclusion of a sample's conclusions from FCA health care litigation, it is evident that both defense and plaintiff experts should expect a high level of scrutiny on their sampling plans, testing methods, and conclusions. Documenting each phase of the statistical sampling process, and its related errors or limitations, are critical components in being able to successfully persuade the District Courts on pre-trial motions or a fact finder that an opposing party's sample is inappropriate, inaccurate, or irrelevant as extrapolated against a total population of medical cases or claims to determine FCA liability and/or economic damages.

Pre-trial and trial litigation related to statistical sampling will continue to remain a key aspect of FCA litigation involving health care defendants. Litigation of sampling issues is necessarily case and fact specific, driven by such elements, among others, as the scope and nature of the federal government claims, the government expert methodology, analysis, and conclusions, population size and characteristics, and the strength of the analysis of defense counsel on the government's sampling evidence and conclusions, and its own proffer of sampling evidence, if it chooses to do so. One thing is certain; without diligence and detail, it is difficult to formulate effective strategies and opinions that are persuasive to the federal Court or other fact finders about whether statistical sampling or its results are accurate and representative of the total population, or should be excluded from consideration in determining FCA liabilities or damages.

Endnotes

1. Federal Register, Vol. 81, No. 126 (June 30, 2016);
2. https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf. See also *United States of America ex rel. Glenda Martin and State of Tennessee ex rel. Glenda Martin v. Life Care Centers of America, Inc.*, 114 F. Supp. 3d 549, 557. See also 31 U.S.C. Section 3730(b).
3. https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015.
4. See *Chaves County Home Health Servs. v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991). See also *United States v. Jones*, 641 F.3d 706, 712 (6th Cir.2011) and *United States v. Rogan*, 517 F.3d 449,453 (7th Cir.2008).
5. See *United States v. Fadul*, Civil Action No. DKC 11-0385 (D. Md. Feb. 28, 2013), pages 1 and 15.
6. *Life Care* at 571-572.
7. *Life Care* at 571.
8. See *United States v. Friedman*, No. 86-610-MA, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993). See also *Life Care* at 571.
9. *U.S. ex rel. Ruckh v. Genoa Healthcare, LLC ("Ruckh")*, No. 8:11-cv-1303-T-23TBM (M.D. Fla. Apr. 28, 2015), page 3.
10. *United States v. Friedman*, No. 86-610-MA, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993).
11. *United States ex rel. Trim v. J.D. McKean*, 31 F. Supp. 2d 1308, 1314.
12. See *United States of America ex rel. Brianna Michaels and Amy Whitesides v. Agape Senior Community , Inc. et al.*, C/A No. 0:12-3466-JFA, Order Resolving Two Interrelated Issues and Certification for Interlocutory Appeal Pursuant to 28 U.S.C. 1292(b), pages 17 and 18.
13. See *United States of America ex rel. Misty Wall v. Vista Hospice Care, Inc. et al. ("Vista")*, No. 3:07-cv-00604-M, Section V, pages 21-23.
14. *Vista*, page 21.
15. *Vista*, pages 9, 23-24.
16. *Vista*, page 22.
17. *Vista*, page 22-24.
18. *Vista*, page 25.
19. *Life Care* at 572. See also *United States of America ex rel., et al. v Aseracare Inc., et al.*, Civil Action No. 2:12-CV-245-KOB, pages 17 and 18.
20. See AU Section 350, Audit Sampling, paragraph .01. See also Segroves, James F. and Kelly A. Carroll, "Numbers Never Lie... or Do They? The Use of Statistical Sampling in False Claim Act Claims, HLB Health Law & Policy Blog, where they reference *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 240 (D.P.R. 2000).
21. See Rhoad, Robert T., Crawford, Jason M., and Mary Kate Healy, "Feature Comment: Extrapolation in FCA Litigation: A Statistical Anomaly or a Tactic Here to Stay?" *The Government Contractor*, Thomson Reuters, Vol 58, No. 2, January 13, 2016, page 1.
22. *Life Care* at 559.
23. *Id*.
24. *Ruckh,* page 4.
25. See Segrovies, James F., pages 2 and 3.
26. *Vista*, pages 25- 27.

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Using Health Insurance Consumer Protections to Increase Reimbursements for Providers and Decrease Out-of-Pocket Costs for Consumers

By Alexandra Berke

A key goal of the Affordable Care Act ("ACA") was the creation of health insurance marketplaces (the "Marketplace") to make insurance available to individuals for direct purchase. As Marketplaces have been implemented, the national rate of uninsured Americans dropped to under 9% for the first time.[1] More health care consumers means more people who need to understand their rights to access care. Understanding consumer health rights can help individuals decrease out-of-pocket costs while increasing reimbursements for their doctors. A few critical statutes, outlined in this article, can help consumers get the care they need, get it paid for by their insurance company, and decrease stress for all parties to keep focus on access to health care instead of dealing with insurance challenges.

It is important to acknowledge that access to health insurance is just the first step in gaining access to health care. To obtain needed medical visits, tests, and treatments, consumers must follow their insurance plan's rules to see in-network providers; get treatments the insurer deems "medically necessary"; and take medications covered by the plan's formulary, or risk loss of benefits. Consumers are often unaware of their insurers' rules, and it can feel like insurers are working to keep it that way.

Too often, consumers first learn they have not been following the rules after treatment, when there is a financial consequence. Not surprisingly, patient advocacy is a growing industry, with individuals and families hiring professional advocates to help manage their medical care, finding the right doctors, working with insurers to cover claims, and contesting medical bills.[2]

The consumer protections outlined in this article can help individuals have care paid for by their insurer, avoiding large unreimbursed provider bills. Demystifying these legal rights can save insureds and their advocates time, money, and frustration, allowing them to focus on their health, instead of the cost of health care.

This article provides a snapshot of New Yorkers' health insurance coverage, and outlines in four parts key consumer protections in New York State law that can be used to help patients, providers, and their advocates navigate the health care system to get the care they need while using their insurance benefits: (1) Part A examines transitional care laws, *i.e.*, maintaining the right to continue seeing a provider even after that provider or individual leaves the insurance network; (2) Part B outlines the right to appeal, who it applies to, and how to prepare a successful appeal; (3) Part C outlines the network adequacy requirements, including what can be done if your insurer is not meeting those requirements, and, finally, (4) Part D provides a brief explanation of the 2015 "Surprise Bill" law.

Snapshot of New Yorkers' Health Insurance Coverage

The Kaiser Family Foundation took a snapshot of where all 19.75 million New Yorkers get their coverage in 2014, the first year New Yorkers could enroll in insurance on the ACA-created Marketplace, known as the "New York State of Health Marketplace."[3] In 2014, 49% of New Yorkers were enrolled in insurance through an employer, 25% were enrolled in Medicaid, 13% in Medicare, and 6% were in non-group plans, including private insurance on the Marketplace.[4] Since the first New York Marketplace open enrollment in 2014, the number of people enrolled in insurance through the Marketplace has increased almost three-fold, from 960,762 to 2.8 million, or 15% of New Yorkers, and the percentage of uninsured New Yorkers has dropped by nearly 850,000 people from ten percent to five percent.[5]

All covered New Yorkers have consumer protection rights linked to the insurance plan the consumer is enrolled with. Each insurance program, including Medicaid, Medicare or employer-based insurance, follows its own, slightly different consumer protection rules, creating numerous potential traps for the unwary consumer.

Consumer Protections Available to the Insureds

(1) Part A: Using Transitional Care Laws to Access Out-of-Network Providers

The cost of seeing an out-of-network provider is borne entirely by the insured if their insurance does not reimburse them for routine out-of-network care, and many do not. Even plans that offer out-of-network reimbursements provide lower amounts than consumers regard as customary. Health insurance enrollment and eligibility is linked to employment, family size and income. When someone changes jobs, gets married or becomes pregnant during the insurance year, they may be enrolled in a different insurance plan. Even if a consumer

does not change the insurance plan they are enrolled in during a coverage year, the insurer may make changes to the network during the plan year or between plan years.[6] The insured may incur costs without realizing a provider is no longer in the network, leaving the provider unpaid and the insured with bills they did not expect and may be unable to pay fully. But, if the insured fits any of the below categories, bills for out-of-network care may be paid by the insurer.

a. Staying Covered When a Provider Leaves the Network

When a provider leaves an insurer's network for reasons unrelated to fraud or losing its license, the insured can continue to see that provider for a statutory period of time as though they are in-network. If the insured is engaged in an ongoing course of treatment when they receive notice that a provider is no longer in-network, they are entitled to 90 days of transitional care. Pregnant women have special protections; if they are in their second trimester of pregnancy at the time the provider left the network, their transitional care lasts through birth and includes post-partum care related to the delivery, even if more than 90 days, as though the provider is in-network.[7]

Without this protection, the pregnant woman would have two options for obtaining coverage under her plan: (1) pay out-of-pocket for all visits, sonograms and lab tests, with no hope of reimbursement, or (2) find a new provider, such as an OB/GYN, who is in-network. Both of these options can be highly disruptive for a pregnant patient who has developed a relationship with her doctor and cannot afford to pay for the full cost of care. Plus, finding a new provider can be challenging because of inaccuracies in provider directories[8] and the fact that doctors often refuse to accept new patients late in their pregnancy.

b. Continuing to See a Provider When the Consumer Switches Insurance Plans

Transitional care may be available when an individual switches insurance to a plan that is regulated by New York State law. To receive transitional care rights when the insured switches insurance plans—not the provider—the individual must either have a disease or condition that is life-threatening, degenerative or debilitating, or be in at least the second trimester of pregnancy.[9] The individual must be joining a plan that is subject to this law, not a self-insured or grandfathered plan that is governed by ERISA and not additionally subject to New York State law. The best way to learn whether a plan is self-insured or grandfathered is to call the plan, or ask the Human Resources office of the company that provides the plan.

If the individual has transitional rights because of a degenerative or disabling condition, they can continue to see their out-of-network provider for up 60 days from the date of enrollment in the new plan, as though still in-network. If the transitional rights stem from the insured's being in the second trimester of pregnancy when she enrolls in her new plan, she can continue to receive care from her now out-of-network provider through post-partum care related to the delivery.

For example, when insurer Health Republic abruptly went out of business in November 2015, numerous enrollees were receiving treatment for cancer from Memorial Sloan Kettering. However, none of the other insurance plans sold through the Marketplace, where the individuals had purchased their Health Republic plan, had coverage for Memorial Sloan Kettering available in-network. Unless the Health Republic insureds could get access to another insurance plan that had Memorial Sloan Kettering in-network, they could use transitional care rights to continue receiving care from their doctors without paying entirely out of pocket.

c. Mechanics of Receiving Transitional Care

No matter why an insured is eligible for transitional care, getting the insurer to pay the out-of-network provider is not self-executing, and requires the enrollee to take action. Plus, the law requires the insurer to cover the out-of-network provider during the transitional period, but the provider is not required to participate.[10] Participation requires the provider to act like an in-network provider with the insurer during the transitional period. This means accepting the insurer's in-network reimbursement rates as payment in full, and adhering to the insurer's policies and procedures, including quality assurance requirements and obtaining pre-authorization or other procedural requirements.[11]

Another hurdle to be met is that each insurer has its own method for authorizing transitional care, so the affected individuals should start coordinating the transitional care as soon as they realize that they need to do so. The process starts with a call to the insurer to get an explanation of its procedure to request transitional care to have the provider bill the insurer.[12] Complaints against insurers who stall or do not follow the law can be directed to the Department of Financial Services ("DFS") through its website for commercial plans,[13] or to the Department of Managed Care for Medicaid plans.[14] Filing a complaint is simple and triggers a process wherein DFS may reach out to the insurer about the complaint.[15]

(2) Part B: Appealing Insurance Denials

When a private insurer denies a claim for any reason, the enrollee has the right to appeal that decision. Both the

reason for denying the claim, and the type of insurance at issue, shape where to direct an appeal and how to frame a winning argument.[16]

Based on a DFS annual report tracking success rates of insurance appeals, appealing an insurer's denial is a worthwhile strategy for the insureds and their providers. There are two types of appeal: (1) internal appeals decided internally by an insurance company representative, and (2) external appeals to DFS, which are decided by a neutral third party. According to DFS records, in 52% of all internal appeals, which are submitted to the insurer itself and can be filed on the basis of any type of denial, the insurer overturned the previous decision.[17] Approximately 40% of the 1,786 external appeals submitted in 2014 were at least partially overturned in favor of the insured.[18] These numbers imply that individuals who receive denials from their insurer could benefit from filing an appeal.

Claim denials fall into two broad categories: (1) the insurer disagrees with the necessity or efficacy of the treatment, claiming that it is not medically necessary, that it is experimental or investigational; or (2) the insurer has a procedural argument against coverage, because the service was received from an out-of-network provider, it is not a covered service, or the service required preauthorization which the insured failed to obtain.

Generally, if the denial falls into the first category, the individual has internal and external appeal rights.[19] Internal appeals are reviewed by the insurer directly and external appeals are accepted by DFS before being randomly assigned to an external review agent.[20] If the denial is primarily procedural, it can be reviewed externally only if there is a medical reason for seeing an out-of-network doctor, such as the out-of-network health service being materially different from the recommended in-network service,[21] or the insurer claims that it has an in-network provider with the appropriate training and experience to meet the health needs of the insured, making out-of-network care unnecessary.[22]

Appeals can be submitted before or after care is received, depending on whether the denial is for a preauthorization or the denial comes after the service has been provided. If the consumer successfully gets the insurer's decision overturned, the insurer must pay for the care that was provided as though it had never been denied, according to the reimbursement rates under the plan.

Medical necessity denials may be appealed externally. Each appeal is extremely fact specific and must link the details of the individuals' medical history with the relevant medical necessity standard. Each insurance plan maintains its own standards for medical necessity, which is the only standard the plan needs to consider when making a decision. Third-party reviewers, who are doctors and nurses contracted by DFS, can use other information to decide if the insurer's treatment denial was in the best interest of the patient, including the attending physician's recommendation, and generally accepted practice guidelines from the federal government, medical societies or boards and associations.[23]

(3) Part C: Network Adequacy Requirements and How to Get Care Out of the Network

Insurance plans must follow network adequacy requirements that control if the plan has a provider who can provide the right care within a reasonable time, without the individual traveling too far from home. Networks are certified by DFS before a plan can be sold in New York State, and are adequate if they can "… meet the health needs of insureds and provide an appropriate choice of providers sufficient to render the services covered under the policy or contract."[24]

The standards for network adequacy are set broadly in the New York State Public Health Law and Insurance Law, with some details outlined more specifically within insurance contracts. For example, enrollees must be able to select from at least three primary care providers within the time and distance travel standards.[25] Time and distance requirements for Medicaid plans are found in the Managed Care model contract[26] and private plans sold through the Marketplace can be found in the standards for plans to participate.[27] The number of providers in each area of specialty practice must be sufficient to meet the needs of the enrollment population and there is no exclusion of any appropriately licensed type of provider as a class.[28]

Complaints about a plan network should be directed to DFS.[29] Although insurance plans are required to update their provider listings within fifteen (15) days of a change in physician network or hospital affiliations,[30] many provider listings contain so many mistakes that individuals may not be able to accurately assess whether their network is adequate. If individuals cannot get access to an in-network provider because the network is inadequate, they can use the external appeal system as described in Part B to get their insurance to pay for an out-of-network provider as though they were in-network.

a. Rights to Begin Seeing an Out-of-Network Provider

When first shopping for a plan, consumers should check to confirm that their current providers are in-network. But they may develop a need to see a specific provider after they have enrolled in a plan, and will be unable to switch during the plan year, creating yet another hurdle for access to care.

Enrollees in HMOs, PPOs and EPOs have the right to go out-of-network if they cannot find an in-network provider who meets the network adequacy requirements discussed above. The member handbook or subscriber contract or certificate should explain the procedure for enrollees to demonstrate that they need go out-of-network. If the internal procedure does not work, enrollees can access the DFS external appeals process mentioned above to appeal the denial of their coverage. As part of the process, patients must enlist their physician to certify that the in-network provider does not have the appropriate training and years of experience treating the patients' condition, or number of procedures performed, to meet the particular health needs of the patients.[31]

These network adequacy protections can be laborious for the individual making the appeal, but using these protections, and complaining to DFS when they do not work, will help improve these processes in the future.

(4) Part D: Protections Against "Surprise Bills"

In 2015, New York enacted a law to protect consumers from "surprise bills." Individuals insured in HMOs had already been protected by surprise bills incurred when they went out-of-network during the course of an emergency, but this law expands those protections to people in non-HMO insurance, covering surprises that occur outside of an emergency. Since many medical bills come as a surprise to the person receiving them, the law carefully defines surprise.

To determine if a bill is a surprise, the first question is whether or not the individual is insured. If the answer is "yes" and the plan is not self-insured, the process moves forward. The next question is whether the service that led to the bill took place in an in-network facility or after a referral to an out-of-network facility.

If an insured individual received services in an in-network hospital or Ambulatory Surgical Center, from an out-of-network doctor, the bill is a surprise if: (1) an in-network doctor was not available; or (2) an out-of-network provider was used without the insured's knowledge; or (3) unforeseen medical circumstances arose at the time that services were being provided. It is not a surprise bill if the insured chose to see an out-of-network provider.[32]

If the insured is referred to an out-of-network provider by an in-network doctor, the bill is a surprise if the patient did not sign a written consent acknowledging that the services would be out-of-network and the costs would not be covered by their insurer. This referral can occur if: (1) a patient is being seen by an in-network doctor, and an out-of-network provider also treats the patient, or (2) an in-network doctor sends a specimen to an out-of-network lab or pathologist, or (3) if the insurer requires a referral for any service.[33]

If the medical bill is a "surprise" under the law, individuals can remove themselves from the dispute over the bill. The individuals assign their benefits to the physician, allowing the physician and the health insurer to negotiate, in front of a third party arbitrator assigned by DFS, as necessary.[34]

This law also attempts to prevent surprise bills by requiring providers to disclose what health care plans they participate with, and which hospitals they are affiliated with at the time an appointment is scheduled. As such, doctors in private practice are required to provide information about the insurance networks of any other providers they are working with on the patient's care.[35] Hospitals are required to update their website to include which insurance plans they participate in, the physician groups they contract with, and which physicians are employed by the hospital. Hospitals also need to provide patients with instructions before they receive non-emergency services to help the patients determine which networks their providers are in, including an explanation that a doctor working at an in-network facility is not necessarily an in-network doctor.

To date, DFS has not released clear data on how this law is working for patients who experience a non-emergency out-of-network referral, but the NYS Department of Health is conducting a statewide audit of 50 to 60 hospitals to determine if they are meeting the notice standards.[36]

Conclusion

Our health insurance system is deeply complex, but within the maze there are rules that help individuals and providers get correctly reimbursed by the insurer. Heightened awareness of the rules by all players in the health insurance market can help patients and families to focus on managing their health, not their health insurance.

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Ransomware Concerns and Risk Mitigation

By Carl Cadregari, CISA

Advanced and changing ransomware infections (malicious software (malware) that fully encrypts data on the computer device attacked and/or those that steal data and then require you to pay for the decryption key) are becoming increasingly prevalent and costly every day. A recent U.S. Government interagency report indicates that, on average, there have been 4,000 daily ransomware attacks since early 2016 (a 300% increase over the 1,000 daily ransomware attacks reported in 2015). Ransomware exploits human and technical weaknesses to gain access to an organization's technical infrastructure in order to deny the organization access to its own data by encrypting that data. Malware infection may also carry additional malicious payloads including spyware applications that may be installed, including ones that exfiltrate usernames and passwords, non-public information (NPI), and other confidential information about the computer, the user, and the data, or may even use the user's email contacts to spread the malware. Given how lucrative it is for those who deploy it, one can assume these attacks will continue for the foreseeable future. A current statistic published by McAfee™ stated that just one organization spreading ransomware made *$121 million* in the last year.

Fortunately, there are measures known to be effective to prevent the introduction of ransomware and to recover from a ransomware attack. This article will highlight several relevant areas that, with proper implementation and assessment, will help support a health care entity's efforts in ransomware attack prevention and recovery from a health care sector perspective. It also addresses guidance supported by the controls included in the Health Insurance Portability and Accountability Act (HIPAA). These controls can assist HIPAA-covered entities (CE) and business associates (BA) with prevention of and recovery from ransomware attacks, and how HIPAA breach notification processes should be managed in response to a ransomware attack.

While this article is intended to focus on the needs of CEs and BAs, several other business sectors and vertical markets such as those that store, process, transmit, and otherwise share personally identifiable information (PII) are likewise targets for ransomware attacks. They include banking, retail, not-for-profit, education, and government/municipalities sectors. Those sectors all have similar laws and regulations that require the protection of PII and the controls noted in this article can support their efforts, too.

In general, institutions that are victims of cyberattacks involving ransomware extortion are encouraged to inform law enforcement authorities and notify their primary regulator(s). In the event that an attack results in unauthorized access to protected data, the institution also has a responsibility to notify its federal and state regulators in accordance with the laws and regulations that govern their institution. Required notifications include those contained in HIPAA,[1] the New York State Information Security Breach Notification Act,[2] Gramm–Leach–Bliley Act,[3] and other applicable state laws may apply based on the data owner's permanent residence.[4]

HIPAA Applicability

The Security Management Process standard of the Security Rule includes requirements for all covered entities and business associates to conduct an accurate and thorough risk analysis of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of all of the ePHI that the entity creates, receives, maintains, or transmits.[5] Likewise, the CE and BA are required to implement security measures sufficient to reduce those identified risks and vulnerabilities to a reasonable and appropriate level, and have planned and continuing periodic technical and nontechnical evaluations, based initially upon the standards implemented under this rule and, subsequently, in response to environmental or operational changes affecting the security of electronic protected health information.[6]

It is expected that CEs and BAs will use a documented and standard[7] process of risk analysis and risk management that satisfies the specific standards and implementation specifications of the Security Rule. It is likewise expected that when the CE and BA are implementing security measures throughout an organization's entire enterprise, identified as a result of an accurate and thorough risk analysis, those steps must be done to a reasonable and appropriate level.[8] Since ransomware attacks are so prevalent, it would be expected that a well-defined process specifically addressing this type of malware would be a required focus area of the risk assessments and mitigation plans.

Changes to the Assurance Guidance for Business Associate Contracts[9]

The May 2016 Office of Civil Rights Cyber Awareness publication added supplementary guidance surrounding when the BA Agreement may need to be supplemented to confirm that the CE has the satisfactory assurances[10] through additional security audits and assessments intended to evaluate the business associates' or subcontractors' security and privacy practices.

Changes to the Breach Notification Guidance from HHS

Per the HHS Ransomware Guidance[11] dated July 2016, "The presence of ransomware (or any malware) on a covered entity's or business associate's computer systems is a security incident under the HIPAA Security Rule. A security incident[12] is defined as the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system. Once the ransomware is detected, the covered entity or business associate must initiate its security incident and response and reporting procedures."[13]

The guidance goes on to state that "whether or not the presence of ransomware would be a breach under the HIPAA Rules is a fact-specific determination." Moreover, "[w]hen electronic protected health information (ePHI) is encrypted as the result of a ransomware attack, a breach has occurred because the ePHI encrypted by the ransomware was acquired (i.e., unauthorized individuals have taken possession or control of the information), and thus is a 'disclosure' not permitted under the HIPAA Privacy Rule." At that point, the CE or BA must follow the guidance and direction of the Breach Rule[14] to determine the outcome of the infection.

In addition to the guidance above, the following are some controls and schemes that warrant consideration.

Ongoing Prevention Controls

1. Conduct ongoing, documented, and thorough information security risk assessments

Maintain an ongoing information security risk assessment program that considers new and evolving threats to online accounts and adjusts customer authentication, layered security, and other controls in response to identified risks. Identify, prioritize, and assess the risk to critical systems, including threats to applications that control various system parameters and other security and fraud prevention measures. In addition, ensure that third party service providers:

- Perform effective risk management and implement controls.
- Properly maintain and conduct regular testing of their security controls simulating potential risk scenarios.
- Are contractually obligated to provide security incident reports when issues arise that may affect the institution.

2. Securely configure systems and services

Protections such as logical network segmentation, offline backups, air gapping, maintaining an inventory of authorized devices and software, physical segmentation of critical systems, and other controls may mitigate the impact of a cyber attack involving ransomware. Consistency in system configuration promotes the implementation and maintenance of a secure network. Essential components of a secure configuration include the removal or disabling of unused applications, functions, or components.

3. Protect against unauthorized access

Limit the number of credentials with elevated privileges across the institution, especially administrator accounts and the ability to easily assign elevated privileges that access critical systems. Review access rights periodically to reconfirm approvals are appropriate to the job function. Establish stringent expiration periods for unused credentials, monitor logs for use of old credentials, and promptly terminate unused or unwarranted credentials. Establish authentication rules, such as time-of-day and geolocation controls, or implement multifactor authentication protocols for systems and services (e.g., virtual private networks). In addition, conduct regular audits to review the access and permission levels to critical systems for employees and contractors. Implement least privileges access policies across the entire enterprise. In particular, do not allow users to have local administrator rights on workstations, and remove access to the temporary download folder.

- Change all default password and settings for system-based credentials.
- Prevent unpatched systems, such as home computers and personal mobile devices, from connecting to internal-facing systems.
- Implement monitoring controls to detect unauthorized devices connected to internal networks.

4. Perform security monitoring, prevention, and risk mitigation

Ensure that protection and detection systems, such as intrusion detection systems and antivirus protection, are up to date and that firewall rules are configured properly and reviewed periodically. Establish a baseline environment to enable the ability to detect anomalous behavior. Monitor system alerts to identify, prevent, and contain attack attempts from all sources. In addition:

- Follow software assurance industry practices for internally developed application.

- Conduct due diligence assessments of third party software and services.
- Conduct penetration testing and vulnerability scans, at least annually and as necessary.
- Promptly manage vulnerabilities, based on risk and track mitigation progress, including implementing patches for all applications, services, and systems immediately upon release.
- Review reports generated from monitoring systems and third parties for unusual behavior.

5. Update information security awareness and training programs, as necessary, to include cyber attacks involving extortion and social engineering testing such as phishing attacks

Conduct regular, mandatory information security awareness training across the institution, including how to identify, prevent, and report phishing attempts and other potential security incidents. Ensure that the training reflects the functions performed by employees.

6. Implement and regularly test controls around critical systems

Ensure that appropriate controls, such as access control, segregation of duties, audit, and fraud detection, and monitoring systems are implemented for systems based on risk. Limit the number of sign-on attempts for critical systems and lock accounts once such thresholds are exceeded. Implement alert systems to notify employees when baseline controls are changed on critical systems. Test the effectiveness and adequacy of controls periodically. Report test results to senior management and to the board of directors or a committee of the board of directors. Include in the report recommended risk mitigation strategies and progress to remediate findings. In addition:

- Encrypt sensitive data on all portable, internal, and external facing data storage devices and systems, for data in transit and, where appropriate, at rest.
- Implement an adequate password policy.
- Review the business processes around password recovery.
- Regularly test security controls, such as Web application firewalls.
- Implement procedures for the destruction and disposal of media containing sensitive information based on risk relative to the sensitivity of the information and the type of media used to store the information.
- Filter Internet access through Web site whitelisting where appropriate to limit employees' access to only those Websites necessary to perform their job functions, so as to reduce the risk of connecting to infected websites.
- Conduct incremental and full backups of important files (including desktops) and store the backed-up data offline. Make certain all protected data is backed up on at least a daily schedule, pay close attention to desktops and laptops, and confirm that data cannot be stored on the local hard drive.

7. Review, update, and test incident response and business continuity plans periodically

Test the effectiveness of incident response plans at the institution and with third party service providers to ensure that all employees, including individuals responsible for managing risk, information security, vendor management, fraud detection, and customer inquiries, understand their respective responsibilities and their institution's protocols. ln addition:

- Ensure that processes are in place that update, review, and test incident response and business continuity plans address cybersecurity threats involving extortion.
- Ensure that incident response and business continuity plans are updated to address notification of service providers, including Internet service providers (lSP), as appropriate, if the institution suspects that a DDoS attack is occurring.

8. Participate in industry information-sharing forums

Incorporate information sharing with other institutions and service providers into risk mitigation strategies to identify, respond to, and mitigate cybersecurity threats and incidents. Since threats and tactics change rapidly, participating in information-sharing organizations can improve an institution's ability to identify attack tactics and to mitigate cyber attacks involving ransomware malware on its systems successfully. In addition, there are government resources, such as the U.S. Computer Emergency Readiness Team (US-CERT), that provide information on vulnerabilities.

Data Recovery

- If you do experience a successful attack, there are some tools available from multiple vendors to possibly recover the system; however, it has been our experience that these are not universally successful. Many times, the malware encryption may be re-

moved to find that all the files that were encrypted were deleted.

- There are many trustworthy organizations that want to help, but be cautious of solutions that require you to send a copy of all the data that was encrypted. Make sure the organization is competent and willing to sign any needed confidentiality agreements.
- If your data is legally protected (i.e., NPI, GLBA, FTC, etc.), make sure you have the correct contracts in place with any third party accessing your data.

Ransomware is an insidious malware infection that can be avoided with the proper due diligence, technical and administrative controls. All of the organization's personnel must be a part of the protection and recovery strategies from the IT department to the CEO. Start today and plan to assess the controls on an ongoing basis to make certain they maintain their efficacy.

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Decisions Regarding Hospice Care for Isolated Patients

A Guide to the 2015 Amendment of the Family Health Care Decisions Act

By Timothy W. Kirk and Randi Seigel

I. Introduction

The Family Health Care Decisions Act (FHCDA)[1] was adopted by New York State in September 2010, after first being introduced in the Assembly 18 years prior.[2] The FHCDA establishes the authority of a patient's family member or close friend (referred to as a "Surrogate"[3]) to make health care decisions when the patient lacks decision-making capacity, has not executed a proxy appointing a health care agent, and does not have a guardian. A Surrogate is authorized to make health care decisions, including to direct the withdrawal or withholding of life-sustaining treatment, provided that conditions set forth in the FHCDA are met.[4]

When adopted, the FHCDA allowed Surrogate decision-making only for patients who were receiving services in a hospital or residential health care facility. In 2011, the FHCDA was amended[5] to allow Surrogate decision-making for patients who were receiving hospice care, where such authority was greatly needed. Until 2015, one category of patients was unable to fully engage the benefits of the 2011 amendment: those patients often referred to as "isolated" or "unbefriended" patients. A 2015 amendment to the FHCDA provides a process through which physicians, acting under the standards that apply to Surrogates, can elect the hospice benefit and consent to a hospice plan of care on behalf of isolated patients.[6]

This article explains the context and content of the amendment, and presents considerations gleaned from our experience consulting with health care provider organizations on its implementation.

II. The FHCDA, Isolated Patients, and Hospice Care

Isolated patients are patients (1) who lack decision-making capacity; (2) who have not appointed a health care agent *or* for whom the appointed health care agent is unable or unwilling to serve; and (3) for whom no Surrogate is reasonably available to make health care decisions.[7] Estimates of the number of isolated patients vary, but a widely cited figure is three to four percent of nursing home residents nationally.[8] While the FHCDA does contain a provision permiting an attending and concurring physician to make health care decisions for isolated patients,[9] two perceived barriers to using this process for decisions regarding hospice care produced reluctance in most New York State hospice providers to admit and care for isolated patients prior to the 2015 amendment.

First, there was lack of clarity regarding whether the provisions in PHL § 2994-g authorized an attending physician to elect the hospice care benefit and admit an isolated patient to a hospice care program. While the applicable Medicare regulation permits a patient "representative" to elect the hospice care benefit and admit a patient to hospice care,[10,11] it defers to applicable state law when defining who may serve as a representative for a patient who is unable to elect the benefit because she is "mentally or physically incapacitated."[12] In New York State, the most commonly applicable law is the FHCDA. And, while some argued that the decision to commence hospice care could reasonably be considered a care decision for which PHL § 2994-g provided sufficient guidance, others argued that electing the hospice care benefit did not clearly fit into any of the three categories of treatment decisions for isolated patients covered by § 2994-g: (i) routine medical treatment, (ii) major medical treatment, or (iii) decisions to withdraw or withhold life-sustaining treatment.[13] In part, this lack of congruence stemmed from the considered judgment of some that the decision to elect the hospice care benefit—and, in so doing, elect to forgo coverage of non-palliative treatment for conditions related to the terminal illness otherwise covered by Medicare—was of a complexity not contemplated by the definition of "health care decision" in § 2994-a(14), and as such exceeded the authority given to attending physicians of isolated patients under § 2994-g.

Second, there was the matter of whether, practically, decisions by attending physicians to withhold or withdraw life-sustaining treatment for isolated patients could reasonably be made in a hospice care environment. Prior to the 2015 amendment, decisions in this category—including "do not resuscitate" orders,[14] which are a common component of plans of care for hospice patients—used criteria which were exceedingly difficult to satisfy.[15] While, anecdotally, there was variation across care institutions regarding how strictly those criteria were interpreted, even if isolated patients were already admitted to hospice care, attending physicians, acting as decision-makers for those patients, found themselves directed to use decision-making criteria for some components of the hospice plan of care that were likely not contemplated by the Legislature to apply to hospice election and hospice care.

III. The 2015 Amendment

The 2015 amendment to the FHCDA[16] addressed both of these perceived barriers by making two changes to extant law. First, it added a new subsection (PHL § 2994-g(5a)) which (1) provides a three-step process for making decisions regarding hospice care for isolated patients and (2) clarifies the criteria to guide such decisions, includ-

ing modifying those used to make decisions regarding major medical and life-sustaining treatments when they are part of a hospice plan of care. Second, it repealed § 2994-g(5)(c), which had directed the selection of a second physician to concur on decisions regarding hospice care for isolated patients in hospitals and residential health care facilities. Revised direction on this matter is now included in § 2994-g(5a).

A. The 2015 Amendment: The Three-Step Care Decision Process

PHL § 2994-g(5a) presents a three-step process for making decisions regarding hospice care for isolated patients. "Decisions regarding hospice care" is a term defined by the statute: "the decision to enroll or disenroll in hospice, and consent to the hospice plan of care and modifications to that plan."[17] As such, the process applies to admitting and discharging isolated patients and establishing and modifying a hospice plan of care, including authorizing or stopping major medical and life-sustaining treatments. The process is as follows (see also fig.1).

> *Step 1.* Patient's attending physician[18] considers options available for a decision regarding hospice care and selects the option most appropriate for the patient per PHL § 2994-d(4-5).[19]
>
> *Step 2.* Concurring physician[20] reviews decision made by attending physician and confirms it was made consistent with the criteria in PHL § 2994-d(4-5).[21]
>
> *Step 3.* Ethics review committee[22] reviews decisions made by attending and concurring physicians and confirms they were made consistent with the criteria in § 2994-d(4-5).[23]

As with any care decision made by a Surrogate, patients who lack decision-making capacity retain the right to be included in discussions of care options, informed of decisions made by Surrogates and their rationale,[24]and retain the right of assent/refusal.[25] In cases where patients object to decisions made by attending physicians acting as Surrogates, judicial guidance should be sought.[26]

The FHCDA includes detailed instruction regarding the identification, selection, and institutional affiliation of attending and concurring physicians,[27] as well as the composition and process of Ethics Review Committees.[28] When making decisions regarding hospice care for a patient in a hospital or residential care facility, a representative from the hospice organization should be invited to participate in Ethics Review Committee deliberations.[29] Careful collaboration between hospitals, residential care facilities, and hospice organizations is essential to ensure that decisions regarding hospice care are made consistent with patient preferences or best interests and in compliance with the FHCDA.

When care decisions are made using this three-step process, the attending physician acts in the role of Surrogate, consenting to start or stop hospice care and to establish or modify the hospice plan of care. The amended language of PHL § 2994-g(5a) makes clear that the three-step process discussed above also applies to the decision to elect the hospice insurance benefit, authorizing attending physicians, in their role as Surrogate, to: "execute appropriate documents for such decisions (including a hospice election form) for an adult patient under this section who is hospice eligible."[30] As such, the first of the two perceived barriers to hospice care for isolated patients has now been removed. When relevant, the attending physician signs the Medicare/Medicaid Notice of Election to elect the hospice benefit and any admission and consent forms that would normally be signed by a Surrogate related to admission and the hospice plan of care.

B. The 2015 Amendment: The Criteria for Decisions Regarding Hospice Care

Because it applies to all decisions regarding hospice care, the amended text of PHL § 2994-g(5a) also effectively changes the criteria used when making decisions regarding major medical and life-sustaining treatment for isolated patients when the decisions are a part of a hospice plan of care.

> The attending physician shall make decisions under this section in consultation with staff directly responsible for the patient's care, and shall base his or her decisions on the standards for surrogate decisions set forth in subdivisions four and five of section twenty-nine hundred ninety four-d of this article.[31]

In changing the criteria to be used from those in § 2994-g(4-5) to those in § 2994-d(4-5), the amendment alters the threshold which must be met in making decisions to withhold or withdraw life-sustaining therapies such as ventilation, dialysis, transfusion, and resuscitation. As discussed above, the threshold in § 2994-g(5) was, in practical terms, rarely met.[32] The criteria in § 2994-d(5)—used by all FHCDA Surrogates when deciding to withhold or withdraw life-sustaining treatment—are, in our experience, more consistent with the goals and philosophy of hospice care and the preferences of many (but not all) hospice patients. Similarly, decisions regarding major medical treatment must also now move through the three-step process in § 2994-g(5a) explained above when they are part of a hospice plan of care. As with any patient in any care environment, credible evidence that the patient would wish to initiate, continue, or discontinue specific treatments in particular circumstances takes precedence over a Surrogate's decision otherwise.

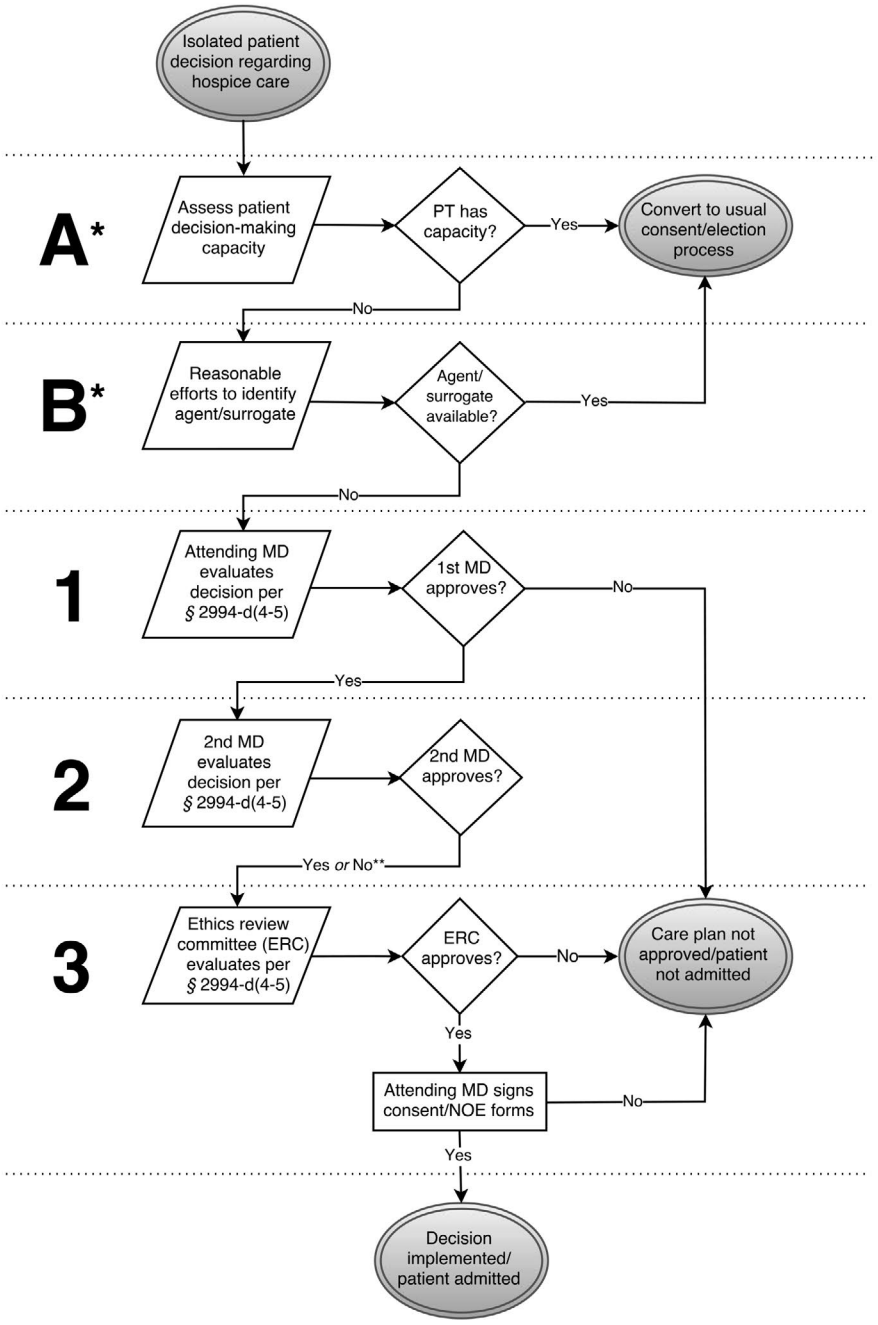
While the 2015 amendment removed a barrier to admission and election of hospice care on behalf of isolated

patients and established a more reasonable decision-making standard for life-sustaining treatment when part of a hospice plan of care, it may have modified the process for making decisions about routine medical treatment[33]—creating a more burdensome process inconsistent with the overall legislative intent behind the amendment. The three-part decision-making process noted above applies to all decisions regarding hospice care, defined as decisions "to enroll or disenroll in hospice, and consent to the hospice plan of care and modifications to that plan."[34]

The hospice "plan of care" is a comprehensive document that, among other things, directs

> all services necessary for the palliation and management of the terminal illness and related conditions and the individual(s) who will provide those services, including: (i) interventions to manage pain and symptoms; (ii) a detailed statement of the scope and frequency of services necessary to meet the specific pa-

Figure 1. Decisions Regarding Hospice Care for Isolated Patients



* Steps A and B confirm the patient is an isolated patient.

** When attending and concurring MDs disagree, the ERC is charged with facilitating resolution of disagreement (PHL § 2994-g(6)).

> tient and family needs;...[and] (iv) drugs, biologicals, treatments, medical supplies, appliances and durable medical equipment that must be provided by the hospice while the patient is under hospice care.[35]

Because of the detailed and comprehensive nature of a formal hospice plan of care, most routine medical treatment decisions—including ones as small and frequent as adjusting medication orders—require a change to the plan of care. Thus, a literal reading of PHL § 2994-g(5a) using the regulatory definition of a hospice "plan of care" would necessitate engaging the three-step process, including Ethics Review Committee review, for each routine medical treatment decision that results in a change in the plan of care. Doing so would likely be unwieldy and create a barrier to timely, optimized care for isolated patients. Unfortunately, neither the statute nor its legislative history indicate whether the Legislature intended to define "plan of care" in the FHCDA consistent with the State and federal regulatory definitions. However, as the intention of the 2015 amendment was to break down the barriers to accessing hospice care for isolated patients,[36] it is consistent with that intention to infer that it was *not* the aim of the Legislature to bog down the decision-making process for routine medical treatment in this manner, thereby creating a new barrier to timely, optimized care.

Rather, it is reasonable to posit that an isolated hospice patient's attending physician, acting as Surrogate, is permitted to make routine medical treatment decisions in consultation with the patient's interdisciplinary care team without engaging the three-step process—similar to how attending physicians make such decisions for isolated patients outside of hospice care.[37] This interpretation is supported by noting that, while PHL § 2994-g(5)(a) instructs the physician to apply the standards in § 2994(d)(4-5), those criteria only apply to "health care decisions" which are decisions "to consent or refuse to consent to treatment."[38] Routine medical decisions rarely require formal, documented consent; they are often made through the discussions between clinicians and patients (or, their Surrogates) which occur in the normal course of care delivery. Indeed, the provision that authorizes attending physicians to make routine medical treatment decisions for non-hospice isolated patients states that "[n]othing in this subdivision shall require health care providers to obtain specific consent for treatment where specific consent is not otherwise required by law."[39] Thus, there is a legal basis to argue that this more practical interpretation, which allows an attending physician to make such routine medical treatment decisions which alter the plan of care without Ethics Review Committee involvement, is permissible.

We strongly advocate for this interpretation, as it permits isolated hospice patients timely access to care—care that can require frequent and prompt care plan changes to prevent suffering and symptom distress in the final weeks of life. We believe that hospice care organizations should be given reasonable latitude to develop clear, internal criteria for the threshold and frequency of engaging Ethics Review Committees for routine medical treatment decisions for isolated patients. However, absent clarification from the Legislature, the courts, or the New York State Department of Health, hospice organizations are left with this ambiguity in the FHCDA.

IV. Implementing the 2015 FHCDA Amendment

When advising health care provider organizations on implementation of, and compliance with, the 2015 FHCDA amendment, we have found it helpful to (1) review with them the overall FHCDA requirements for health care decision-making by Surrogates (for example, reminding clients that a power of attorney does not authorize health care decisions in New York State); (2) review current organizational policies and procedures guiding decision-making by health care Surrogates, including whether such are being followed; and, insofar as is practicable, (3) integrate the requirements of the amendment into pre-existing organizational policies, procedures, and practices. Whether such integration is preferable to developing new policies, procedures, and practices will, of course, depend on the strength of an organization's existing infrastructure and a needs assessment conducted jointly with each client.

In particular, integration of the 2015 amendment presents an opportunity to review organizational practices surrounding

(1) assessment and documentation of patient decision-making capacity;

(2) identification and documentation of patient wishes and preferences;

(3) identification, documentation, and engagement of health care agents[40] and Surrogates;

(4) identification and documentation of specific procedures, time intervals, care plan changes, and health status changes which present decision points that require discussion with, and consent of, agents and Surrogates (including consent to routine medical treatment decisions as discussed above);

(5) composition, process, and engagement of Ethics Review Committees; and

(6) ways in which organizations educate staff about, and assess practice compliance with, policies and procedures governing 1-5.

In order to ensure consistency of isolated patients' access to hospice care, and maintain compliance with the FHCDA, applicable State and federal conditions of participation, and licensure requirements, we believe that it's imperative for organizations to take a systematic approach to addressing these matters at the level of policy

and procedure rather than engaging admission and care of isolated patients on an *ad hoc* basis. Additionally, given the ambiguity left in the FHCDA for routine medical treatment decisions, a hospice organization can better defend its approach to how these decisions are made for isolated patients if it has a systematic, thoughtful method which is applied to all decisions made for isolated patients.

V. Conclusion

The 2015 amendment to the FHCDA increases access to hospice care for isolated patients by explicitly authorizing attending physicians, acting under the standards that apply to Surrogates, to elect the hospice insurance benefit and consent to the plan of care, including decisions about life-sustaining treatment. It does so using a carefully designed three-step process in which a concurring physician and Ethics Review Committee ensure that a physician Surrogate's consent to hospice care generally, and the individualized hospice plan of care specifically, are aligned with patient preferences (if known) and patient best interests. The amendment also changes the criteria used by physician Surrogates when making decisions regarding major medical and life-sustaining treatments for isolated patients to those used by any Surrogate, provided such decisions are made as part of a hospice plan of care. We have identified and responded to ambiguity regarding routine treatment decisions for isolated hospice patients. Advising care provider clients on integrating the 2015 amendment into their organizational practice provides an opportunity for health care attorneys to partner with organizations in reviewing their overall policies and procedures for surrogate decision-making, with a dual aim of protecting patient rights and complying with applicable law.

Endnotes

1. New York Pub. Health Law (PHL) Article 29-CC.
2. A.7166 (1993) (M. of A. Gottfried). The bill was not named the "Family Health Care Decisions Act" until 1995.
3. A "Surrogate" is defined under the law as "the person selected to make a health care decision on behalf of a patient" pursuant to PHL § 2994-d(1). PHL § 2994-a(29).
4. *See* PHL § 2994-d(4), (5).
5. 2011 Sess. Law News of N.Y. Ch. 167 (A. 7343-A) (McKinney's).
6. 2015 Sess. Law News of N.Y. Ch. 107 (A. 2150) (McKinney's).
7. *See generally* PHL § 2994-g(1), (2); Pope, T.M., Sellers, T., *Legal briefing: the unbefriended: making healthcare decisions for patients without surrogates (part 1),* J Clin Ethics 2012; 23:84-96.
8. *See* Brill, J.E., *Advocating for the unbefriended elderly,* Washington, DC: National Long-Term Care Ombudsman Resource Center, 2010, p. 3. *Available at* http://ltcombudsman.org/uploads/files/issues/Informational-Brief-on-Unbefriended-Elders_0.pdf; Karp, N., Wood, E. *Incapacitated and alone: health care decision-making for the unbefriended elderly,* Washington, DC: American Bar Association, 2003, p. 13. *Available at* http://www.americanbar.org/content/dam/aba/administrative/law_aging/2003_Unbefriended_Elderly_Health_Care_Descision-Making7-11-03.pdf.
9. PHL § 2994-g.
10. Nationally, over 90% of hospice care recipients are enrolled in Medicare or Medicaid, giving the Medicare Conditions of Participation and related federal regulations significant influence over the structure and delivery of hospice care in the United States. *See* National Hospice and Palliative Care Association, *NHPCO's Facts and Figures: Hospice Care in America* (2015), Alexandria, VA: National Hospice & Palliative Care Association, p. 10. *Available at* http://www.nhpco.org/hospice-statistics-research-press-room/facts-hospice-and-palliative-care.
11. 42 C.F.R. § 418.24 (2014).
12. 42 C.F.R. § 418.3 (2014).
13. *See* PHL § 2994-g(3)-(5) and PHL § 2994-a(19).
14. "Cardiopulmonary resuscitation is presumed to be life-sustaining treatment without the necessity of a determination by an attending physician." PHL § 2994-a(19).
15. Prior to the amendment, attending and concurring physicians were required to determine "to a reasonable degree of medical certainty that: i. life-sustaining treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and ii. the provision of life-sustaining treatment would violate accepted medical standards." PHL § 2994-g(5)(b).
16. 2015 Sess. Law News of N.Y. Ch. 107 (A. 2150).
17. PHL § 2994-a(5a).
18. As defined in PHL § 2994-a(2).
19. PHL § 2994-g(5a)(a).
20. As identified per PHL § 2994-g(5a)(b).
21. *Id*.
22. As defined and composed in § 2994-m.
23. PHL § 2994-g(5a)(c).
24. PHL § 2994-c(4).
25. PHL § 2994-c(6).
26. *Id*.
27. *See* PHL § 2994-a(2) and § 2994-g(5a)(b), respectively.
28. *See generally* PHL§ 2994-m.
29. PHL§ 2994-m(4)(c).
30. PHL § 2994-g(5a).
31. PHL § 2994-g(5a)(a).
32. *See* n.14 and discussion in text.
33. As defined in PHL § 2994-g(3).
34. *See* n.17 and discussion in text.
35. 10 N.Y.C.R.R. § 793.4(c)(2); *see also e.g.*, 42 C.F.R. § 418.56(c), (d).
36. *See generally* A.2150 (2015) (M. of A. Gottfried).
37. *See* PHL § 2994-g(3)(b).
38. *See* PHL § 2994-a(13).
39. *See* note 35.
40. As such term is defined in PHL § 2980(5).

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Three Years Into the Non-Profit Revitalization Act of 2013

Expectations of, and Challenges Confronting, Not-for-Profit Boards

By Susan F. Zinder

I. Introduction

On December 18, 2013 New York Governor Andrew Cuomo signed into law the Nonprofit Revitalization Act of 2013 ("NPRA").[1] By adopting NPRA, the legislature sought to modernize New York's Not-for-Profit Corporation Law (the "NPCL") and strengthen the New York not-for-profit sector by increasing flexibility in board operations while raising board oversight expectations as to financial and operational matters, requiring board (rather than management) oversight of the annual audit, and increasing oversight of conflict of interest practices (particularly related party transactions).[2]

NPRA's adoption highlighted that not-for-profit governing boards need to actively understand their organizations' financial management and operational practices to fulfill their traditional oversight responsibilities and secure their organizations' futures. Adopted following the implementation of the Sarbanes-Oxley public company governance requirements, and the significant losses experienced by non-profits that invested in Bernard Madoff's funds, New York's adoption of NPRA demonstrated its expectations regarding effective not-for-profit governance. In fact, the day after NPRA was signed into law, New York State Attorney General Eric Schneiderman (the "AG") entered into an agreement with the Metropolitan New York Coordinating Council on Jewish Poverty ("Met Council") to reform its governance practices in the wake of charges that its CEO took kickbacks from its insurance broker for over 20 years unbeknownst to its board.[3]

In light of NPRA's implementation, and subsequent reporting in the mainstream press regarding not-for-profit operations and regulatory guidance, this article discusses certain post-NPRA situations and guidance that may help counsel educate not-for-profit board members in the fulfillment of their duties of care, obedience and loyalty.

II. Care in Action (or Not)

Under the duty of care, as set forth in Section 717(a) of the NPCL, directors are expected to act "with the care an ordinarily prudent person in a like position would exercise under similar circumstances." This formulation of the business judgment rule does not require that a decision be correct. It requires that a board member be attentive to the issues facing the organization and actively make decisions based on the information she receives in the belief that her decision is in the best interest of the organization.

Some may assume that, with large operating budgets, millions of dollars in annual operating revenue from city and state contracts, and large numbers of employees, our client institutional health care providers and social service agencies have boards comprised of sophisticated business executives, capable of guiding their institutions to success and financial stability. Yet any correlation between the size of an organization's budget and the ability of directors to effectively guide their organizations through difficult times is belied when an organization's critical challenges are revealed in the mainstream press.

(a) Abyssinian Development Corporation

According to *Crain's New York Business*, Abyssinian Development Corporation ("ADC"), may be

> Harlem's third largest landlord, after the New York City Housing Authority and Columbia University… [It] created public schools, ran after-school programs, trained Harlem residents for jobs, operated homeless shelters and assisted senior citizens…. [It set] in motion the renaissance of 125th Street…. [Yet by] 2011, unrestricted assets had slipped to less than $5 million, while liabilities had risen to more than $160 million.[4]

According to its Board Chair, by November 2015, even after it had sold off some of its real estate assets, ADC was still unable to afford accountants to prepare annual audits and tax filings and so had not submitted three years of filings (including corporate filings under the NPCL) required by the New York City Mayor's Office of Contract Services.[5] As a result of its filing failures, in September 2015 New York City advised ADC that $3 million in city contracts had been suspended.[6] Shortly thereafter it was reported that the AG had begun an investigation into ADC.[7]

Faced with the loss of the city contracts and the State investigation, ADC's board chair recognized the challenge of effective governance when he characterized his then-current board as being composed of individuals who are "faith based salt of the earth" and the organization as needing "new governance," including a "board chair who can attract others who can catch the vision to run this… more in line with the best secular business practices…. It's going to be tough. Tough for me to swallow but very necessary."[8]

The board chair's statement, coupled with ADC's failure to issue financial statements and submit the required filings,[9] raises questions about whether ADC's board was even able to fulfill its duty of care to the organization. To date no report has been issued describing any outcome to

the investigation and there are no court findings in the matter. However, one can expect that the outstanding investigation has, at a minimum, required the organization to respond using its limited resources, and will result in governance changes similar to those that were required of the Met Council board to reinstate its contracts following the revelations that it had not caught its CEO taking kickbacks over a 20-year period.

(b) The Federation Employment and Guidance Services ("FEGS")

The ADC press reports demonstrate that one of the greatest governance challenges for our clients is attracting individuals capable of fulfilling their duty of care for effective financial and organizational oversight. The 2015 collapse and bankruptcy of FEGS also highlights this challenge. FEGS was founded in 1934 as a small non-profit employment agency. By the time it filed for bankruptcy 80 years later, its 29 board members and approximately 1,900 employees were providing a wide array of social services to over 120,000 individuals each year.[10] With an annual budget of approximately $229 million, it was one of the seven largest Jewish charities in the United States.[11] In November 2014, the New York Office of the Medicaid Inspector General claimed that FEGS's licensed home care services agency had overcharged Medicaid approximately $21 million out of $81 million in total Medicaid billings between 2006 and 2009.[12] A month later FEGS suddenly announced that it was facing a $20 million shortfall, and had an "urgent financial and cash crisis [with] resources…rapidly depleting."[13] By March 2015 it filed for bankruptcy. The affidavit of FEGS' CEO at the time of the bankruptcy filing is telling:

> No single, but rather a confluence of factors and events have led to FEGS' financial crisis. A continuing decrease in revenue without essential corresponding cost cuts led to substantial operating losses and escalating financial difficulties over the last several years. For example, while revenues fell between fiscal 2013 and 2014, aggregate salaries and benefits increased 7%. General operational and administrative inefficiencies also pervaded [FEGS's] programs. An outdated financial management system led to delays and considerable losses in billing and cash collections, causing a further drain on available cash and resources and also compromised management's ability to make responsive business decisions in a timely manner. [FEGS] was also overburdened by multiple space obligations which substantially exceeded [its] physical needs and financial capabilities…. An overly prohibitive administrative cost structure…was significantly more than target industry standards…. Contributing to [FEGS's] dwindling cash flow and mounting operating losses was [its] historical concentration on top line growth without due concern to contract viability within [its] existing administrative framework and business models.[14]

"The ADC press reports demonstrate that one of the greatest governance challenges for our clients is attracting individuals capable of fulfilling their duty of care for effective financial and organizational oversight."

Subsequent reviews of the organization's financials revealed that 74 percent of FEGS's 350 programs were losing money. Moreover, the corporation's attempt to turn its information technology department into a for-profit subsidiary that could provide information technology services to other social services agencies had instead cost FEGS more than $72 million between 2008 and 2014.[15]

The affidavit of FEGS' CEO causes an outside observer to wonder about the effectiveness of the board's oversight and its fulfillment of its corporate duties. The board's apparent failure to address FEGS' financial situation before it became untenable meant the loss of a critical New York social services agency. It also has had implications for the individual board members themselves. The Manhattan District Attorney's office, the New York Attorney General, and the U.S. Attorney General's office are all reported to have opened investigations (both civil and criminal) into the charity's failure, focusing on its for-profit subsidiary, whether anyone inappropriately benefited from it at the expense of FEGS, and the performance of the board.[16] Even without announced resolutions to the investigations, there is little doubt that they have been costly in time, reputation and finances, to both the debtor and to the individual board members who have had (and will have) to respond to the investigations with legal counsel.

III. Duty of Obedience—The Cooper Union for the Advancement of Science and Art ("Cooper Union")

Both not-for-profit and for-profit board members are expected to fulfill their duties of care and loyalty (see be-

low); however, not-for-profit board members owe their organizations an additional duty, namely that of obedience to the organization's mission. This duty requires that board members deploy corporate resources for the tax-exempt mission of the organization as expressed in its charter documents.[17] But neither an organization's financial assets nor the seeming sophistication of its board members nor their commitment to the organization can guarantee that the board's governance practices will advance the corporate purpose. This was highlighted when the AG announced that he had resolved an investigation into the board of Cooper Union.[18]

The investigation was triggered by the protests and lawsuit filed by a faculty/student committee against the board in response to its decision to have Cooper Union charge tuition. Peter Cooper founded Cooper Union in 1859 with a bequest primarily of real estate assets in order to provide a free applied sciences education to all of its students who were to be admitted regardless of race, religion or sex. Its operations have since been funded through the income stream generated by its assets, particularly the land underneath the Chrysler Building. In 2006, believing that campus modernization would strengthen the organization's future, the board approved a construction plan to be financed by a mortgage secured by the Chrysler Building property.

The project's success hinged on several assumptions regarding expense reductions, fundraising, tax benefits, and investment gains. In addition, the board tied the compensation of the president of the school to the completion of the project. Yet, as the project took shape, and the 2008 economic recession took hold, the underlying financial projections failed. As a result, in 2013 the board was forced to stabilize the school's finances by charging tuition for essentially the first time in its history.

The faculty/student committee sued the board, alleging that its decision to charge tuition contravened the school's underlying mission. The AG then intervened in the committee's suit. The board defended itself, claiming that the charter gave it authority over how to pursue the school's educational objectives.[19]

In the September 2015 settlement of the suit, the AG avoided concluding that the board had failed in its duty of obedience to the school's mission. He asserted that there was no clear basis for concluding that the board had definitively violated its duty of obedience because of the age of the charter and because it had not previously been subject to judicial review. Moreover, from a practical viewpoint, continuing the litigation would entail costs the school could ill afford, and that at the time of settlement it would be "impractical for Cooper Union to comply, whether in part or in whole," with Peter Cooper's original bequest, as "Cooper Union does not now, and will not at any time in the foreseeable future, have the resources to restart and maintain…a tuition-free model."[20]

Yet the AG clearly had concerns that the board had lost sight of the importance of free tuition to the school's mission. According to the A.G's report, the financial plan failed "because its four key, *inadequately assessed assumptions* all went unrealized" (emphasis added). At the time the plan was approved

> [t]here was no [board] debate over four key optimistic assumptions that were at the heart of the loan plan. There was no substantive discussion of an apparent conflict of interest involving a key decision maker. There was no review of the future downsides to the overall plan even if it worked properly, and no acknowledgement of or planning for the potential failure of the plan…. There is no record of any contingency planning for the failure of one or more of the plan's key assumptions. There is no record that the Board ever discussed the potential need to charge tuition, and the likely impact of that decision, if the plan did not perform as expected.[21]

Indeed, "[the] decision to pursue the 2006 loan plan… demonstrated a weakness in trustee oversight functions that would persist over the following decade."[22]

In order to settle the suit, Cooper Union was required to adopt various "reforms of the school's outdated governances," including, accepting the appointment of a state-mandated independent financial monitor. Among the other reforms the AG required the board adopt, was a mandate that the board create a committee "dedicated to development of a strategic plan to return the school to its traditional tuition-free policy."[23] This mandate is clearly a reflection of the AG's concerns that part of the school's mission was sacrificed when the board decided to charge tuition. Factoring in the cost of the AG's investigation and settlement, as well as the reputational hit the organization incurred when it announced and implemented its new tuition structure, it is clear that the decision to impose school-wide tuition resulted in significant unanticipated costs to Cooper Union and its board.

IV. Duty of Loyalty

Careless decision-making may result in reputational and financial costs to both an organization and its board members, but on its own it rarely (if ever) results in enforcement actions, even if the decisions undermine an organization's mission. Boards are not only required to act carefully in support of a mission, but are required to make decisions "in good faith." "Bad faith" decisions, i.e., those in which directors place their own interests above those of the organization, trigger the duty of loyalty and result in enforcement. An example is the multi-year prison sentence imposed upon William Rapfogel, former Met Council CEO, for taking millions of dollars in kick-

backs from Met Council's insurance broker over a 20-year period. In contrast, the board's failure to catch Rapfogel's fraud cost Met Council temporarily suspended contracts (while the fraud was investigated), and the acceptance of governance reforms and enhanced oversight, but not enforcement against the board or its members.[24] Met Council's board may not have effectively overseen its CEO, but it did not breach its duty of loyalty, and so the board was not subject to criminal enforcement.

(a) Homeland Foundation, Inc. ("Homeland")

Homeland represents a post-NPRA example of an organization and individuals who subjected themselves to increased enforcement for violations of the duty of loyalty. In September 2015, trustees of the Homeland Foundation, Inc., settled an investigation by the AG that they had breached their fiduciary duties by issuing grants to organizations connected with certain of the trustees in violation of Homeland's charter. Much of the subject grant funding went to schools that individual trustees or their children attended. In addition, a trustee and officer diverted to herself proceeds of a life insurance policy that were intended for the organization. In light of the various conflicts of interest, Homeland was required to implement various governance reforms, including removing certain members from its board, expanding its board, and revising its bylaws and conflicts of interest policy. Importantly, individual trustees were forced off the Homeland board and were required to repay Homeland over $4 million. The trustee who diverted funds to herself was banned for life from serving on a non-profit board, but other board members who did not benefit from the grants were barred from serving on other non-profit boards for a minimum of three years.[25]

(b) Carnegie Hall

To increase their oversight of potential conflicts and enforcement of the duty of loyalty, NPRA mandated that boards adopt conflicts of interest policies requiring that their members "act in the corporation's best interest," disclose any potential conflicts, and that any "related party transactions" be approved by the uninterested board members only after a determination that the transaction is "fair, reasonable and in the corporation's best interest."[26]

Changing board culture to reflect NPRA's standards can still pose challenges to affected not-for-profit organizations—even those that are receptive to NPRA's message. In September 2015, the mainstream press reported that the Carnegie Hall board chair had advised its board that the Executive and Artistic Director was not providing full financial information regarding Carnegie Hall's operations and had entered into a related party transaction without first obtaining the board's approval as required by NPRA.[27] When the matter hit the press it identified serious disagreements within the board and brought unwanted attention to the organization. In response, the board engaged outside counsel to review the board chair's accusations. By November, Carnegie Hall reported that the review found no evidence that the Executive and Artistic Director had impeded its proper governance, but acknowledged the importance of the chair's concerns, particularly in the wake of NPRA.[28] However, the public nature of the dispute appeared to undermine the organization and resulted in the loss of a significant donor, i.e., the board chair, who resigned.[29]

V. Regulatory Guidance for Board Members

Recognizing that unpaid not-for-profit board members are frequently challenged to fulfill their oversight responsibilities, both state and federal regulators have proactively issued guidance expressing their opinions as to how boards can (and should) use their care, obedience and loyalty to oversee their organizations.

(a) Charities Bureau of the Office of the New York State Attorney General ("Charities Bureau")

On April 13, 2015, the Charities Bureau of the Office of the Attorney General (the "Charities Bureau") issued three publications, including *Conflicts of Interest Policies Under the Nonprofit Revitalization Act of 2013, Whistleblower Policies Under the Nonprofit Revitalization Act of 2013* and *Internal Controls and Financial Accountability for Not-For-Profit Boards*. These publications try to explain to individual board members NPRA's expectations and requirements for oversight of conflicts of interest, related party transactions and whistleblower policies, as well as the importance of board oversight of an institution's internal controls.[30] A month later, the Charities Bureau published an updated version of *Right from the Start: Responsibilities of Directors of Not-for-Profit Corporations* intended to more generally educate not-for-profit boards regarding their common law duties of care, loyalty and obedience.[31] The publication lists multiple items that an individual should understand both before becoming, and while serving as, a board member. These include the organization's charter documents (including its 1023 application for federal tax exemption) and mission, its finances (including its annual financial statements, budget and cash flows, and audit letters), programs and activities. They are also expected to review the organization's governmental filings and ensure regulatory filings, such as CHAR filings (which ADC missed), are timely, accurate and up to date. From an operational perspective, the Charities Bureau expects each board member to understand "the organizational chart and… the accountability structure of the organization." While many not-for-profit boards have frequently been financially focused, the Charities Bureau is saying that financial understanding is necessary but it alone is not sufficient to fulfill a board member's responsibilities.[32]

(b) Board Guidance from the Federal Government

NPRA's adoption signaled, with its emphasis on the disclosure of conflicts of interest and the independent review of related party transactions, the importance New

York places on board members fulfilling their duty of loyalty by placing the organization ahead of their personal interests. U.S. Deputy Attorney General Sally Quillian Yates made perhaps the strongest statement of any regulator regarding the expectations of a board member's duty of loyalty in her memorandum "Individual Accountability for Corporate Wrongdoing" (the "Yates Memo").[33] The memorandum directed United States Attorneys to focus on individual accountability under both civil and criminal statutes when confronted by corporate misconduct. Board members may understandably want to protect individuals who made decisions on behalf of an organization that becomes subject to a federal investigation. The subject individuals may be respected long-term directors, officers or employees and also may be friends with some board members. Yet the Yates Memo states that in order for a corporation subject to a federal civil or criminal investigation to receive any credit for cooperating with the government, the board may not, and will not be able to, protect individual officers and directors from potential liability. It must report all information regarding their activities to the involved U.S. Attorney. Indeed, the Yates Memo announced that the Department of Justice would no longer resolve cases without a plan intended to hold individual corporate actors accountable for their actions.[34] It makes clear the government's position that a director's compliance oversight responsibilities and duty of loyalty to the organization take precedence over any sense of loyalty or responsibility owed to a target individual.

A few months before the Yates Memo was issued, the Office of the Inspector General of the United States Department of Health and Human Services (the "HHS OIG"), in collaboration with the American Health Lawyer's Association (the "AHLA"), the Association of Healthcare Internal Auditors, and the Health Care Compliance Association, updated its educational resource for healthcare governing boards *Practical Guidance for Health Care Governing Boards on Compliance Oversight (the "Compliance Guidance")*. As with the previously issued guidance, the document was intended to help boards fulfill their duties of care, loyalty and obedience as related to corporate compliance oversight. The Compliance Guidance emphasized that boards are expected to ensure that "(1) a corporate information and reporting system exists and (2) the reporting system is adequate to assure the board that appropriate information relating to compliance with applicable laws will come to its attention timely and as a matter of course." In order to do so, the HHS OIG expects that boards will monitor changes in the organization's regulatory and operating environment, and use that information to assess the "scope and adequacy of the compliance program [and its implementation by corporate officers and employees] in light of the size and complexity of their organization…."[35] Key among its recommendations is that the board set up clear reporting lines of responsibility for the compliance function and become familiar with who has compliance responsibilities and how the reporting lines work so that it fully understands how the organization approaches regulatory risk and how the compliance function operates within its organization to address that risk.

"Understanding the organization's processes for identifying and addressing operational and financial risks and opportunities—as well as compliance risks—is essential in order for a board member to fulfill her common law duties."

VI. Conclusion

The Compliance Guidance can be read solely as a compliance resource. But doing so misses a critical educational opportunity for boards that reinforces lessons learned from the above-described situations. Quite simply, if a board wants to fulfill its duties and effectively govern its organization (including managing risk and achieving corporate compliance), it must be familiar with and understand its overall organization the operation and the discrete functions within the organization, as well as the individuals charged with its management. Deleting the word "compliance" from passages of the Compliance Guidance leads to an obvious conclusion: for an organization to be successful in its compliance and its operational endeavors, its board members "need to be fully engaged in their oversight responsibilities." Whether they are overseeing compliance (including related party transactions), finance, operations, fundraising, risk management, quality or any organizational function, board members need to receive that information "in a format sufficient to satisfy [their] interests or concerns [and] fit their capacity to review that information.… Regular internal reviews that provide a board with a snapshot of where the organization is, and where it may be going,…should produce better…results and higher quality services."[36] Understanding the organization's processes for identifying and addressing operational and financial risks and opportunities—as well as compliance risks—is essential in order for a board member to fulfill her common law duties.

In the post-NPRA New York environment regulators, both federal and state, have provided boards with guidance to help them with their jobs. This guidance, together with press reports, cases and other governmental action, have placed boards on notice that poor decision-making

will subject an organization to financial and reputational risk that threatens its ongoing viability. Additionally, conflicted loyalties will subject board members to individual financial risk and potential incarceration. Counsel needs to proactively and regularly remind board members of these risks by educating both the board, and management, on how to address organizational risks through greater board understanding of their organizations, their financial and other challenges, and the legal and operational environment in which they operate.

Endnotes

1. Chapter 549 of the Laws of 2013, as amended by Chapter 23 of the Laws of 2014 and Chapter 555 of the Laws of 2015. For a good summary of NPRA's provisions, see Mark Thomas, *The Nonprofit Revitalization Act of 2013*, 19 N.Y.St.B.A. Health L.J., Summer/Fall 2014, pp. 39 - 41. It is also worth noting that since NPRA's adoption, the legislature has adopted various clarifications to specific definitions and provisions, but while the revisions are notable in advising boards as to the content of their corporate documents and certain deliberations, this article takes a more general approach to NPRA's provisions, and does not detail the revisions contained within the amendments. See Chapter 23 of the Laws of 2014 and Chapter 555 of the Laws of 2015.
2. Press Release, New York State Attorney General Eric Schneiderman, *A.G. Schneiderman's Nonprofit Revitalization Act Signed Into Law,* December 19, 2013, http://www.ag.ny.gov/press-release/ag-schneidermans-nonprofit-revitalization-act-signed-law.
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4. Aaron Elstein, *Rev. Calvin Butts seeks salvation for the church-based organization that resurrected Harlem*, Crain's New York Business, Nov. 22, 2015, http://www.crainsnewyork.com/article/20151122/REAL_ESTATE/311229998/rev-calvin-butts-seeks-salvation-for-the-church-based-organization-that-resurrected-harlem.
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6. Juan Gonzalez, *Housing and social services arm of Harlem's Abyssinian Baptist Church cut off from $3.1M in city contracts due to overdue tax filings,* N.Y. Daily News, September 30, 2015, http://www.nydailynews.com/new-york/harlem-housing-developer-cut-3-1m-nyc-contracts-article-1.2379319.
7. Juan Gonzalez, *NY attorney general probes financially troubled Harlem nonprofit*, N.Y. Daily News, Nov. 17, 2015, http://www.nydailynews.com/new-york/ny-attorney-general-probes-financially-troubled-nonprofit-article-1.2438520.
8. *See supra*, note 4.
9. When working with their clients, counsel should remember that failure to submit required filings is not a risk exclusive to financially strapped clients. Even seemingly well-financed organizations, with access to highly competent counsel and high profile board members, may fail to submit the basic "CHAR" filings required to fundraise within the New York, and may thus face reputational costs from disclosure of such failings. On September 30, 2016, the A.G. announced that the private foundation of Republican Presidential Nominee Donald J. Trump was to immediately cease fundraising activities because it was "in violation of section 172 of Article 7-A New York's Executive Law" having solicited contributions in New York even though it had not registered with the Charities Bureau, had not submitted required annual financial reports, and had not submitted annual audits. Press Release, New York State Attorney General Eric Schneiderman, *New York Attorney General's Office Issues Notice Of Violation Directing Trump Foundation To Cease And Desist New York Solicitations,* October 3, 2016, http://www.ag.ny.gov/press-release/new-york-attorney-generals-office-issues-notice-violation-directing-trump-foundation. The violations were reported both locally and nationwide by a variety of media outlets while Mr. Trump was campaigning. See, e.g., Michael Virtanen, AP, *Attorney General to Trump Foundation: Stop Fundraising in New York*, Wash. Post, October 3, 2016, https://www.washingtonpost.com/politics/attorney-general-to-trump-foundation-stop-fundraising-in-ny/2016/10/03/3e721510-8990-11e6-8cdc-4fbb1973b506_story.html, and see Glenn Blain, *AG Eric Schneiderman orders Donald Trump foundation to cease fundraising in N.Y.,* N.Y. Daily News, Oct. 3, 2016, http://www.nydailynews.com/news/politics/schneiderman-orders-trump-foundation-cease-fundraising-n-y-article-1.2815824. The decision to order the Trump Foundation to cease fundraising appears to have followed from a decision by the AG to investigate the Trump Foundation after allegations that it had donated to a Florida politician's campaign and had purchased a painting that was housed at Trump's private club, Mar-a-Lago. See, e.g., Ken Lovett and Adam Edelman, *AG Eric Schneiderman to investigate Donald J. Trump Foundation as House Dems call for federal probe, N.Y. Daily News,* Sept. 13, 2016, http://www.nydailynews.com/news/politics/dems-call-federal-probe-trump-charity-donation-fl-ag-article-1.2790975.
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15. Josh Nathan-Kazis, *FEGS Execs Got Fat Payouts as Bankruptcy Loomed Amid Rampant Mismanagement*, The Forward, September 30, 2015, http://forward.com/news/national/321474/fegs-execs-got-payouts-while-staffers-struggled-and-services-suffered/.
16. See, e.g., Josh Nathan-Kazis, *Prosecutors Interviewed FEGS Board Members and Former Staff*, The Forward, May 13, 2016, http://forward.com/news/340646/prosecutors-interviewed-fegs-board-members-and-former-staff/.
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21. *Id.* at 18, 14, and 17.
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32. *Id*. at p. 2 and 3.
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Government Education Loan Repayment Programs for Primary-Care Health Professionals

By Albert Feuer

Many physicians are burdened with substantial educational loans when they graduate from medical school. The average education indebtedness for a graduate of an American medical school is more than $180,000, and 45 percent have more than $200,000 of debt.[1] Physicians and other health care professionals providing care in communities that have shortages of primary-care practitioners, however, are eligible for government loan forgiveness and repayment programs.[2]

I. Introduction

This article will summarize the terms of the three major government loan repayment programs available to New York primary-care health professionals:[3]

(1) the National Health Service Corps ("NHSC") Loan Repayment Program;

(2) the National Nurse Corps ("National Nurses") Loan Repayment Program; and

(3) the New York State Regents Physician ("NY Physicians") Loan Forgiveness Award Program.[4]

This article will also discuss the extent, if any, to which primary-care health professionals who participate in such programs are taxable on these program payments. Subjecting such participants to income tax and employment taxes substantially reduces the value of these benefits, and their effectiveness at increasing access to primary care.

II. The Three Major Government Loan Repayment Programs

A. National Health Service Corps (NHSC) Loan Repayment Program

The National Health Service Corps ("NHSC") Loan Repayment Program was established in 1987.[5] The program is described in detail in a federal publication ("NHSC Loan Guidance"),[6] and granted 2,934 new awards worth $125.9 million in 2015.[7] Participation is limited to health care providers with a degree in medicine, osteopathic medicine, dentistry, or another health profession, or an appropriate degree from a graduate program of behavioral and mental health, or those certified as a nurse midwife, nurse practitioner, or physician assistant.[8]

The NHSC Loan Repayment Program requires participants to provide "primary health services in a health professional shortage area" of the United States.[9] These areas include facilities throughout the country. Numerous facilities are in New York State, including many in New York City.[10] Recipients of these awards may not be forced to relocate to fulfill their service commitments, unlike the recipients of NHSC scholarships.[11] The NHSC Scholarship Program[12] was introduced more than ten years earlier and imposes virtually identical statutory service obligations to retain the NHSC award.[13] Participants who agree to work two years in such an area are entitled to up to $50,000 in loan forgiveness payments for undergraduate or graduate education loans.[14] The service commitments, unlike those made with NHSC scholarships, are made at the end rather than the start of an applicant's professional education. The application requires applicants to present detailed information about each of their outstanding education loans.[15] The applicable loans are not limited to loans by schools, tax-exempt entities or by governments, but include commercial loans.[16] The general rule for tax-exempt scholarships is that such awards may only be used for qualified educational expenses, such as tuition, but not for other expenses, such as room and board.[17] The NHSC loan program, however, also applies to loans for reasonable living expenses.[18] An award, which may not exceed $50,000, is paid to the awardee in a lump sum at the start of the service period.[19]

If the awardee does not complete the two-year service commitment, a portion of the award must be repaid together with the highest interest rate permitted by law, plus the product of $7,500 and the number of months of obligated service that were not completed by the individual, unless performance would be impossible or would involve an extreme hardship.[20] No penalties are imposed if the awardee does not reduce the loan balance or if the awardee does not seek another award.[21] This may reflect the fact that the governing statute requires that payments be made to the participant's creditor,[22] even though, as described above, the payments are made to the participant. However, participants may not obtain an additional $50,000 continuation award in exchange for an additional two-year commitment unless they show that they have fulfilled their service obligation and have reduced the outstanding balance on the total of their undergraduate and graduate loans by at least $50,000 after receiving the initial award.[23]

The NHSC Loan Guidance describes the award as "exempt from Federal income and employment taxes."[24]

B. National Nurse Corps (National Nurses) Loan Repayment Program

The National Nurse Corps ("National Nurses") Loan Repayment Program was established in 1992.[25] The program is described in detail in a federal publication (*National Nurses Guidance*),[26] and granted 590 new awards worth $39.6 million in 2015.[27] Benefits are limited to those

with nursing degrees, which, unlike the NHSC program, need not be a graduate degree.[28]

The program requires participants to serve in the United States "at a healthcare facility with a critical shortage of nurses" or as a nursing school faculty member.[29] These areas include facilities throughout the country. Numerous facilities are in New York State, including many in New York City.[30] A participant who agrees to work two years in such a position is entitled to forgiveness payments of 60 percent of his or her nursing education loans.[31] Applicants must present detailed information about each of their outstanding education loans.[32] The applicable loans are not limited to loans by schools, tax-exempt entities or by governments, but include commercial loans.[33] Like the NHSC Loan Repayment Program, this program also applies to loans for reasonable living expenses.[34] Award payments are made to the participant in a pro rata fashion each month of the two-year period.[35]

If the participant does not complete the two-year service commitment, an appropriate portion of the award must be repaid with interest, unless performance would be impossible or involve an extreme hardship.[36] Unlike the NHSC Loan Repayment Program, no additional penalties are imposed in case of a service breach. Like the NHSC program, no penalties are imposed if the participant does not reduce the loan balance.[37] This may again reflect the fact that the governing statute requires that payments be made to the participant's creditor.[38] However, a participant may not obtain an additional continuation award of forgiveness payments of 20 percent of his or her initial nursing education loan balance in exchange for an additional one year commitment unless he or she shows that he or she has fulfilled his or her service obligation and reduced the outstanding balance on his or her nursing school loans by at least the initial 60 percent award minus the tax withholdings on those payments after receiving the payments.[39]

The *National Nurses Guidance* describes the award as "subject to Federal taxes."[40] The federal government "will withhold Federal income tax and Federal Insurance Contributions Act (FICA) tax (Social Security and Medicare) from a participant's award."[41] Thus, the award payments are treated as though the federal government is acting on behalf of the participant's actual employer to supplement his or her wages. Those employers must regularly certify that participants are fulfilling their service commitment by remaining their employees.[42]

C. New York State Regents Physician (NY Physicians) Loan Repayment Program

The New York State Regents Physician Loan Forgiveness Award Program ("NY Physicians Loan Repayment Program") is set forth in a New York statute[43] and a New York regulation.[44] The program is described in detail in a New York State publication (*NY Physicians Guidance*).[45] Although the program is called a loan forgiveness program, as described below, the program forgives none of the applicant's education loans outstanding when the applicant's award is made. The program was established in 1985.[46] At least eighty awards are made each year.[47] Benefits are limited to those licensed to practice medicine.[48]

The program requires participants to "practice medicine in an area of New York State designated by the regents as having a shortage of physicians."[49] These areas include facilities throughout the state including many in New York City. Participants who agree to work two years in such an area are entitled to up to $20,000 in loan forgiveness payments for undergraduate or graduate education loans.[50] The application does not require applicants to present any information about their outstanding education loans, although the *NY Physicians Guidance* states that "[t]he amount of the award received will be based upon the amount of undergraduate and medical school loans and loan interest expense incurred by the physician."[51] Nor does the application, the statute, or the regulation define undergraduate and medical school loans. However, the president of the New York State Higher Education Services Corporation is required to verify the approved applicants' "(i) eligibility; and (ii) total undergraduate and medical school student expense before the awards are approved."[52] The participant is paid up to $10,000 at the start of each of the two years of the service period.[53]

If the participant does not complete the two-year service commitment, twice the appropriate portion of the award must be repaid with interest, unless performance would be impossible or involve an extreme hardship.[54] By taking twice the appropriate portion, these remedies, like those for a breach of the NHSC Loan Repayment Program service obligation, include a substantial penalty. Like the NHSC program, no penalties are imposed if the participant does not reduce the loan balance.[55] Participants who have fulfilled their contract obligations may obtain an additional $20,000 continuation award in exchange for an additional two-year commitment.[56] Applicants for these continuation awards, unlike for the two federal continuation awards, need not show that they reduced the outstanding balance on their undergraduate or graduate loans by any amount after receiving the initial award.[57]

The *NY Physicians Guidance* recommends that participants "contact their tax advisor for possible tax implications of these awards."[58] It also provides that New York issues participants a Form 1099-MISC with respect to each annual $10,000 annual payment.[59] The New York State Comptroller characterizes the award as other income in item 3 of the Form 1099-MISC, and will not provide the Internal Revenue Service (the "Service") with any further information about the award.[60] In contrast, as discussed above, the federal government treats National Nurse Loan Repayment Program payments as W-2 compensa-

tion made in concert with the compensation paid to the program participant by his or her employer.

III. Tax Treatment of Government Loan Forgiveness and Repayment Programs

Traditionally, a taxpayer's gross income, the starting point for determining the taxpayer's taxable income, includes all cash payments and reductions of indebtedness, such as the forgiveness of loans. Provisions were added to the tax law in the 1980s to exclude certain reductions in education loans. Further provisions were added in the 2000s to exclude payments under certain government loan repayment programs. By the 2000s, substantial discrepancies arose (1) between the operations of the NHSC Loan Repayment Program and its governing law, and (2) between the operation of the NY Physicians Loan Repayment Program and the applicable tax rules.

A. The Original Treatment by the Internal Revenue Code of 1954

As originally adopted, the Internal Revenue Code of 1954 included in a taxpayer's gross income the amount of any loan forgiveness, *i.e.*, a reduction of indebtedness.[61] Section 108 excluded some reductions of indebtedness from gross income, but only those for indebtedness incurred by corporations or in the course of trade of business. The scholarship exclusion from gross income was found inapplicable to the reduction of school debt. In particular, the Internal Revenue Service ("IRS") concluded in a 1956 private letter ruling that a 20 percent reduction of an individual's medical school indebtedness to a state by the same state in exchange for the recipient working in a designated community was not a scholarship that was excluded from gross income.[62] Moreover, the Supreme Court in 1969, in *Bingler v. Johnson*,[63] upheld the IRS regulations that tax-free scholarships may not require a substantial *quid pro quo* from the awardee. Thus, the IRS held, in Rev. Rul. 73-256, that an award to pay the awardee's costs of attending medical school, which required the awardee to work after graduation for limited periods in rural areas, is not a scholarship that is excluded from gross income.[64]

B. The 1984 Addition of an Exclusion for the Discharge of Student Loans for Those Who Perform Public Service

In 1984, the Internal Revenue Code of 1954 was amended to provide that gross income does not include the discharge of a student loan made by a government agency or an educational organization if the loan provided the loan would be discharged "if the individual worked for a certain period of time in certain professions for any of a broad class of employers."[65] Student loans were limited to loans that assisted the recipient to attend a specified educational organization.[66] This was effective for discharges on or after January 1, 1983.[67]

If there had been no similar change to the scholarship rules, there would be better tax treatment for awards that were forgivable loans in exchange for the preferred services than for awards that were forfeitable if the same preferred services were not performed. No tax would be imposed when the loan was made, and no tax would be imposed when the loan was forgiven. In contrast, tax would be imposed when the scholarship was made, although there may have been a later deduction for any scholarship repayments under the claim of right doctrine set forth in Section 1341 of the Code of 1954. Thus, the worst tax treatment would be for a scholarship awardee who performed the preferred services and would be taxable on receiving the scholarship, but would never get an offsetting deduction. However, the scholarship changes were far more limited. In 1980, a federal award that required service as a federal employee was exempted from the usual rules providing for taxability if service was required to retain the scholarship.[68] In 2001, this rule was replaced by an exemption for the NHSC Scholarships and a similar Armed Forces health professions program.[69]

The Service held that under this loan repayment section there is an exclusion from income for reductions by law schools of the school loans for graduates "working in a law-related public service position or other endeavor for a required minimum period."[70] Similarly, both the 1956 private letter ruling and the 1973 Revenue Ruling finding taxability for reductions of indebtedness for physicians, would be reversed for reductions made after 1982.

C. The Adoption of the NY Physicians Loan Forgiveness Award Program, the NHSC Loan Repayment Program, National Nurses Loan Repayment Program When Their Benefits Were Subject to Income Tax

The NY Physicians Loan Forgiveness Award Program was established in 1985 with the expectation of generating a better incentive for physicians to practice in physician shortage areas than medical scholarships that were forfeited if the graduates did not practice in the same shortage areas.[71] The legislation doing so contained the following provisions:

> The legislature finds that the existing regents physician shortage scholarship requires students to indicate their willingness to practice in shortage areas several years prior to graduation. In the intervening years, students elect to drop out of school or repay the state, thereby diminishing the number of physicians who must serve in these shortage areas.
>
> The legislature finds and declares that a program available to medical school graduates which would assist in the repayment of education loans for service in physician shortage areas would provide

> an immediate solution to the maldistribution problem. . .
>
> Therefore, the purpose of this legislation is: . . .
>
> (2) to increase the number of physicians practicing in areas of New York state designated by the regents as having a shortage of physicians.[72]

The program is called a loan forgiveness program, although the program does not forgive any education loans. Instead, the participant is given funds to repay such loans. The program may be described as providing a new loan which is forgiven if a promised period of service is completed. However, the new loan is not used to pay education expenses when incurred. Thus, the loan does not qualify as a student loan whose reduction of indebtedness is excluded from income under the provisions of Section 108 described above. In 2006, in *Moloney v. C.I.R.*,[73] the Tax Court held that a government payment of some law school education loans of an attorney who agreed to work for another government agency, under a similar loan repayment program, must be included in the lawyer's gross income. In that case, the government agency award letter described the award as included in the participant's taxable income.[74] The timing of the inclusion was not at issue therein.

One may argue that the NY Physicians Loan Forgiveness awards are included in gross income when received, rather than when they are no longer subject to forfeiture, under traditional compensation principles.[75] As discussed above, this is how New York State treats such awards. For example, in 2013, a Washington federal district court in *The Vancouver Clinic, Inc. v. U.S.*,[76] concluded that a clinic that requires the newly hired physician to work for the clinic for five years, in exchange for two advances of funds to the physician during the physician's first and second years of employment, must treat such advances as W-2 income in the year the advance was paid.[77]

When the Internal Revenue Code of 1954 was replaced by the current Internal Revenue Code of 1986 (the "Code"), no change was made in either the provisions of Section 61 for the inclusion in income of reductions in the taxpayer's indebtedness, or the exclusions in Section 108 for reductions in student debt provisions.

The NHSC Loan Repayment Program was established in 1987.[78] Like the NY Physicians Loan Repayment Program, it seemed to be an attempt to provide better incentives for health care professionals to work in underserved areas than a pre-existing scholarship program, the NHSC Scholarship Program, whose grants were forfeited if a service commitment was not fulfilled. Unlike the New York statute, the federal statute provided that payments are not made to the participant, but to the participant's lenders.[79] If the contracted services are not performed, the federal government may recover the award payments and damages.[80] However, the payments are not used to pay education expenses when incurred, but money borrowed to pay such expenses. Thus, such awards do not qualify as a reduction of indebtedness for a scholarship loan that is excluded from gross income. The program, as originally enacted, therefore provided that if a participant is subjected to an income-tax liability as a result of the award, the federal government may, but need not, reimburse the participant for such tax liability.[81]

"One may argue that the NY Physicians Loan Forgiveness awards are included in gross income when received, rather than when they are no longer subject to forfeiture, under traditional compensation principles."

On April 3, 1989, the Department of Health and Human Services issued interim regulations governing the NHSC Loan Repayment Program.[82] Two points were clarified.

First, program payments that may be made by

> the Secretary in advance of service will be limited to one month or less. The Secretary may establish different levels of annual loan repayment to encourage Program participants to serve in a manner which is in the best interest of the Loan Repayment Program.[83]

Second, the voluntary reimbursements to a participant for income-tax liability resulting from such an award will be made only under unusual circumstances and the reimbursements may not exceed 20 percent of the award.[84]

The NHSC Loan Repayment Program was made more attractive to participants by the National Health Service Corps Revitalization Amendments of 1990.[85] In addition to increasing the maximum amount of annual loan repayments, the amendment provided that income-tax reimbursement payments of at least 39 percent of the award would be added to the awards for contracts entered into after October 1, 1990.[86] Thus, participants would no longer have to be concerned that income taxes

would substantially reduce the ability of participants to use the award to repay their education loans.

In 1992 the last substantive change was made to the regulations governing the NHSC Loan Repayment Program.[87] There was no change with respect to 42 C.F.R. § 65.25 (c), which describes the program's tax reimbursement provisions even though, as described above, those provisions were changed substantively in 1990. There was, however, a significant change in the payment provisions. The sentence limiting advance award payments to one month in advance of the services was deleted.[88] The prior practice had been to make no advance payments, but instead to provide quarterly payments after the completion of each quarter of service.[89] The change was intended to make the program more competitive with employers who offered physicians large signing bonuses that could be immediately used to reduce their outstanding debt by permitting a lump sum payment at the start of the participant's service.[90] There was, however, no change in the provisions of 42 C.F.R. § 65.25 (a), providing that payments are made to the lenders of the participant rather than the participant.

In 1992, the National Nurses Corps Loan Repayment Program was established.[91] The statute provides that payments are not made to the participant, but to the participant's lenders.[92] As with the NHSC Loan Repayment Program, these awards did not then qualify as a reduction of indebtedness for a scholarship loan that is excluded from gross income. The statute did not provide for any tax reimbursements. No regulations have been issued with respect to the substantive terms of this statute. It is thus unclear why the payments are now being made directly to the participants, even if, unlike the NHSC program, the loan payments are being verified, as discussed above.

In 1992, the Code was amended to provide an exception for NHSC Scholarships from the rule that scholarships that required a substantial quid pro quo were not exempt from income.[93] Scholarships under similar federal programs, which are forfeited if postgraduate service commitments are not fulfilled, continue to be included in the participant's gross income.[94]

D. The 2004 Addition of an Exclusion for Payments under the NHSC Loan Repayment Program

In 2004, the Code was amended to exempt NHSC Loan Repayment Program awards from federal taxes. In particular, the following was added as a Code Section 108(f)(4) exclusion:

> In the case of an individual, gross income shall not include any amount received under section 338B(g) of the Public Health Service.[95]

Moreover, such amounts are also excluded from income for the purpose of all federal employment taxes.[96] Both changes were made for taxable years beginning after December 31, 2003.[97]

There were four notable features about these 2004 changes:

> The changes did not affect other federal loan repayment programs, such as the National Nurses Loan Repayment Program, whose benefits were still subject to income tax and employment taxes as described above.
>
> The changes did not affect other state loan repayment programs, such as the New York Physicians Loan Repayment Program, whose benefits were still subject to income tax and employment taxes.[98]
>
> The new tax provision applies to any payments under the NHSC Loan Repayment Program, not merely to payments to the creditors of the participant. However, the NHSC Loan Repayment Program statute limits payments to payments to creditors.
>
> No substantive changes are made to the public health statutes or regulations that govern the NHSC Loan Repayment Program. Thus, the provisions requiring income-tax reimbursements discussed above remain in place even though no tax liability is being imposed unless the payments are taxable for not being consistent with the governing statute.

Nevertheless, without any further changes to the statute or the regulations governing NHSC Loan Repayment Program, three major changes appear to have been made to the NHSC program which are apparent in the current *NHSC Loan Guidance*:

> No mention is made of the statutory tax reimbursement provision. Instead, the Guide correctly declares "NHSC Loan Repayment funds are exempt from Federal income and employment taxes."[99] It is not clear that such a statement absolves the federal government from its obligation to make the extant reimbursement payments.
>
> Awards are no longer made to the participant's creditors, but to the participant.[100] In a set of frequently answered questions, the second response is that "Payments are made to the bank account of record, which you [the participant] submitted online during the application process."[101]

> Despite the statutory requirement that the federal government make the loan payments on behalf of the participant,[102] a participant is not required to verify having so used the award.[103]

Although the latter two discrepancies make the plan a more effective tool for recruiting and retaining primary-care providers,[104] there seems to be no legal basis for their implementation. On the other hand, the legislative history of the 2004 provisions shows that Congress knew before it passed that legislation that the NHSC payments were being made to the participants, who would perform the desired medical services, rather than to their creditors.[105] For example, the Joint Committee of Taxation described the law before the enactment of the 2004 provisions as follows:

> The National Health Service Corps Loan Repayment Program (the "NHSC Loan Repayment Program") provides education loan repayments to participants on condition that the participants provide certain services. *The recipient of the loan repayment is obligated to provide medical services* in a geographic area identified by the Public Health Service as having a shortage of health-care professionals.[106]

E. The 2004 Addition of an Exclusion for Payments Under State Loan Repayment Programs That Address Health Professional Shortages

In 2010, the Code was amended to exempt awards from state programs, such as the New York Physicians Loan Repayment Program, from federal taxes. In particular, the Code Section 108(f)(4) would also exclude from gross income amounts received:

> under any other State loan repayment or loan forgiveness program that is intended to provide for the increased availability of health-care services in underserved or health professional shortage areas (as determined by such State).[107]

The change was effective for taxable years beginning after December 31, 2008.[108]

There were four notable features about this 2010 change:

> The provision did not affect other federal loan repayment programs, such as the National Nurses Loan Repayment Program, whose benefits were still subject to income tax, and apparently employment taxes.
>
> The provision does not require that payments be made to the participant's creditors, but applies to any payments under a state loan repayment program, such as the New York payments which are made to the participant.
>
> The provision does not restrict the kind of loan that may be forgiven or repaid by the state programs. Thus, loans need not have any educational connection.
>
> There there were no subsequent substantive changes to the statutes or regulations governing New York Physicians Loan Repayment Program.

Two advice memoranda from the Office of the Chief Counsel of the Internal Revenue Service discussed the significance of this additional exclusion from gross income in a manner that suggests that the IRS may seek to narrow the exclusion by adding limits that are not part of the Code.[109]

In C.C.A. 201147001 (Aug. 15, 2011), the IRS held that the new exclusion applied to a program whose goal "is increasing medical and dental services access to target Group M populations, not student loan repayment." In this case, loan repayment funds were provided after an awardee provided a year of satisfactory service to Group M populations. The ruling did not clarify who received the loan repayments, although there is a statement that loan repayments were "limited to educational loans that were made for undergraduate, graduate, medical or dental education at an accredited institution in the United States." The NHSC Loan Repayment Program is available to foreign educated physicians. The Code does not prevent applicable state programs from doing the same. Furthermore, the new Code provision does not limit the kind of loan to be repaid. The NHSC Loan Repayment Program and the New York Physicians Loan Repayment Program also make payments before the provision of the desired health care services.

In C.C.A. 201104032 (Sept 24, 2010), the IRS reached the obvious conclusion that the exclusion does not apply to payments of multiples of the in-state tuition of a State's medical school to encourage health professionals to perform a period of service in a designated eligible service area. The IRS correctly observed this was not a loan repayment program. However, the IRS relied on two factors: (1) the plan participants need not have outstanding student or other types of loans or indebtedness to participate, and (2) the plan participants were not required to repay any debt. However, if the second factor were a disqualifying condition for a loan repayment program, the NHSC Loan Repayment Program payments would not qualify for the exclusion. Furthermore, as discussed above the new Code provision does not require that a repayment program provide that the participants use the funds to repay loans, but merely that the payments be made pursuant to a loan repayment program to provide

for the increased availability of health care services in underserved or health professional shortage areas.

There is little question that the New York Physicians Loan Repayment Program conforms to the post-2008 statutory exclusion. The New York legislature explicitly declared that the purpose of the program was "to increase the number of physicians practicing in areas of New York state designated by the regents as having a shortage of physicians."[110] Thus, the requisite intention is present. Program payments are only made to those professionals who New York State has found to have sufficient outstanding undergraduate and graduate loans. Thus, the program is a loan repayment program. Consequently, program payments are not subject to federal income tax or federal employment taxes.

Thus, there is no reason why New York State has continued to report program payments as miscellaneous income on IRS Form 1099-MISC for payment on or after the 2009 effective date of this provision. However, the New York Physicians Loan Repayment Program did not change its operations in response to the enactment of this legislation. The *NY Physicians Guidance* for 2007 and 2016 both provide that:

> Note: Physicians who are awarded the Regents Physician Loan Forgiveness Award are provided with IRS Form 1099 (miscellaneous) for their tax records. Award recipients should contact their tax advisor for possible tax implications of these awards.[111]

The 1099-MISC filings continue to have the same effect. The amounts are reported to the IRS as miscellaneous income without any explanation by New York State. Most tax preparers will simply include the $10,000 amount as miscellaneous income on the participant's tax return. The more knowledgeable preparers will include an explanation of why the amount is excluded, which will add to the cost of the return and may not prevent questions about the exclusion. The Internal Revenue Service often presumes that the report is correct and seeks to tax the award. Unless the participant has a knowledgeable tax advisor, who is willing and able to correspond with the IRS, which again costs money, the participant will be forced to pay Federal and state income tax on the amount.

IV. Conclusions

The National Health Service Corps ("NHSC") Loan Repayment Program provides tax-free awards up to $50,000 to help primary care health care professionals with graduate training pay their outstanding educational loans in exchange for a two-year commitment to provide care in underserved areas, which include facilities throughout the country including New York State. There are, however, significant penalties if the commitment is not fulfilled. It would be advisable for Congress to amend the statute so that it is consistent with the program operations, namely that payments are made to participants, not to their creditors. There will then be no question that the plan awards are tax-free because they are consistent with the governing statute and the tax reimbursement provisions may be deleted. Congress can decide if it wants participants to show that loan balances have been reduced by the amount of the program payments during the service period. No such reporting now seems to be required in practice.

The National Nurse Corps Loan Repayment Program provides taxable awards to help nurses pay a substantial part of their outstanding nursing educational loans in exchange for a two-year commitment to provide care in underserved areas, which include facilities throughout the country including New York City. It would be advisable for Congress to amend the statute so that it is consistent with the program operations, namely that payments are made to participants, not to their creditors. Congress can decide if it wants participants to show that loan balances have been reduced by the amount of the program payments. Such reporting seems to be required in practice. Congress can also decide whether such awards should receive the same tax-free treatment as the NHSC Repayment awards.

The New York State Regents Physician Loan Forgiveness Award Program provides tax-free $20,000 awards to help physicians pay their outstanding educational loans in exchange for a two-year commitment to provide care in underserved areas, which include facilities throughout New York State including New York City. There are, however, significant penalties if the commitment is not fulfilled. It is advisable for New York State to

> rename the program as a loan repayment program to avoid any confusion about the program's terms and operation for both potential applicants and taxing authorities.
>
> request and obtain a ruling that program payments are not subject to federal income or employment tax, so that no post-2008 participants will have to pay any federal or employment taxes on such awards.
>
> adjust the award application to better resemble the corresponding federal applications, which define the kinds of loans that may be repaid with its award, and require applicants to list their outstanding loans. This would make it more likely that applications are completed consistently, accurately and are easy to verify by New York State.

consider whether it is appropriate to follow the federal model and adopt similar tax-free loan repayment programs for non-physicians, such as dentists, nurses, or mental health professionals.

In short, it is advisable for the federal government to conform the law to how it operates its loan repayment programs, and to consider whether all the repayments should be tax-exempt. Similarly, it is advisable for the federal government to consider the extent to which the tax-free treatment of scholarship programs should be consistent with the treatment of the similar loan repayment programs that try to encourage health care professionals to practice in underserved areas. It is also advisable for New York State to conform the operations of its loan repayment programs to the current federal tax laws, and to consider whether it wishes to assist a broader set of health care professionals than physicians.

Endnotes

1. Medical Student Education: Debt, Costs, and Loan Repayment Fact Card, AAMC (Oct. 2015), available at https://aamc-orange.global.ssl.fastly.net/production/media/filer_public/85/46/8546295b-76bf-4dd5-bd34-0e0e3daf1bc2/2015_debt_fact_card.pdf (last visited November 7, 2016).
2. *See generally* Jimmy Karnezis, Physician Loan Repayment Guide (May 24, 2016) (describing many federal and state loan repayment programs for physicians), available at https://www.credible.com/blog/physician-loan-repayment-guide/ (last visited November 7, 2016) and Alexandra Hegji, David P. Smole, and Elayne J. Heisler, *Federal Student Loan Forgiveness and Loan Repayment Program*, Cong. Res. Serv. Report. R43571 (July 28, 2016) (describing the federal programs and their history), available at https://www.fas.org/sgp/crs/misc/R43571.pdf (last visited November 7, 2016). *But see id.*, at 25-27 (describing the debate about the effectiveness of loan forgiveness and repayment programs).
3. There are also much smaller federal loan repayment programs for medical students or health professions faculty. *See generally* National Health Service Corps Students to Service Loan Repayment Program FY 2017Application and Program Guidance (August 2016), available at http://nhsc.hrsa.gov/loanrepayment/studentstoserviceprogram/applicationguidance.pdf (last visited November 7, 2016), and Faculty Loan Repayment Program Fiscal Year 2016 Application & Program Guidance (May 2016), available at http://www.hrsa.gov/loanscholarships/repayment/Faculty/guidance.pdf (last visited November 7, 2016). *Cf.* Ariha Setalvad, *4 Things You Need to Know About Employer Student Loan Repayment*, DailyWorth, March 23, 2016 (discussing employer student loan repayment benefits, including their tax treatment and growing popularity), available at https://www.dailyworth.com/posts/4228-learn-about-employer-student-loan-repayment-setalvad (last visited November 7, 2016).
4. Another available program, but not discussed in this article, is the Public Service Loan Forgiveness (PSLF) Program, whose benefits, the forgiveness of "Direct Loans" that are unpaid after 10 years of payments while engaged in public service, do not become available until 2017. *See generally Public Service Loan Forgiveness: Questions and Answers for Federal Student Loan Borrowers*, U. S. Dept. Ed. (December 2015), available at https://studentaid.ed.gov/sa/sites/default/files/public-service-loan-forgiveness-common-questions.pdf (last visited November 7, 2016).
5. Public Health Service Amendments of 1987, P.L. No. 100-177 §§ 201-05, 101 STAT 986, 992-1003 (1987) set forth the program in 42 U.S.C. § 254L-1 (2016).
6. *See National Health Service Corps Loan Repayment Program Full- & Half-Time Service Opportunities Fiscal Year 2016 Application & Program Guidance January 2016*, U.S. Dept. Health & Human Services, Health Resources and Services Administration ("NHSC Loan Guidance"), available at http://nhsc.hrsa.gov/loanrepayment/lrpapplicationguidance.pdf (last visited September 28, 2016) and The National Health Service Corps: An Introduction (June 26, 2014) U.S. Dept. Health & Human Services, Health Resources and Services Administration, available at https://www.apa.org/careers/early-career/financial/national-health-service.pdf (last visited September 28, 2016). Many of the program terms are set forth in 42 C.F.R. §§ 62.21-.29.
7. *See* HHS Awards More than $240 Million to Expand the Primary-care Workforce, HRSA Press Office (Oct 15, 2015) (it is not clear whether this amount includes continuation awards), available at http://www.hhs.gov/about/news/2015/10/14/hhs-awards-more-240-million-expand-primary-care-workforce.html (last visited September 28, 2016).
8. 42 U.S.C. § 254L-1(b).
9. 42 U.S.C. § 254L-1(f)(1)(B)(iv).
10. *See generally* https://nhscjobs.hrsa.gov/external/search/index.seam (last visited September 28, 2016).
11. *Cf.* NHSC Loan Guidance, *supra* note 6 and National Health Service Corps Scholarship Program School Year 2016-2017 Application & Program Guidance (March 2016), U.S. Dept. Health & Human Services, Health Resources and Services Administration ("NHSC Scholarship Guidance"), available at https://www.nhsc.hrsa.gov/downloads/spapplicationguide.pdf (last visited September 28, 2016). The latter warns that recipients may be forced to relocate to fulfill NHSC assignments, *id.*, at 5 and 23, whereas the former describes how applicants are required to find positions at NHSC approved sites.
12. *See generally* NHSC Scholarship Guidance, *supra* note 11.
13. Pub. L. No. 94-484 Title IV, § 408(b)(1), 90 Stat. 2243, 2281 (1976).
14. *Cf.* 42 U.S.C. § 254L-1(f)(B)(5) (loan repayment awards) and 42 U.S.C. § 254L-1(g)(2)(A) (scholarship awards).
15. NHSC Loan Guidance, *supra* note 6 at 34-35.
16. 42 U.S.C. § 254L-1(g)(1).
17. *See generally* Section 117 of the Internal Revenue Code of 1986 (the "Code") and *Tax Benefits for Education for Use in Preparing 2015 Returns*, IRS Publication 970 at 5-8 (Jan. 29, 2016), available at https://www.irs.gov/pub/irs-pdf/p970.pdf (last visited September 28, 2016).
18. 42 U.S.C. § 254L-1(g)(1)(C).
19. NHSC Loan Repayment Program, U.S. Dept. Health & Human Services, Health Resources and Services Administration, available at http://nhsc.hrsa.gov/loanrepayment/loanrepaymentprogram.html (last visited September 28, 2016).
20. 42 U.S.C. § 254O(c)(1) and NHSC Loan Guidance, *supra* note 6, at 29-31.
21. NHSC Loan Guidance, *supra* note 6, at 30-32.
22. 42 U.S.C. § 254L-1(g)(1).
23. *Id*. at 36.
24. *Id*. at 4.
25. Health Professions Education Extension Amendments of 1992, Pub. L. No. 102-108 § 211(a)(3), 106 Stat. 1992, 2078-79 (1992) set forth the program in 42 U.S.C. §§ 297n (b)-(d).
26. *See NURSE Corps Loan Repayment Program Fiscal Year 2016 Application and Program Guidance January 2016*, U.S. Dept. Health & Human Services, Health Resources and Services Administration (the "National Nurses Guidance"), available at http://www.hrsa.gov/loanscholarships/repayment/nursing/guidance.pdf (last visited September 28, 2016).

27. *See* HHS Awards More than $240 Million to Expand the Primary-Care Workforce, HRSA Press Office (Oct 15, 2015) (it is not clear whether this amount includes continuation awards) available at http://www.hhs.gov/about/news/2015/10/14/hhs-awards-more-240-million-expand-primary-care-workforce.html (last visited September 28, 2016).
28. 42 U.S.C. § 297n(a).
29. *Id.*
30. See generally https://datawarehouse.hrsa.gov/tools/analyzers/HpsaFindResults.aspx (last visited September 28, 2016).
31. 42 U.S.C. § 297n(b).
32. National Nurses Guidance, *supra* note 26 at 26-28.
33. *Id.* at 33.
34. *Id.*
35. *Id.* at 14.
36. National Nurses Guidance, *supra* note 26, at 19-21.
37. *Id. But see id.*, at 15 (the program will verify that program payments are being used to pay the participant's educational loans).
38. 42 U.S.C. § 297n(a).
39. *Id.* at 16-17.
40. *Id.* at 4.
41. *Id.*
42. National Nurses Guidance, *supra* note 26 at 14.
43. N.Y. Ed. L. § 605.9 (2016).
44. N.Y. Comp. Codes R. & Regs. tit. 8 § 145-6.2 (2016).
45. *See Regents Physician Loan Forgiveness Award Program Candidate Information Bulletin 2016 Competition* (January 2016), The University of the State of New York, The State Ed. Dept. (the "NY Physicians Guidance"), available at http://www.highered.nysed.gov/kiap/scholarships/documents/2016RegentsPhysicianLoanForgivenessBulletin.pdf (last visited September 28, 2016).
46. Laws 1985, ch 31, §§ 1 and 15.
47. *See* The Regents Physician Loan Forgiveness Award Program, Office of Postsecondary Access, Support & Success, New York State Education Department (February 25, 2016), http://www.highered.nysed.gov/kiap/scholarships/rplfap.htm (last visited September 28, 2016).
48. N.Y. Ed. L. § 605.9a. There have been proposals to expand eligibility to dentists and nurses. *See, e.g.*, S6332 (Sponsor Klein) (January 25, 2010) status and full text available at http://open.nysenate.gov/legislation/bill/S6332-2009 (last visited November 7, 2016); A905 (Sponsor Gunther) (January 6, 2010) status and full text available at https://www.nysenate.gov/legislation/bills/2009/A905 (last visited November 7, 2016); and A420 (Sponsor Gunther) (January 4, 2012) status and full text available at https://www.nysenate.gov/legislation/bills/2011/A420 (last visited November 7, 2016) (proposing the inclusion of dentists in the current program), and S808 (Sponsor Breslin) (January 6,2016) status and full text available at https://www.nysenate.gov/legislation/bills/2015/s808/amendment/original (last visited November 7, 2016); A01201 (2015) (Sponsor Magnarelli) (January 6, 2016) status and full text available at https://www.nysenate.gov/legislation/bills/2015/A1201 (last visited https://www.nysenate.gov/legislation/bills/2015/s808/amendment/original) (proposing to have a repayment program for nurses similar to the current one for physicians).
49. N.Y. Ed. L. § 605.9.a.
50. N.Y. Ed. L. § 605.9.c and NY Physicians Guidance, *supra* note 45, at 1.
51. NY Physicians Guidance, *supra* note 45, at 1.
52. N.Y. Ed. L. §§ 601.1, 605.9.c.2.
53. NY Physicians Guidance, *supra* note 45, at 1-2.
54. N.Y. Ed. L. § 605.9.d.
55. *Id.*
56. NY Physicians Guidance, *supra* note 45, at 1.
57. NY Physicians Guidance, *supra* note 45.
58. *Id.* at 2.
59. *Id*.
60. March 7, 2016 telephone conversation with representative of the New York State Tax and Finance Department.
61. Section 61(a)(12) of the Internal Revenue Code of 1954 as originally adopted.
62. PLR 5604265200A (April 26, 1956).
63. Bingler v. Johnson, 394 U.S. 741 (1969).
64. *See* Rev. Rul. 73-256; 1973-1 C.B. 56. *See also* Rev. Rul. 77-44; 1977-1 C.B. (Grants limited to those expressing moral obligation to work in state public schools). *Cf.* I.R.S. Priv. Ltr. Rul. 201328020 (April 12, 2013) (grants to college students requiring vague community services are exempt scholarships).
65. Deficit Reduction Act of 1984, Pub. L. No. 98-369 § 1076, 98 Stat. 494, 1053-54 (added the predecessor of the current Sections 108(f)(1) and (2)).
66. *Id.*
67. *Id.*
68. Pub. L. No. 96-541 § 5, 94 Stat. 3204, 3205-06 (1980) (adding a predecessor of Code § 117(c)).
69. Economic Growth and Tax Relief Reconciliation Act of 2001, Pub. L. No. 107-16 § 413, 115 Stat. 38, 64 (1980) (adding the current Code § 117(c)).
70. Rev. Rul. 2008-34, 2008-2 C.B. 76.
71. Laws 1985, ch. 31, §§ 1 and 15.
72. New York Laws 1985, ch. 31, § 1.
73. Moloney v. C.I.R., T.C. Summary Opinion 2006-53, 2006 Tax Ct. Summary LEXIS 144 (April 17, 2006).
74. *Id.* at *4.
75. In contrast, under Code Section 83(a)(2) and Treas. Reg. 1.83-3(e), non-cash payments for the performance of services are not included in gross income if there is a substantial risk that they will be forfeited. Whether there is a substantial risk depends on the facts and circumstances. In particular, there may be no such risk if almost all participants complete their service commitment.
76. The Vancouver Clinic, Inc. v. U.S., No. 3:12- CV-05016-RBL, 2013 U.S. Dist. LEXIS 51802 (W.D. Wash. Apr. 9, 2013).
77. *Id.*, at *8-*9.
78. Public Health Service Amendments of 1987, Pub. L. No. 100-177 §§ 201-05, 101 STAT 986, 992-1003 (1987).
79. 42 U.S.C. § 254L-1(g)(1) (1987) set forth at 101 STAT 995 (1987).
80. 42 U.S.C. § 254O(a)(c)(1) set forth at 101 STAT 997 (1987).
81. 42 U.S.C. § 254L-1(g)(3) (1987) set forth at 101 STAT 995 (1987).
82. 54 Fed. Reg. 13458-68 (April 3, 1989).
83. 42 C.F.R. § 65.25 (a), 54 Fed. Reg. 13463 (April 3, 1989).
84. 42 C.F.R. § 65.25 (c), 54 Fed. Reg. 13463 (April 3, 1989).
85. National Health Service Corps Revitalization Amendments of 1990, Pub. L. No. 101-597, 104 STAT. 3013-3036 (1990).
86. 42 U.S.C. 254L-1 (g)(3) as added by National Health Service Corps Revitalization Amendments of 1990, Pub. L. No. 101-597 §§ 202(g) and 501, 104 STAT. 3013, 3026 and 3036, respectively (1990).
87. 57 Fed. Reg. 56994-96 (December 2, 1992).
88. *Id.* at 56995.

89. *Id.*

90. *Id.*

91. Health Professions Education Extension Amendments of 1992, Pub. L. No. 102-108 § 211(a)(3), 106 Stat. 1992, 2078-79 (1992).

92. 42 U.S.C. § 297n(b) and (c) as set forth at 106 Stat. 1992, 2078-79 (1992).

93. Economic Growth and Tax Relief Reconciliation Act of 2001, Pub L. No. 107-16 §§ 413(a)(1)-(2), 115 Stat. 38, 64 (2001).

94. *See, e.g.*, the Physicians Shortage Area Scholarship Program, the Public Health Service Scholarship Program, and the Nurse Corps Scholarship Program.

95. American Jobs Creation Act of 2004, Pub. L. No. 108-357 § 320, 118 Stat. 1418, 1473 (2004).

96. *Id.*

97. *Id.*

98. *Id.* (there was an exception for state programs that unlike New York were federally funded).

99. NHSC Loan Guidance, *supra* note 6, at 4.

100. *Id.*

101. Q & A 2, Frequently Asked Questions, Health Resources and Sources Administration, U.S. Dept. Health and Human Services, available at http://www.nhsc.hrsa.gov/loanrepayment/faqs/index.html#g2 (last visited November 7, 2016).

102. 42 U.S.C. § 254L-1(g)(1).

103. *Cf.* Q & A 7, Frequently Asked Questions, Health Resources and Sources Administration, U.S. Dept. Health and Human Services (Imposing such a requirement on applicants for a continuation award), available at http://www.nhsc.hrsa.gov/loanrepayment/faqs/index.html#g7 (last visited November 7, 2016).

104. These positive changes were counterbalanced by the significant increase in penalties on participants who breached their service commitment that was enacted in 2001. Health-care Safety Net Amendments of 2002, Pub L. No. 107–251 § 313(a), 116 Stat. 1621, 1651-1652 (2002).

105. *See* Joint Committee on Taxation, General Explanation of Tax Legislation Enacted in the 108th Congress No. JCS-5-05 (May 2005), at 241. In footnote 417 on the next page there is a reference made to even clearer statements that repayments are made to the participants a year earlier in S. Rep. No. 108–266 at 121 (May 14, 2004).

106. *Id.* at 241 (emphasis added).

107. Patient Protection and Affordable Care Act Pub. L. No. § 10908, 124 Stat. 119, 1021 (2010).

108. *Id.*

109. *See also* IRS News Release 2010-74, 2010 IRB LEXIS 377 (June 16, 2010) (suggesting that participants may wish to seek income tax and employment tax refunds because the 2010 changes were effective retroactively to the 2009 tax year).

110. New York Laws 1985, ch. 31, § 1.

111. *Cf.* NY Physicians Guidance, *supra* note 45 at 2 and Regents Physician Loan Forgiveness Award Program Candidate Information Bulletin 2007 Competition (May 31, 2007), The University of the State of New York, The State Ed. Dept. at 2 (the "NY Physicians Guidance"), available at http://www.highered.nysed.gov/kiap/pdf/2007regentsphysicianloanforgivenessbulletin.pdf (last visited November 7, 2016).

Albert Feuer is an Employee Benefits Attorney in the Law Offices of Albert Feuer in Forest Hills, NY. The author thanks Anna Masilela for her valuable assistance in writing this article.

NEWS flash

What's Happening in the Section

Section Officer Nominations

The Section's Nominating Committee proposed the following candidates for election at the upcoming Annual Meeting:

Chair Elect: [TBD]

Secretary: [TBD]

Treasurer: [TBD]

The current Chair-Elect, Laurence Faulkner, will begin his term as Chair in June 2017. Laurence is Director of Corporate Compliance & General Counsel of ARC of Westchester County.

Upcoming Events

- **Annual Meeting.** The Section's Annual Meeting will be held at the New York Hilton Midtown, NYC on Wednesday January 25, 2017. Once again, the program will be Hot Topics in Health Law. The program and registration information are available on the Section's website.

Recent Events

- **Health Law Section 20th Anniversary Reception.** The NYSBA Health Law Section was founded in 1996, largely through the efforts of Barry A. Gold, a health care attorney in Albany who passed away in 2002. A reception was held on October 27, 2016 at the Bar Foundation to celebrate the Section's 20th Anniversary.

- **Section Fall Meeting: Disrupting the System**. This program, held in Albany on October 28, offered a look at innovative programs that are designed to facilitate access to comprehensive, coordinated care to improve patient satisfaction and clinical outcomes. A diverse panel of speakers described innovative, collaborative initiatives that are disrupting the health care system, and the practical ways to overcome the real and perceived barriers to sustained implementation. Anoush Koroghlian Scott of Whiteman Osterman & Hanna was Program Chair; Christopher Chase of the NYS Department of Health and Brigid Maloney of Hodgson Russ were Co-Chairs. Topics included In-House General Counsel: Hot Topics; Medical-Legal Partnerships in Health Care; Collaborative Affiliations Among Large Systems and Physician Practices: Tales From the Trenches; Medical-Legal Implications and Sustainability of SHIN-NY Regulations in Healthcare Delivery System; Concierge Medicine/Telemedicine/Direct Primary Care; and Ethics of Health Information Technology Privacy.

Welcome New Members

The following members joined the Health Law Section since publication of the last issue of the *Health Law Journal*.

Allyson Michelle Beach
Elana Bengualid
Gina Dolan
Victor D. Gonzalez
Rachael Naomi Pine
Barbara A. Jaccoma
Adam David Lancer
Ana Simone Salper
Kelly Busch
Kathryn J. Coleman
Caitlin Donovan
M. Kathleen Fagan
Eric D. Farrell
Brad M. Gallagher
Scott T. Hanson
Robert A. Hussar
Kelly Michael Monroe
Jessica L. Tomkiell
Frank J. Fanshawe
Kathleen McGivern
Kelly Marie Colasurdo
Bridget Kehm
Hon. William P. Polito
Anne Augustine
Adam Haney
Steven Paul Przybyla
Brandon Michael Berkowski
Rosemary Picciano
Bryan R. Denberg
Alexander C. Palasek
Jessica Lyn Rosenthal
Jamila K. Jones
William James McClellan
Halah Elchorbagy
Lori Lynn Moraine
Rachel Elizabeth Pearson
Steven C. Sunshine

Section Committees and Chairs*

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

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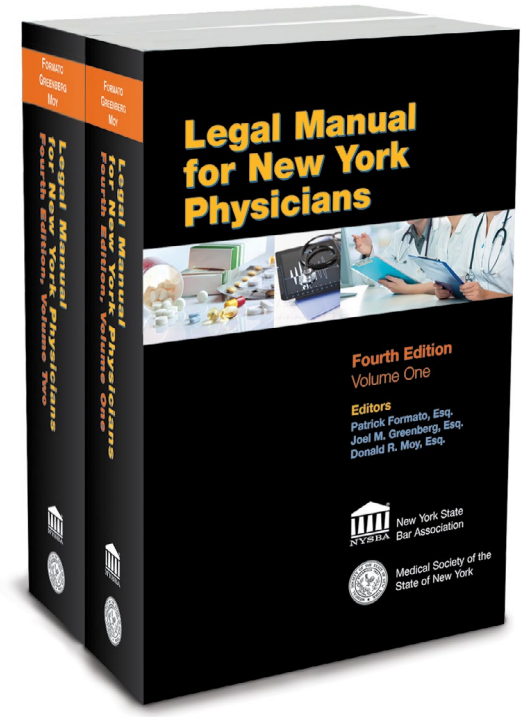

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