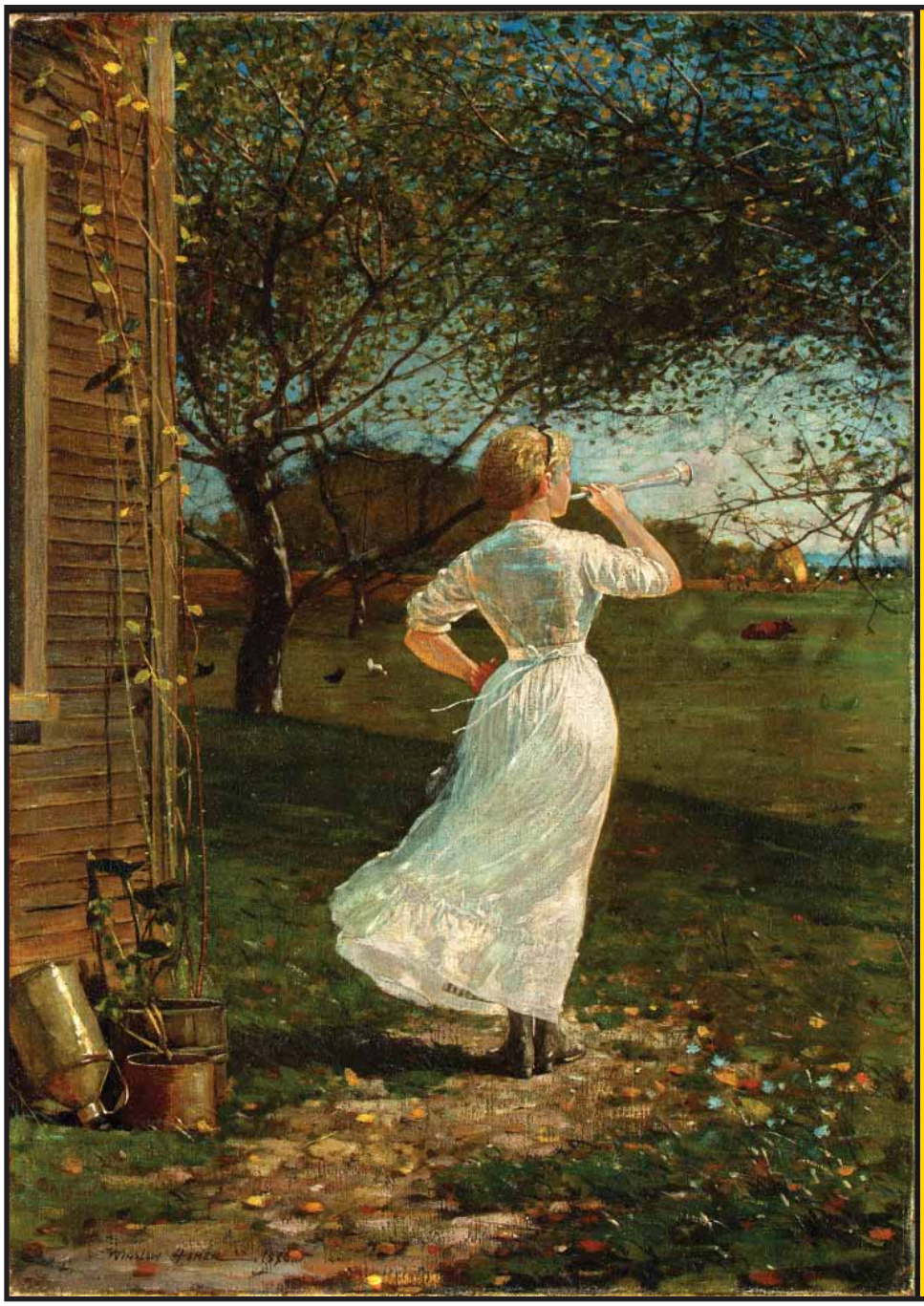
NYSBA SPRING 2014 | VOL.19 | NO. 1

Health Law Journal

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



Inside

NEW YORK STATE BAR ASSOCIATION

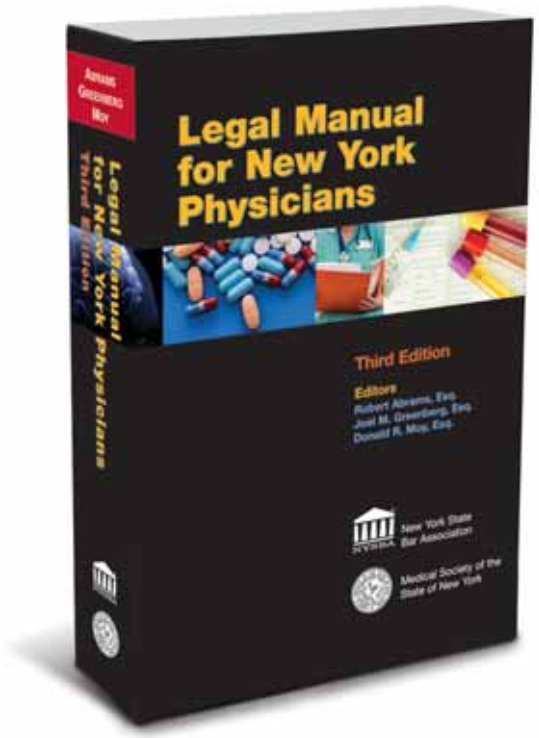
Legal Manual for New York Physicians

Third Edition

Section Members get 20% discount* with coupon code PUB2142N

The Third Edition of *Legal Manual for New York Physicians,* includes new chapters on the Physician-Patient Privilege, the Impact of Federal Health Care Reform on Physicians and Electronic Records and Signatures for the Health Care Provider and covers over 50 topics.

This comprehensive text is a must-have for physicians, attorneys representing physicians and anyone involved in the medical field. The third edition of *Legal Manual for New York Physicians* is co-published by the New York State Bar Association and the Medical Society of the State of New York.



PRODUCT INFO AND PRICES

41329 | 2011 | 1,130 pp. | softbound

Non-Members	$145
NYSBA Members	**$125**

Order multiple titles to take advantage of our low flat rate shipping charge of $5.95 per order, regardless of the number of items shipped. $5.95 shipping and handling offer applies to orders shipped within the continental U.S. Shipping and handling charges for orders shipped outside the continental U.S. will be based on destination and added to your total.

Discount good until June 13, 2014

To order call **1.800.582.2452**
or visit us online at **www.nysba.org/pubs**

Order multiple titles to take advantage of our low flat rate shipping charge of $5.95 per order, regardless of the number of items shipped. $5.95 shipping and handling offer applies to orders shipped within the continental U.S. Shipping and handling charges for orders shipped outside the continental U.S. will be based on destination and added to your total. Prices do not include applicable sales tax.

Mention code: PUB2142N when ordering.

NYSBA

HEALTH LAW JOURNAL

Spring 2014

Vol. 19, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

Table of Contents

Cover artwork:
The Dinner Horn (Blowing the Horn at Seaside) by Winslow Homer (1836-1910)

A Message from the Section Chair

Annual Meeting

The Section's Annual Meeting held on January 29 was very successful and well received. Attendance numbers were the highest ever; responses to the NYSBA's satisfaction survey have been uniformly positive. Margaret J. Davino, Esq. did an outstanding job. Margie and I appreciate greatly the hard work of the Section leaders who planned and / or participated in the various sessions: Vice-Chair (now Chair-Elect) Kenneth (Ken) Larywon, Esq.; Karen L. Illuzzi Gallinari, Esq.; Harold N. Iselin, Esq.; Ross P. Lanzafame, Esq., James (Jim) Lytle, Esq.; Ruth Scheuer, Esq.; Samuel (Sam) J. Servello, Esq.; and Carolyn Shearer, Esq.

Thanks to the other speakers who joined with them for the informative and interesting presentations: Alison Burke, J.D. (Regulatory Update with Jim and Ross); Katherine Dunphey, MPA and Richard Lombardo, Esq. (CMS Payment and Reimbursement Issues); Sandra Maliszewski, M.S.N., J.D. M.B.A. (Mobile Health Apps); Harry Ostrer, M.D. and Ann M. Willey, Ph.D., J.D. (Genetics, Ethics and the Law with Sam and Karen); Lisa Sbrana, Esq. (Health Exchange); Sandi Toll, Esq. (Health Insurance Developments with Harold) and Terence Bedient and Paula Breen (OPMC and the Committee on Physician Health with Ken and Carolyn).

We are especially grateful to the New York State legislative health leaders, Hon. Kemp Hannon, Chair of the Senate Committee on Health and Hon. Richard N. Gottfried, Chair of the New York State Assembly Committee on Health, who spoke together and gave us an interesting précis of the legislative session under way.

Jason Brooks, Esq. provided a valuable service coordinating the video support for Margie so that the sessions ran smoothly.

NYSBA Diversity Initiative—Health Law Section's Action

The Section continues to participate enthusiastically in the NYSBA's Diversity Initiative. In 2011, the Section developed the Minority Summer internship in Health Law. Lisa D. Hayes, Esq., Chair of the Diversity Subcommittee of the Section's Membership Committee, and Karen L. Illuzzi Gallinari, Esq., Membership Committee Chair, arranged for last summer's placement of interns in the General Counsel's offices of three hospitals / health care systems. The Section split the cost of each intern's stipend of $5,000 with the sponsoring institution. The interns were: Jessica Maxwell, Catholic Health Services of Long Island (David DeCerbo, Esq. and Martha (Mickey) Kranz, Esq.); Dionne Shuler, Continuum Health Partners (now the Mount Sinai Health System) (Beth Essig, Esq., General Counsel for Mount Sinai Health System); and Patricia Llanos, NYU Medical Center (Annette Johnson, J.D., Ph.D. and Lynn Feldman Lowy, Esq.). It would be hard to imagine more experienced practitioners or better teachers and mentors than Annette, Beth, Dave, Lynn, and Mickey. The interns attended the Annual Meeting as the Section's guests; they remarked how fascinating and educational they found their internship and what impressive role models were the lawyers for whom they worked.

The Section also agreed to co-sponsor with many other Sections an annual NYSBA event entitled "Smooth Moves: Career Strategies for Attorneys of Color," which was held on Tuesday, April 1 at Lincoln Center's Stanley Kaplan Playhouse from 4 to 7 p.m. The event consisted of a 90 minute CLE program followed by a networking reception and the presentation of the George Bundy Smith Pioneer Award.

Section Committees

Section Committees continue to be very active. Please see the Committee reports in this edition of the *Journal*. Several of the committees are planning timely and interesting panels or CLEs. Join a Committee or two or more to become more engaged in the Section!

Of note, as mentioned in the reports of the Committees in this edition of the *Journal*, the Section's Committee on Ethical Issues in the Provision of Health Care, chaired by Larry Faulkner, Esq. and Alice Herb, J.D. LLM., joined with the New York City Bar Association Health Law Committee, chaired by Ron Lebow, Esq., to plan two presentations; Albany and New York City were connected by video conferencing from the respective bar association headquarters. The Ethical Issues Committee's outreach to the City Bar health law group is a good example of the benefits of productive collaboration with our health law colleagues in other bar associations.

"Palliative Care in New York State" Booklet

David C. Leven, Esq. and Mary Beth Morrissey, Esq. prepared an excellent booklet entitled "Palliative Care in New York State," which was published in April 2012. David and Mary Beth offered to update the book in conjunction with the Health Law Section. The Ethical Issues in the Provisions of Health Care Committee and Robert Swidler, Esq. will review the update. We are pleased that David and Mary Beth included the Health Law Section in this project, which is a very worthwhile public service.

Membership Event

Annual American Health Lawyers Meeting—New York City—June/July

The Annual American Health Lawyers Meeting will be held in New York City. June 29 will be the In-House Session and June 30 to July 2 will be the Annual Meeting. Thanks to the good offices of former Section Chair Ari J. Markenson, Esq., the Section will particiapte in the AHL Annual Meeting. The Meeting Agenda will include a New York State Legal Update followed by a Members' Reception. The Legal Update will be spearheaded by Section Chair Margaret J. Davino, Esq. The Membership reception will be held under the capable aegis of our exceptional Membership Committee Co-Chair Karen L. Illuzzi Gallinari, Esq., NYSBA Section liaison Lisa Bataille and Administrative Assistant Kathy Plog. We expect that the Legal Update and Reception will be interesting and enjoyable. Stay tuned for more details!

New Executive Committee Appointment

I am pleased to report that Carolyn Shearer, Esq. has agreed to serve as a Member-at-Large of the Section's Executive Committee. Carolyn served with Ken Larywon as Co-Chair of the very productive and energetic Professional Discipline Committee. Carolyn, who is Senior Counsel at Bond, Schoeneck & King, brings her seasoned governmental and private practice expertise to the Executive Committee discussions and plans.

Kathleen M. Burke

In the New York State Courts

By Leonard M. Rosenberg

Court of Appeals Holds Clinic Not Liable for Employee's Unauthorized Disclosure of Patient's Medical Information

Doe v. Guthrie Clinic, Ltd., 2014 WL 66644 (N.Y. Jan. 9, 2014). Plaintiff sued a healthcare clinic after a nurse employed at the clinic recognized the patient and disclosed his treatment information to the patient's girlfriend. Finding the clinic not liable for the nurse's actions, the Court of Appeals held that the clinic's duty to safeguard the patient's medical information is limited to those risks that are reasonably foreseeable and to actions within the scope of employment.

Plaintiff sought treatment at a healthcare clinic for a sexually transmitted disease ("STD"). When a nurse at the clinic recognized Plaintiff as her sister-in-law's boyfriend, she accessed his medical records and learned that Plaintiff was being treated for an STD. While Plaintiff was still awaiting treatment, the nurse sent text messages to her sister-in-law informing her of Plaintiff's condition. The sister-in-law, in turn, immediately forwarded the messages to Plaintiff. After Plaintiff complained to the clinic about the nurse's behavior, the clinic fired the nurse and advised Plaintiff that his confidential health information had been improperly disclosed, and that appropriate disciplinary action had been taken.

Plaintiff sued in federal court, asserting, among other claims, breach of fiduciary duty to maintain the confidentiality of personal health information. The United States District Court for the Western District of New York dismissed the action, and Plaintiff appealed. The Second Circuit, finding that the nurse's actions could not be imputed to the clinic because they were not foreseeable or taken within the scope of her employment, certified the question whether Plaintiff may bring a cause of action directly against the clinic for breach of the fiduciary duty of confidentiality, in the absence of *respondeat superior* liability.

The New York Court of Appeals answered the certified question in the negative, declining to impose strict liability on the clinic for the nurse's improper disclosure. In reaching its conclusion, the Court cited its decision in *N.X. v. Cabrini Medical Center,* 97 N.Y.2d 247 (N.Y. 2002), in which it declined to hold a medical corporation to a "heightened duty" for an employee's misconduct. The court reasoned that while "a hospital has a duty to safeguard the welfare of its patients…[that duty] does not render a hospital an insurer of patient safety…[and] is circumscribed by those risks which are reasonably foreseeable." Based on that reasoning, the Court limited the medical corporation's duty of safeguarding its patients' medical information to those risks that are reasonably foreseeable and to actions within the scope of employment.

Addressing the concerns of the dissent, the Court advised that a medical corporation may still be held liable for its own conduct, such as negligent hiring, negligent supervision or failing to establish adequate policies and procedures to safeguard the confidentiality of patient information. Such potential liability, the Court reasoned, incentivizes medical providers to install appropriate safeguards to protect patient information.

Based on the Court of Appeals' decision, the Second Circuit affirmed the judgment of the District Court, dismissing the action.

The Court of Appeals Holds That OMIG May Remove a Physician From Medicaid After Being Investigated by OPMC, Even if OPMC Deems the Physician Fit to Continue Practicing Medicine, as Long as OMIG States Its Reasons for Doing So

Koch v. Sheehan, 21 N.Y.3d 697, 976 N.Y.S.2d 4 (2013). This claim arose after the Office of the Medicaid Inspector General ("OMIG") removed a physician from the Medicaid program because he had entered into a consent order, agreeing to probation, after being investigated by the New York State Office of Professional Medical Conduct ("OPMC") for physician misconduct. Both the Supreme Court and the Appellate Division had held that OMIG was not permitted to terminate a physician from the Medicaid program simply because he had pled no contest to the charges against him, when the Board of Professional Medical Conduct ("BPMC," the adjudicatory arm of OPMC) had required probation only, and permitted the physician to continue to practice medicine.

The Court of Appeals upheld the determination that OMIG's actions had been arbitrary and capricious, but on different grounds. The Court of Appeals explicitly rejected the premise that OMIG could not remove a physician from Medicaid even if BPMC deemed the physician fit to practice. In doing so, it relied upon 18 NYCRR 515.7(a), which permits OMIG to impose sanctions upon any physician once OMIG has received notice that the physician was subject to investigation into professional misconduct, and "after resolution of the proceeding by stipulation or agreement" (*i.e.*, a consent order). The Court held that OMIG was thus permitted to remove any physician from Medicaid once he or she has been investigated by OPMC. OMIG is not required to conduct an independent

investigation or defer to BPMC, and it may remove the physician even if BPMC has seen fit to let the physician continue to practice.

Nevertheless, the Court held that in this particular case, OMIG's decision was arbitrary and capricious, because the agency had not provided any explanation for why it had made its determination. The Court noted that the OMIG auditor had merely repeated vague assertions from the consent order, and had failed to provide a basis for terminating the physician from the Medicaid program. Since there was inadequate record support for OMIG's decision, it was arbitrary and capricious and an abuse of discretion.

The Court rejected the physician's argument that by permitting OMIG to terminate him from Medicaid, he did not receive his full bargained-for settlement with BPMC, as both offices are part of the Department of Health. The Court held that, as OMIG and BPMC have separate statutory authority and purposes, a settlement with one does not bind the other.

Court of Appeals Holds That Drug Testing Laboratory Under Contract to County Probation Department May Be Held Liable to Probationer for Negligent Testing

Landon v. Kroll Laboratory Specialists, 999 N.E.2d 1121, 977 N.Y.S.2d 676 (2013). Plaintiff was convicted of second degree forgery and sentenced to a five-year term of probation. As a condition of his probation, he was required to submit to random drug testing. Defendant laboratory was engaged by the Orange County Probation Department ("OCPD") to test the samples. On December 17, 2007, Plaintiff's probation officer collected an oral fluid sample from plaintiff for testing. The same day, Plaintiff obtained an independent blood test, for purposes of protecting himself against any false positive result on the official test. The independent test came back negative for controlled or illicit substances. The defendant's oral sample results, however, found the sample positive for THC. On the basis of the result, OCPD commenced a violation of probation proceeding against plaintiff, seeking to revoke his probation and have him incarcerated.

Plaintiff was arraigned on the violation one day before his probation was set to expire. He provided the court with the negative independent test result he had obtained, and submitted to a urine test, which was likewise negative for THC. After several court appearances, during which his probation was extended, the petition was withdrawn and the OCPD proceedings were terminated in plaintiff's favor. Plaintiff thereafter commenced an action against defendant, alleging that it issued the positive finding both negligently and as part of a policy of deliberate indifference to his rights. Plaintiff alleged that the test cutoff level employed by defendant was lower than federal standards, which defendant failed to disclose when it reported its results. Plaintiff also alleged that the defendant failed to confirm the results of the oral screening through the use of gas chromatography-mass spectrometry, as is required by state laboratory standards. Finally, plaintiff alleged that defendant failed to require the taking of a urine sample simultaneously with the oral sample, as is required by guidelines to protect federal workers from false positive results. Plaintiff alleged that the foregoing failures were the result of systemic negligence in defendant's testing practices, forcing him to serve an extended period of probation, suffering loss of freedom, emotional harm, and pecuniary damages in the form of the attorneys' fees he expended to defend himself in the violation of probation proceedings.

The Supreme Court granted defendant's motion to dismiss for failure to state a cause of action, but the Appellate Division reversed. The Court of Appeals thereafter affirmed the Appellate Division's reinstatement of plaintiff's complaint. In its analysis, the Court reasoned that, although there was no direct contractual relationship between the plaintiff and defendant, and the contract between the defendant lab and the county would not ordinarily be a source of tort liability to third parties, there are certain circumstances where a duty of care to individuals outside of the contractual relationship may arise. That duty arises where, as here, "the contracting party, in failing to exercise reasonable care in the performance of its duties, launches a force or instrument of harm," and that this duty is distinct from the duty of contractual performance. Accordingly, accepting the allegations in the complaint as true, the defendant lab did not exercise reasonable care when it released the report finding that plaintiff had tested positive for THC, as it had not adhered to professionally accepted testing standards.

The Court of Appeals further held that strong public policy considerations also weighed in favor of the plaintiff, since the release of a false positive report could have profound consequences under the circumstances, and that its holding is in keeping with other jurisdictions, and the holdings of several federal courts. It rejected defendant's argument that plaintiff had failed to state a cognizable harm, particularly given the procedural posture of the matter insofar as its holding relates only to standards on a motion to dismiss. The Court was careful to indicate that, while it would find a duty that runs from the defendant lab to the plaintiff sufficient to sustain his complaint, its decision was not intended to express any opinion on the ultimate merits.

Fourth Department Holds That Defendant Who Had Unprotected Sex While Knowingly Being HIV Positive Cannot Be Found Guilty of First Degree Reckless Endangerment

People v. Williams, 111 A.D.3d 1435 (4th Dep't 2013). Defendant was charged with reckless endangerment in the first degree for engaging in unprotected sex with the victim on two to four occasions without disclosing

his HIV-positive status. Shortly after their sexual relationship ended, Defendant told the victim that a former sexual partner had tested positive for HIV and urged the victim to be tested. The victim was diagnosed as HIV positive several months later. Defendant was charged with reckless endangerment in the first degree (Penal Law § 120.25). Defendant moved the Supreme Court to dismiss the indictment based on the legal insufficiency of the evidence before the grand jury. The Supreme Court reduced the indictment to reckless endangerment in the second degree (§ 120.20). The Fourth Department affirmed.

The Court first explained the standard for reckless endangerment in the first degree. Specifically, pursuant to Penal Law § 120.25, "[a] person is guilty of reckless endangerment in the first degree when, under circumstances evincing a depraved indifference to human life, he [or she] recklessly engages in conduct which creates a grave risk of death to another person." To show depraved indifference to human life, the People must show that the accused has a culpable mental state showing an "utter disregard for the value of human life—a willingness to act not because one intends harm, but because one simply doesn't care whether grievous harm results or not." Moreover, the actor's reckless conduct must be so imminently dangerous that it presents a grave risk of death.

Here, the Court found that the evidence was legally insufficient to show that Defendant acted with depraved indifference and Defendant's conduct did not present a grave risk of death to the victim. First, the evidence was legally insufficient to establish depraved indifference because, even though Defendant engaged in unprotected sex without disclosing his HIV status, Defendant wrote a letter apologizing to the victim and encouraged her to get tested. Therefore, Defendant's conduct lacked the "wanton cruelty, brutality, or callousness" required for a finding of depraved indifference to the victim since the evidence could not support a finding that Defendant did not care at all.

Second, the Court held that the evidence did not establish that Defendant's conduct presented a grave risk of death to the victim. The Court relied on the victim's physician, an infectious disease expert, who testified that the ability to treat HIV has increased dramatically over the past 15 years and is no longer considered a death sentence. The doctor stated when a patient promptly learns that he or she is infected, seeks treatment, takes medication, eats well, does not smoke, and reduces alcohol intake a person who is HIV positive can live a "very healthy, normal lifestyle." The physician expected a similar prognosis for the victim.

First Department Holds That 2½-Year Medical Malpractice Statute of Limitations Period Provided for in CPLR 214-a Does Not Apply to Chiropractic Malpractice Actions

Perez v. Fitzgerald, 2014 N.Y. Slip Op. 00744, 2014 WL 463318. In May 2005, Plaintiff was injured in a car accident. Following the accident, Plaintiff sought chiropractic treatment for neck and arm pain from Defendant Jane Fitzgerald, D.C. On May 24, 2005, Dr. Fitzgerald ordered an MRI. Although Dr. Fitzgerald used the radiology report to treat Plaintiff (indicating only that Plaintiff had herniated / bulging discs in her neck), Dr. Fitzgerald did not personally review the MRI film. In July 2006, Dr. Fitzgerald again treated Plaintiff for complaints involving neck pain and hand numbness, but did not order a follow-up MRI.

From 2005 through 2007, Plaintiff also sought care from several physicians for complaints of hypothyroidism, high blood pressure and cholesterol. Yet, Plaintiff never disclosed to any of these physicians that she was seeing a chiropractor or suffered from neck pain and hand numbness. In mid-to-late 2007, Plaintiff met with a new chiropractor who recommended that Plaintiff obtain a new MRI and see an orthopedist. When Plaintiff obtained the second MRI in 2008, it revealed that Plaintiff had a tumor in her spine for which Plaintiff underwent surgery.

In June 2009, Plaintiff filed this action against Dr. Fitzgerald, alleging medical malpractice. Plaintiff's lawsuit was commenced beyond the 2½-year statute of limitations provided for in CPLR 214-a, which governs causes of action for "medical, dental or podiatric malpractice," but was within the 3-year statute of limitations applicable to other claims for professional malpractice pursuant to CPLR 214(6).

At trial, Dr. Fitzgerald twice moved to dismiss Plaintiff's complaint as time-barred according to CPLR 214-a. Decision was reserved for post-trial briefing. After the jury found that Dr. Fitzgerald had departed from accepted chiropractic practices in failing to order a second MRI, the trial court granted Dr. Fitzgerald's motion to dismiss the complaint. On appeal, the First Department reversed, holding that the CPLR 214-a's 2½-year statute of limitations does not apply to chiropractic malpractice actions.

In determining what constitutes "medical malpractice" for the purposes of CPLR 214-a, the First Department reviewed the statute's legislative development and case law history. Legislatively, the First Department noted that while CPLR 214-a was enacted as a response to the high cost and potential unavailability of medical malpractice insurance, and was twice amended to include protection for "dental" and "podiatric" malpractice, the term "medical malpractice" was never defined within the statute. As such, the First Department's analysis turned to case law precedent.

Chief among the cases reviewed by the First Department was the Court of Appeals decision in *Bleiler v. Bodnar*, 65 N.Y.2d 65 (1985). In *Bleiler*, the Court of Appeals held that CPLR 214-a applies to healthcare

professionals engaged in conduct that "constitutes medical treatment or bears a substantial relationship to the rendition of medical treatment by a licensed physician." The First Department then noted that what constitutes "medical treatment" for purposes of CPLR 214-a is restrictive and does not include everything listed under the definition of the "practice of medicine" provided for in Education Law § 6521. At the same time, the First Department recognized that there have been cases where physical therapists, technicians and nurses committed "medical malpractice" that fell within the purview of CPLR 214-a. Yet, the First Department held that those cases were distinguishable from the case at bar as those cases involved treatment rendered by healthcare providers at the direction of a physician or pursuant to hospital protocol—and were cases where the alleged injury occurred during the course of medical treatment or bore a substantial relationship to such treatment pursuant to a referral or prescription from a physician.

Here, the First Department held that Dr. Fitzgerald's chiropractic care did not emanate from a physician referral and was not an integral part of any other medical treatment or care. Of significance to the Court was the fact that Plaintiff failed to inform any other physician of her chiropractic treatment. Moreover, the First Department stated that while Dr. Fitzgerald's care may have met the broad definition of the "practice of medicine" under Education Law § 6521, that fact did not, by itself, render it "medical treatment" within the meaning of CPLR 214-a.

Supreme Court Holds That, for Purposes of a Medical Malpractice Claim, No Special Relationship Existed Between Physician and Patient's Wife Whom Patient Murdered

Devito v. Peri, 40 Misc.3d 1243(A), 977 N.Y.S.2d 666 (Sup. Ct. Kings Cty. 2013). Plaintiff Theresa DeVito is the daughter of the decedent and Angelo DeVito ("Patient"). Patient, who had been prescribed Zoloft for depression by defendant James Peri, M.D., shot and killed the decedent (Patient's wife) at their home in April 2012.

In November 2012, Plaintiff commenced this lawsuit against Dr. Peri, alleging three causes of action. Plaintiff's first cause of action alleged medical malpractice in that Dr. Peri inappropriately and improperly prescribed Patient Zoloft without giving warning to Plaintiff's family of potential side effects of the drug. Plaintiff alleged that this departure from the standard of care proximately caused Patient to kill his wife. Plaintiff asserted a second cause of action for lack of informed consent claiming that Dr. Peri did not inform the decedent of Zoloft's risks. Lastly, Plaintiff interposed a cause of action for the decedent's wrongful death.

After the filing of Plaintiff's complaint, Dr. Peri moved pursuant to CPLR 3212 for summary judgment. In response to Dr. Peri's motion, Plaintiff argued that Dr. Peri owed a duty to the decedent arising from Dr. Peri's treatment of patient with a medication known to cause violence. Plaintiff further contended that Dr. Peri and the decedent maintained a special relationship, and that as a result, Dr. Peri had a duty and obligation to protect the decedent as well as inform her about the risks involved with the use of Zoloft.

The Court rejected all of Plaintiff's arguments and granted summary judgment in favor of Dr. Peri. At the outset, the Court noted that in order to reach any discussion about deviation from accepted medical practice, a duty must exist. Although generally, a physician's duty is limited to his/her own patients, the Court held that such duty can in limited circumstances encompass non-patients who have a special relationship with either the physician or the patient.

The Court then reviewed several decisions where the New York Courts had declined to find a duty between a physician and patient's family member, but stated that a duty could exist if: (i) the family member had engaged the physician and relied exclusively on the physician's professional advice; (ii) the physician's acts created a serious risk of physical harm to the family member and the physician knew or should have known that the failure to warn created a risk of peril; or (iii) the physician was in position to exercise control over a patient's dangerous conduct, although the duty to control is largely confined to instances involving in-patient treatment.

Here, the Court concluded that no special relationship existed between the decedent and Dr. Peri that would extend a duty to the decedent.

The Court found that the treatment in this case was sought by Patient himself and its purpose was to treat Patient's health conditions, not to prevent injury to the decedent. There was no evidence that Dr. Peri ever contemplated treating the decedent in conjunction with Patient. Thus, Dr. Peri's only duty was to Patient. The fact that decedent was involved in Patient's care and was sometimes present during office visits did not alter the Court's findings.

Next, the Court found that Patient had no history of violence and there were no reports that Patient had ever displayed any proclivity towards violence. As such, the Court concluded that Dr. Peri had no duty to attempt to control the conduct of Patient.

Lastly, the Court assessed whether Dr. Peri's actions in prescribing Zoloft created a risk of harm to decedent—a fact that Dr. Peri knew or should have known to warn about. The Court found that there was no evidence that Dr. Peri knew or should have known that the failure to warn of any of Zoloft's alleged side effects heightened the decedent's risk of harm. In fact, the Court stated that the manufacturer's own warnings failed to identify any risk of a homi-

cidal side effect. Rather, the manufacturer's warning label indicated an increased risk of suicide in young adults—a risk not present in this case because of Patient's age. Upon these facts, the Court concluded that no special relationship existed between Dr. Peri and the decedent which would evoke a duty to warn. As such, the Court dismissed Plaintiff's first cause of action for medical malpractice.

The Court also dismissed Plaintiff's second and third causes of action. The Court found that Plaintiff's second cause of action had to be dismissed because lack of informed consent, as governed by Public Health Law § 2805-d(3), applies only to a patient. Similarly, the Court held that Plaintiff's wrongful death action was barred because the medical malpractice claim upon which it was based had been dismissed by the Court. Accordingly, the Court granted summary judgment in favor of Dr. Peri.

Court Upholds Release of Hospital Signed by Physician Returning to Work After Addiction Counseling, but Refuses to Dismiss Claim Against the Committee for Physicians Health for Failure to Disclose Findings in IME Report

Christophel v. New York-Presbyterian Hosp., No 154413/13, 2013 WL 6409968 (Sup. Ct. N.Y. County Dec. 6, 2013). This claim was brought by the estate administrator of Dr. Janet Christophel, an anesthesiologist who died due to an overdose of the anesthesia medication Propofol. Dr. Christophel had become addicted to Propofol while working in a residency program for the defendant New York-Presbyterian Hospital/Weill Medical College of Cornell University (the "Hospital"). After notifying the Hospital of her addiction, Dr. Christophel entered into a rehabilitation program, which included outpatient services at defendant Bridge Back to Life ("Bridge"), as well as assistance from defendant Committee for Physicians Health ("CPH"). After entering treatment, Dr. Christophel was cleared to return to work. While at work, she apparently resumed using Propofol. After several months, she resigned from the residency program, and shortly thereafter died from an overdose of Propofol.

Plaintiff sued the Hospital, Bridge, and CPH, alleging that they were individually and/or collectively negligent in allowing Dr. Christophel to die. The defendants moved to dismiss.

The Hospital sought dismissal on the basis of a release signed by Dr. Christophel before she returned to work, in which she agreed to release the Hospital from any claims arising from her return to work, and from her failure to comply with the conditions of her return to work, which included refraining from drug use. The plaintiff attempted to attack this release in several ways, none of which convinced the court.

First, the court was not swayed by the fact that the agreement was not signed by anyone from the Hospital and Dr. Christophel's signature was not witnessed. The court found that there was no purpose to anyone at the Hospital signing the agreement, and it was sufficient that the Hospital prepared it and presented it to her for execution.

Second, the court rejected the plaintiff's claim that Dr. Christophel's signature may not have been authentic, because the plaintiff failed to present any opinion from a handwriting expert.

Third, the court rejected the plaintiff's ethical argument based upon the condition of Dr. Christophel at the time she signed the release, and the lack of evidence that she had an opportunity to consult with an attorney, finding that Dr. Christophel was an educated person and there was no evidence that she did not understand what she was signing.

Finally, the court held that enforcing the release would not be against public policy. The court differentiated *Ash v. New York Univ. Dental Ctr*, 164 A.D.2d 366 (1st Dep't 1990), in which a waiver of negligence claims signed by low income patients who agreed to receive dental care from students had been set aside for public policy reasons. In *Ash*, the patients had been of limited means, and therefore had not had free choice in whether to obtain the potentially substandard dental care. However, the release signed by Dr. Christophel had clearly been in her best interest, and did not put her in a disadvantageous position. Thus, the court upheld the validity of the release and dismissed the Hospital from the lawsuit.

Bridge claimed that it should be protected under the Hospital's release as well. The court rejected this position, because Bridge was not a party to the release and was not related to the Hospital. The court also noted that Bridge's motion was supported by an attorney affidavit that made unsubstantiated allegations about what Bridge had known and decisions it had made. Thus, the court did not dismiss Bridge from the lawsuit.

The court also denied CPH's motion to dismiss. CPH asserted protection under Public Health Law §§ 230(11)(a), (b), (c), and (g)(i-v), which govern its reporting obligations. While being evaluated by CPH, Dr. Christophel had been referred to a psychiatrist for analysis, which psychiatrist issued a report to CPH. The plaintiff asserted that certain findings in this report should have been made available to the Hospital and Bridge. CPH insisted that it was not obligated to do so.

The court rejected this argument because the Public Health Law provisions cited by CPH were not applicable to the plaintiff's argument. Under § 230(11)(g)(i-iv), CPH is required to immediately report information concerning any physician believed to

be an imminent danger to the public to the New York State Department of Health. CPH members are immune from liability for damages stemming from such report. CPH asserted that the report it received from the psychiatrist who examined Dr. Christophel did not indicate that she was an imminent danger to the public, and therefore no report was required.

The court held that the plaintiff was not claiming that there had been professional misconduct or any other conduct that would fall under the provisions of § 230. He merely asserted that certain cautionary language should have been shared with the other defendants in order to assist them in evaluating Dr. Christophel's fitness for work and ability to be in proximity to Propofol. Thus, the cited regulations were inapplicable. However, the court declined to determine at this point in the litigation whether CPH was in fact obligated to share the information in the report with the other defendants.

Spoliation Sanctions Denied; Court Finds That Clinical Lab's Workstation Report Is Worksheet Required to Be Kept for Only One Year

Johnson v. Edwards, 41 Misc. 3d 756, 971 N.Y.S.2d 848 (Sup. Ct. Kings Cty. 2013). In a medical malpractice and wrongful death suit against Enzo Clinical Laboratory, Plaintiff alleged that the laboratory failed to timely provide the deceased's physician with results of blood test. During discovery Plaintiff demanded a copy of the workstation report, but Enzo was no longer in possession of it. In response, Plaintiff sought sanctions for the spoliation of evidence.

The issue in the case was whether, under the New York Department of Health Regulations, Enzo Laboratories was required to keep the workstation report for one year or seven years. In this case, the workstation report displayed the results of the machine that analyzed the blood sample. This was not the final report, which was produced to Plaintiff. The regulation at issue states:

> (c) All records and reports of tests performed including the original or duplicates of original reports received from another laboratory shall be kept on the premises of both laboratories and shall be exhibited to representatives of the department on request. Records listed below shall be retained by the laboratory for at least the period specified….
>
> (5) The following types of laboratory reports shall be retained for at least the period specified:
>
> (i) tissue pathology including exfoliative cytology—20 years;
>
> (ii) syphilis serology—negative report—two years;
>
> (iii) cytogenetics—25 years; and
>
> (iv) all others—7 years.
>
> (6) Worksheets containing instrument readings and/or personal observations upon which the outcome is based shall be retained for one year.

10 NYCRR 58-1.11.

Plaintiff contended that the regulation required Enzo to retain the workstation report for seven years under paragraph (c)(5)(iv), while Enzo contended it was only obligated to hold the workstation report for one year. There was no indication that Enzo Laboratory had destroyed the workstation reports in response to the lawsuit or Plaintiff's demand that it be produced, or otherwise acted willfully to dispose of the report. The Court stated that the only culpable state of mind Plaintiff could attribute to Enzo Laboratory is negligence in failing to preserve the report under the standard of care dictated by the Department of Health regulation.

The Court held that under the regulation Enzo Laboratory only had an obligation to keep the workstation report for one year. The Court focused on the distinction between a final report and documentation of the data that is generated in preparation of the final report. The Court held that since the workstation report in question is generated in preparation of report, Enzo Laboratory only had a duty to retain it for one year, pursuant to section 58-1.11 (c) (6). Therefore, since the summons and complaint were served upon Enzo Laboratory more than one year after the workstation report was created, the Court held that Enzo did not spoliate evidence, and denied Plaintiff's motion.

Federal Court Enjoins United Health Care From Terminating Physician From Medicare Advantage Plan Until Arbitrator Has Opportunity to Hear the Dispute

Fairfield Cnty. Med. Ass'n v. United Healthcare of New England, 3:13-CV-1621 SRU, 2013 WL 6334092 (D. Conn. Dec. 5, 2013) *aff'd as modified sub nom. Fairfield Cnty. Med. Ass'n v. United Healthcare of New England, Inc.*, 13-4608-CV, 2014 WL 485933 (2d Cir. Feb. 7, 2014). In October 2013, United Health Care issued letters to more than 2,000 physicians in Connecticut, stating that they would be removed from United's Medicare Advantage Network, effective February 1, 2014. In response, two Connecticut physician groups—the Fairfield County Medical Association and the Hartford County Medical Association—sued on Nov. 6, 2013, in the U.S. District Court for the District of Connecticut, on behalf of their physician-members. Since the physician-members contracts with United contained arbitration clauses, Plaintiffs only sought an injunction in aid of arbitration. The District Court granted the preliminary injunction and the Second Circuit affirmed, but modified the in-

junction by decreasing the time span of the injunction.

Plaintiffs sought the injunction to preserve the status quo and thus to allow its physician-members time to pursue their arbitration rights. Plaintiffs alleged that United breached the physicians' network participation agreements, because their removal was a termination rather than an amendment of the agreements, that United could only terminate the agreements on the physician's anniversary date, and that United was required to provide a justification for termination. United argued that it has a unilateral right to terminate participating physicians from participation in the Medicare Advantage plan by "amendment" of that plan, and that its notice letters to the physicians constituted an amendment. The District Court did not agree with United's interpretation since it was not supported by the language of the contract or the parties' experience under it.

The District Court also rejected United's jurisdictional and standing arguments. The Court reasoned that since the first cause of action alleged that United failed to comply with the procedural requirements of the Medicare Act, such claim provided basis for federal jurisdiction, and thus the Court had supplemental jurisdiction over the second cause of action, which alleged that United took actions that constitute a material breach of contract under Connecticut common law. The District Court also held that Plaintiffs had associational standing because (1) Plaintiffs' members had standing to bring the action as individuals; (2) the lawsuit furthered the purpose and mission of the Plaintiff associations by ensuring the continued success of all their (physician) members, as well as ensuring the vitality of the medical delivery system in their respective geographies; and (3) Plaintiffs had raised cognizable legal rights and issues both under the regulations of the Medicare Act and under contract law for which equitable and legal remedies are available.

The District Court found a likelihood of success of the merits, in that the language of the contract could not support the interpretation that United had the unilateral right to terminate participating physicians from participation in the Medicare Advantage plan by "amendment."

The District Court also found irreparable harm, reasoning that if the terminations were allowed to happen they would likely disrupt physicians' relationships with their patients, harm the physicians' reputations, and make it more difficult to compete in the market for Medicare services.

The District Court entered a temporary injunction, preventing United from removing the Connecticut physicians from its rosters until an arbitrator ruled on the merits of the case. On appeal, the Second Circuit affirmed the District Court's decision, but modified the injunction and held that the physician-members must file their arbitrations within thirty days of the Second Circuit's decision.

[Ed. Note: Garfunkel Wild, P.C. represents the Plaintiffs in this suit]

Qui Tam Complaint Dismissed for Failure to Allege Submission of Actual Claim to the Government

United Ex. Rel Siegel v. Roche Diagnostics, Corp., 2013 WL 6847689 (E.D.N.Y. Dec. 30, 2013). Plaintiff brought a *qui tam* action under the False Claims Act ("FCA") alleging that third party medical providers submitted false claims to Medicare and Medicaid for tests not actually performed by defendant's fluid testing machines. Defendant moved to dismiss for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted. The Court granted Defendant's motion to dismiss, finding that Plaintiff failed to allege either knowledge of falsity or the submission of actual claims to the government by Defendant or its customers.

Defendant Roche Diagnostics manufactured a machine that tested for various bodily fluids and stored the results on compact discs. Plaintiff alleged that the Administrative Director of Laboratories for one of Defendant's customers, North General Hospital, alerted Defendant that the machine produced false positive results. Plaintiff alleged that each time a medical provider billed Medicare or Medicaid for one of these inaccurate tests, it made a "claim" under the FCA, for which Defendant is liable.

The FCA imposes liability upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim" to the Government or "knowingly makes, uses or causes to be made or used, a false record or statement material to such a claim." Finding that Plaintiff failed to allege either knowledge of falsity or the submission of actual claims to the government by the defendant or its customers, the Court granted Defendant's motion to dismiss.

In reaching its decision, the Court analyzed recent amendments to § 3730(e)(4) of the FCA as a result of the enactment of the Patient Protection and Affordable Care Act ("PPACA"). Prior to the PPACA's enactment, § 3730(e)(4) provided that no court had jurisdiction over an action when the allegations were previously publicly disclosed. As such, a defendant invoking the public disclosure bar challenged a court's subject matter jurisdiction. After the PPACA's enactment, § 3730(e)(4) was changed to "a court shall dismiss an action or claim" when the provision applies. In light of these amendments, the Court held that the Court may not refer to evidence outside the pleadings, as it would on a motion challenging jurisdiction, and the burden is on the defendant to establish that the issues had been previously publicly disclosed. Finding that nothing in the parties' submissions suggest that Plaintiff's complaint is based on prior public disclosures, the Court did not address whether the Plaintiff qualified as the original source of information.

Turning to whether the complaint should be dismissed for failure to plead the claims with specificity, the Court held that although the Second Circuit has yet to explain exactly what Rule 9(b) demands of FCA claims, courts in the Circuit have required a heightened standard with respect to pleading an actual claim under the FCA. The Court held that Plaintiff's conclusory allegation that "'medical providers billed Medicare and Medicaid' for the purportedly inaccurate and/or unperformed tests for which those providers allegedly paid [Defendant]" failed to meet this heightened standard. The Court also held that although Rule 9(b)'s particularity standard may be relaxed when facts are "peculiarly within the opposing party's knowledge" or the case involves complex or extensive fraudulent schemes, such exceptions did not exist here. Holding that alleged fraud for unperformed medical tests is not complex and there is no reason to believe Defendant had knowledge of the false claims submitted by third party medical providers, the Court found no basis to relax the pleading standard.

Finally, the Court held that the Plaintiff failed to establish that Defendant acted with the requisite state of mind to sustain its FCA claim. Specifically, the Court held that Plaintiff failed to adequately plead that Defendant was or should have been aware that providers were billing the government for tests that were not performed. Likewise, the Court rejected as conclusory Plaintiff's suggestion that Defendant "knew of the issues, but let them linger for years."

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

In the New York State Legislature

By James W. Lytle

For the fourth consecutive year, Governor Andrew Cuomo and the Legislature reached agreement on a budget prior to the commencement of the 2014-2015 fiscal year. In this election year, the $137.9 billion adopted budget reflects many of the priorities advanced by Governor Cuomo in his proposed budget, including tax cuts and tax reform, augmented by the Legislature's inclusion of substantial increases in aid to education and a larger commitment to the expansion of pre-kindergarten programs.

For healthcare purposes, much of the legislative action in Albany occurs during budget consideration. As the Governor noted in his Executive Budget presentation, this year's budget, in particular, is "more than numbers" and is, in fact, "a specific action agenda" with "more policies and more program development than in previous years." Sometimes with only a vague relationship to the State's spending policies, a host of new policy initiatives—contained in what are referred to as Article VII legislation, in reference to the State's Constitution's provisions relating to the Executive Budget—were unveiled as part of the Governor's proposed budget, both in the healthcare arena and elsewhere. The healthcare initiatives span the full range of issues, including federal health reform, the implementation of the Medicaid Redesign Team recommendations, public health initiatives, new funding for health information technology, and CON reforms—not all of which were ultimately embraced by the Legislature.

Indeed, particularly in the health and human services area, the Legislature inserted itself more directly in the implementation of key policy initiatives, such as the expenditure of federal Medicaid waiver funds, the development of the statewide health information technology system and in the allocation of capital support for healthcare institutions, and a number of the Governor's policy initiatives were outright rejected by the Legislature. While the Executive branch continues to dominate in healthcare policymaking in New York, the Legislature clearly made its presence felt this year—probably for good and for ill—in a host of areas.

Some of the highlights of what did and did not get enacted in the budget follow.

Capital Investment in Health Care Facilities. The budget adopted the Governor's proposal to establish a grant program to assist facilities in transforming the health care system in the amount of $1.2 billion. The Legislature broadened eligibility beyond hospitals, nursing homes, diagnostic and treatment centers, and other clinics licensed under the Public Health Law or the Mental Hygiene Law to include assisted living, primary care and home care providers. In addition, the budget expanded the existing Health Facility Restructuring Program from hospitals only to include diagnostic and treatment centers, nursing homes, and any other not-for-profit entities with an operating certificate. The Governor's repeated attempt to establish a pilot program to allow for private equity ownership / investment in hospitals was again rejected.

Certificate of Need (CON) Redesign. The Executive Budget proposed to streamline certain elements of the State's CON program by eliminating the necessity of establishing "public need" or "financial feasibility" for certain primary care facilities, reducing the character and competence look-back period, and authorizing the establishment of retail "limited service clinics" and urgent care centers—all of which were rejected by the Legislature. The only arguably CON-related initiative contained in the budget was an unusual provision designed to subject a controversial hospital-affiliated physician office building in the Bronx to a "public community forum" to consider whether the size and scope of the facility was appropriate.

Nurse Practitioner Modernization Act. Nurse Practitioners (NPs) with more than 3,600 hours of experience will no longer need a formal collaboration agreement with a physician, and would not need to follow written protocols if they document a collaborative relationship with a physician in the appropriate specialty. In the event of any unresolved disputes between an experienced NP and a physician over a treatment issue, the physician's views would prevail. Various data would be required to be reported and a report will be issued by the Commissioner of Education, in consultation with the Commissioner of Health, on the implementation of these provisions by September 1, 2018.

Medicaid Global Cap and MRT Waiver: The budget continues authorization for the Division of Budget and Commissioner of Health to make adjustments to spending in the event that Medicaid spending growth exceeds the existing annual Medicaid Global Cap of approximately 3.8%. The Department of Health is authorized to share savings when Medicaid spending is below the cap, with provisions inserted by the Legislature that would require posting of the shared savings plan and legislative and stakeholder input. The budget also authorized the expenditure of funds generated by the long-awaited

Medicaid waiver—which, as of this writing, has just been formally approved—but the Legislature established an advisory panel to review recommendations for the use of federal waiver funds and required the Commissioner to provide quarterly updates on waiver initiatives.

Health Information Technology: The budget appropriates $55 million for the Statewide Health Information Network for New York ("SHIN-NY"), but the Legislature subjected the appropriation to the development of a plan "detailing sufficient resources" that might be available to support the expenditure and established a workgroup to "evaluate the state's health information technology infrastructure." The workgroup, which will be composed of physician, hospital, representatives from the regional health information organizations, Department of Health staff and others, is required to submit a report to the Legislature and the Executive by December 1, 2014.

Basic Health Plan: The budget authorized the establishment of a Basic Health Plan (BHP), pursuant to the Affordable Care Act, which would provide coverage for individuals between 133% and 200% ofthe federal poverty level (FPL), including for lawfully present immigrants and permanent residents under the color of the law (PRUCOL) under 133% FPL who are not eligible for Medicaid due to their immigration status. Individuals would be able to apply and enroll for the BHP at any point during the year and receive 12-month continuous eligibility. BHP coverage would be offered by insurers and health maintenance organizations, including Medicaid health plans.

Out-of-Network Coverage: In response to concerns over the narrowness of networks on and off the State's health insurance exchange, the Governor proposed and, with some modifications, the Legislature adopted new requirements to enhance access to out-of-network care under certain circumstances, to ensure more transparency in plan networks and to protect consumers from unexpected bills for services by providers outside of their plans' networks. These provisions will generally take effect beginning April 1, 2015. While a detailed analysis of these provisions would exceed this column's space, the complex set of new requirements will result in greater notice of out-of-network benefits and costs to consumers, will impose notice requirements on providers and on plans related to network participation, will subject out-of-network services to certain reimbursement and cost-sharing limitations and may require, in limited circumstances, the offering of out-of-network coverage by plans if that coverage in not otherwise available. A workgroup was also established that will make recommendations related to the availability and adequacy of out-of-network coverage in the individual and small-group markets, as well as recommendations related to an alternative methodology to determine out-of-network reimbursement rates. The workgroup will issue its recommendations by January 1, 2016.

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

In the New York State Agencies

By Francis J. Serbaroli

Expand Medicaid Coverage of Enteral Formula

Notice of Emergency Rulemaking. The Department of Health amended Section 505.5 of Title 18 NYCRR to expand Medicaid coverage of enteral formula for individuals with HIV infection, AIDS or HIV-related illness or other diseases. Filing date: September 5, 2013. Effective date: September 5, 2013. *See* N.Y. Register September 25, 2013.

Medical Assistance Rates of Payment for Residential Treatment Facilities for Children and Youth

Notice of Adoption. The Office of Mental Health amended Part 578 of Title 14 NYCRR to remove the trend factor from the 2013-14 Medicaid rate calculation and to adjust the occupancy rates. Filing date: September 9, 2013. Effective date: September 25, 2013. *See* N.Y. Register September 25, 2013.

Medicaid Managed Care Programs

Notice of Emergency Rulemaking. The Department of Health repealed Subparts 360-10 and 360-11 and sections 300.12 and 360-6.7 and added a new Subpart 360-10 to Title 18 NYCRR to repeal old and outdated regulations and to consolidate all managed care regulations to make them consistent with statute. Filing date: September 12, 2013. Effective date: September 12, 2013. *See* N.Y. Register October 2, 2013.

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

Notice of Emergency Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the provision of continuous PC and continuous CDPA

services. Filing date: September 17, 2013. Effective date: September 17, 2013. *See* N.Y. Register October 2, 2013.

Patient Rights

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 836 and added a new Part 836 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: September 23, 2013. Effective date: September 25, 2013. *See* N.Y. Register October 9, 2013.

Electronic Prescriptions and Records for Hypodermic Needles and Hypodermic Syringes

Notice of Adoption. The Department of Health amended sections 80.131 and 80.133 of Title 10 NYCRR to allow a practitioner to issue an electronic prescription for hypodermic needles and syringes. Filing date: September 24, 2013. Effective date: October 9, 2013. *See* N.Y. Register October 9, 2013.

Hospital Pediatric Care

Notice of Revised Rulemaking Proposal. The Department of Health proposed an amendment of Part 405 of Title 10 NYCRR to amend pediatric provisions and update various provisions to reflect current practice. *See* N.Y. Register October 16, 2013.

Death Certificates

Notice of Adoption. The Department of Health amended section 35.4 of Title 10 NYCRR to issue a death certificate to any applicant upon the request of a sibling of the deceased. Filing date: October 8, 2013. Effective date: October 23, 2013. *See* N.Y. Register October 23, 2013.

Hospice Operational Rules

Notice of Proposed Rulemaking. The Department of Health proposed an amendment of Parts 700, 717, 793 and 794 of Title 10 NYCRR to implement hospice expansion. *See* N.Y. Register October 23, 2013.

Tanning Facilities

Notice of Adoption. The Department of Health amended Subpart 72-1 of Title 10 NYCRR to further clarify the authority of local jurisdictions to enact and enforce local regulations governing tanning facilities. Filing date: October 22, 2013. Effective date: November 6, 2013. *See* N.Y. Register November 6, 2013.

Unauthorized Providers of Health Services

Notice of Adoption. The Department of Financial Services added Subpart 65-5 of Title 11 NYCRR to establish standards and procedures for the investigation and suspension or removal of a health service provider's authorization. Filing date: October 24, 2013. Effective date: November 13, 2013. *See* N.Y. Register November 13, 2013.

Capital Projects for Federally Qualified Health Centers (FQHCs)

Notice of Proposed Rulemaking. The Department of Health proposed the amendment of section 86-4.16 of Title 10 NYCRR to exempt capital projects with a total budget of less than $3 million from Certificate of Need requirements. *See* N.Y. Register November 13, 2013.

Assisted Living Residences (ALRs) and Adult Care Facilities (ACFs)

Notice of Proposed Rulemaking. The Department of Health proposed the amendment of sections 487.4 and 488.4 of Title 18 NYCRR and sections 1001.7 of Title 10 NYCRR to simplify the pre-admission and annual

resident medical evaluation process for ALRs and ACFs. *See* N.Y. Register November 20, 2013.

Definition of Pediatric Severe Sepsis Update

Notice of Proposed Rulemaking. The Department of Health proposed the amendment of section 405.4 of Title 10 NYCRR to update the pediatric severe sepsis definition to be consistent with generally accepted medical standards and to reflect current practices. *See* N.Y. Register December 4, 2013.

Hospital Indigent Care Pool Payment Methodology

Notice of Emergency / Proposed Rulemaking. The Department of Health proposed the addition of section 86-1.47 to Title 10 NYCRR to establish the methodology for indigent care pool payments to general hospitals for the 3-year period 1/1/13 through 12/31/15. Filing date: November 20, 2013. Effective date: November 20, 2013. *See* N.Y. Register December 11, 2013.

Advance Directives

Notice of Proposed Rulemaking. The Department of Health proposed the amendment of section 400.21 and the repeal of sections 405.43 and 700.5 of Title 10 NYCRR to establish a decision making process to allow competent adults to appoint an agent to decide about health care treatment. *See* N.Y. Register December 11, 2013.

NYS Medical Indemnity Fund

Notice of Emergency Rulemaking. The Department of Health amended Part 69 of Title 10 NYCRR to provide the structure within which the NYS Medical Indemnity Fund will operate. Filing date: November 27, 2013. Effective date: November 27, 2013. *See* N.Y. Register December 18, 2013.

Presumptive Eligibility for Family Planning Benefit Program

Notice of Emergency / Proposed Rulemaking. The Department of Health proposed the amendment of section 360-3.7 of Title 18 NYCRR to set criteria for the Presumptive Eligibility for Family Planning Benefit Program. Filing date: December 2, 2013. Effective date: December 2, 2013. *See* N.Y. Register December 18, 2013.

Prevention of Influenza Transmission

Notice of Emergency Rulemaking. The Office of Mental Health added Part 509 to Title 14 NYCRR to require unvaccinated personnel to wear surgical masks in certain OMH-licensed or operated psychiatric centers during flu season. Filing date: December 2, 2013. Effective date: December 2, 2013. *See* N.Y. Register December 18, 2013.

Incident Reporting in OASAS-Certified, Licensed, Funded or Operated Programs

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 836 and added new Part 836 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 20, 2013. Effective date: December 20, 2013. *See* N.Y. Register January 8, 2014.

Credentialing of Addictions Professionals

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 853 and added new Part 853 to Title NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 20, 2013. Effective date: December 20, 2013. *See* N.Y. Register January 8, 2014.

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

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 810 and added new Part 810 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 20, 2013. Effective date: December 20, 2013. *See* N.Y. Register January 8, 2014.

Patient Rights

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 815 and added new Part 815 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 20, 2013. Effective date: December 20, 2013. *See* N.Y. Register January 8, 2014.

Criminal History Information Reviews

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services added Part 805 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 20, 2013. Effective date: December 20, 2013. See N.Y. Register January 8, 2014.

Children's Camps

Notice of Emergency Rulemaking. 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: December 20, 2013. Effective date: December 20, 2013. *See* N.Y. Register January 8, 2014.

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

Notice of Emergency Rulemaking. The Department of Health amended Parts 487 and 488 of Title 18 NYCRR to revise Parts 487 and 488 in regards to the establishment of the Justice Center for Protection of People with Special Needs. Filing date: December 24, 2013. Effective date: December 24, 2013. *See* N.Y. Register January 8, 2014.

Disclosure of Quality and Surveillance-Related Information

Notice of Proposed Rulemaking. The Department of Health proposed adding section 400.25 to Title 10 NYCRR to disclose identified nursing quality indicator information upon request to any member of the public. *See* N.Y. Register January 8, 2014.

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

Notice of Emergency Rulemaking. The Office of Mental Health repealed Part 524 and added new Part 524; and amended Parts 501 and 550 of Title 14 NYCRR to enhance protections for people with mental illness served in the OMH system. Filing date: December 20, 2013. Effective date: December 20, 2013. *See* N.Y. Register January 8, 2014.

Rates of Reimbursement—Hospitals Licensed by the Office of Mental Health

Notice of Emergency / Proposed Rulemaking. The Office of Mental Health amended Part 577 of Title 14 NYCRR to remove the 2014 trend factor for article 31 private psychiatric hospitals effective January 1, 2014. Filing date: December 20, 2013. Effective date: December 20, 2013. *See* N.Y. Register January 8, 2014.

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

Notice of Emergency Rulemaking. The Office for People with Developmental Disabilities amended Parts 624, 633 and 687; and added Part 625 to Title 14 NYCRR to enhance protections for people with developmental disabilities served in the OPWDD system. Filing date: December 24, 2013. Effective date: December 25, 2013. *See* N.Y. Register January 8, 2014.

Updates to SSI Offset and SNAP Benefit Offset

Notice of Emergency / Proposed Rulemaking. The Office for People with Developmental Disabilities amended sections 671.7 and 686.17 of Title 14 NYCRR to adjust reimbursement to affected providers for rent and food costs. Filing date: December 31, 2013. Effective date: January 1, 2014. *See* N.Y. Register January 15, 2014.

Appeals, Hearings and Rulings

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 368, and amended Part 831 of Title 14 NYCRR to consolidate Part 800s regulations promulgated prior to two divisions (DSASA and DAAA) becoming one office. Filing date: January 14, 2014. Effective date: January 29, 2014. *See* N.Y. Register January 29, 2014.

Repeal of 14 NYCRR Parts 10, 51, 71 and 103

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Parts 10, 51, 71 and 103 of Title 14 NYCRR to repeal outdated regulations. Filing date: January 14, 2014. Effective date: January 29, 2014. *See* N.Y. Register January 29, 2014.

Repeal of 14 NYCRR Parts 10, 51, 71 and 103

Notice of Adoption. The Office of Mental Health repealed Parts 10, 51, 71 and 103 of Title 14 NYCRR to repeal several outdated regulations. Filing date: January 14, 2014. Effective date: January 29, 2014. *See* N.Y. Register January 29, 2014.

Repeal of 14 NYCRR Parts 10, 51, 71 and 103

Notice of Adoption. The Office for People with Developmental Disabilities repealed Parts 10, 51, 71 and 103 of Title 14 NYCRR to repeal several outdated regulations. Filing date: January 14, 2014. Effective date: January 29, 2014. *See* N.Y. Register January 29, 2014.

Provider Requirements for Insurance Reimbursement of Applied Behavior Analysis

Notice of Emergency Rulemaking. The Department of Financial Services added Part 440 (Regulation 201) to Title 11 NYCRR to establish standards of professionalism, supervision, and relevant experience for providers of Applied Behavior Analysis. Filing date: January 17, 2014. Effective date: January 17, 2014. *See* N.Y. Register February 5, 2014.

Reduction to Statewide Base Price

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.16 of Title 10 NYCRR to continue a reduction to the statewide base price for inpatient services. Filing date: January 16, 2014. Effective date: January 16, 2014. *See* N.Y. Register February 5, 2014.

Statewide Pricing Methodology for Nursing Homes

Notice of Emergency Rulemaking. The Department of Health added section 86-2.40 to Title 10 NYCRR to establish a new Medicaid reimbursement methodology for nursing homes. Filing date: January 17, 2014. Effective date: January 17, 2014. *See* N.Y. Register February 5, 2014.

Episodic Pricing for Certified Home Health Agencies (CHHAs)

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.44 of Title 10 NYCRR to exempt services to a special needs population from the episodic payment system for CHHAs. Filing date: January 17, 2014. Effective date: January 17, 2014. *See* N.Y. Register February 5, 2014.

Change to Previous Regulations on Reimbursement of Prevocational Services Delivered in Sheltered Workshops

Notice of Adoption. The Office for People with Developmental Disabilities amended section 635-10.5 of Title 14 NYCRR to allow reimbursement for individuals who were enrolled in prevocational services in sheltered workshops before July 1, 2013. Filing date: January 21, 2014. Effective date: February 5, 2014. *See* N.Y. Register February 5, 2014.

Empire Clinical Research Investigator Program (ECRIP)

Notice of Emergency Rulemaking. The Department of Health added section 86-1.46 to Title 10 NYCRR to ensure that the redesigned ECRIP will continue individual physician research awards and provide larger center awards to teaching hospitals. Filing date: January 24, 2014. Effective date: January 24, 2014. *See* N.Y. Register February 12, 2014.

Capital Projects for Federally Qualified Health Centers (FQHCs)

Notice of Emergency Rulemaking. The Department of Health amended section 86-4.16 of Title 10 NYCRR to state that capital projects with a total budget of less than $3 million shall be exempt from Certificate of Need (CON) requirements. Filing date: January 24, 2014. Effective date: January 24, 2014. *See* N.Y. Register February 12, 2014.

Restraint and Seclusion

Notice of Proposed Rulemaking. The Office of Mental Health proposed the amendment of Parts 27, 526 and 587 of Title 14 NYCRR to update regulations governing the use of restraint and seclusion in mental health facilities. *See* N.Y. Register February 12, 2014.

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, Associate, of Greenberg Traurig's Health and FDA Business Group, and Edward Ohanian, a law clerk in Greenberg Traurig's Albany office, 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 Eugene M. Laks

RX Now, Inc., d/b/a Procare Pharmacy (DOH administrative hearing decision dated November 19, 2013, James F. Horan, *Administrative Law Judge).* Based upon an inventory audit of the pharmacy's bills to wholesalers for 10 specific drugs, the OMIG concluded that the pharmacy had billed Medicaid $1.8 million since enrollment in Medicaid for prescription drugs that the pharmacy did not possess. A Medicaid overpayment of $1.8 million was recovered through withholding. In addition, the supervising pharmacist had paid undercover police officers posing as Medicaid recipients for drug prescriptions without dispensing the drugs and the pharmacy had billed the Medicaid program as if the drugs had been dispensed. The pharmacist was convicted on felony and misdemeanor counts based on his activities and sentenced to prison. The pharmacy closed and defaulted during the hearing. The owner and the pharmacist were excluded from the Medicaid program for two years and five years respectively. The audit findings and exclusions were sustained by the ALJ.

Christian Ambulette, Inc. (DOH administrative hearing decision dated October 9, 2013, Larry G. Storch, *Administrative Law Judge).* This was an OMIG audit of a statistical sample of 200 Medicaid claims for ambulette services during the period January 2004 through December 2005. An extrapolated overpayment of approximately $2 million, the meanpoint estimate, was claimed based on the OMIG audit findings. The disallowances were based upon a finding that the provider did not appropriately record time of service by hour and minute for pick up and drop off. The ALJ did not sustain the OMIG audit

findings, holding that the OMIG audit methodology was not supported by the applicable regulation for ambulette services in effect at the time of service.

LIN-WIL Transportation, Inc. (DOH administrative hearing decision dated April 25, 2013, Denise Lepicier, *Administrative Law Judge).* This was an audit of the provider's Medicaid payments for transportation services for the period January 2005 through December 2008. A determination of Medicaid overpayments of approximately $320,000 was based upon an extrapolation of audit findings from a statistical sample of 200 claims.

The provider did not contest several audit findings. Only disallowances relating to the use of a replacement vehicle and a typographical error in a driver's license number were contested and were overturned by the ALJ. The ALJ held that a repetitive typographical error in a driver's license number after the number was originally incorrectly entered into the ePaces computer program did not warrant disallowance of the claims. The Medicaid audit adjustments were reduced.

Michael Lance Klein, M.D. (DOH administrative hearing decision dated January 29, 2013, Denise Lepicier, *Administrative Law Judge).* The Department of Health Administrative Law Judge sustained Medicaid audit adjustments for the difference between what was paid to the physician by the Medicaid program and the amount, based on Medicare payment records, that should have been paid by the Medicaid program as a secondary payor to Medicare for services provided to dual-eligible persons and related adjustments for failure of the physician to bill Medicare for some dual-eligible persons.

New York State Attorney General Press Releases

Compiled by Joseph Murphy

***Suffolk County Nursing Home Sued and Nine Employees Arrested for Pattern of Neglect, Including Death of Resident and Cover-up*—February 11, 2014**—A Suffolk County nursing home, its owners and seven employees were arrested for alleged involvement with the death of a 72-year-old resident who did not receive necessary overnight ventilation care. Those arrested allegedly failed to monitor the patient or respond to alarms and falsified records or gave false statements to cover up the incident. Two other employees were also arrested and charged with other incidents of neglect and providing false statements. The owners of the facility also face a civil suit alleging $60 million in Medicaid overpayments, systematic resident neglect and corporate looting, underreporting of accidents and falsifying records. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-suffolk-county-nursing-home-employees-and-lawsuit.

***Senior Center Aide Pleads Guilty in Attempt to Steal More Than $10k From Elderly Woman in Her Care*—February 6, 2014**—A Long Island personal care assistant admitted to taking a check from the checkbook of an 88-year-old woman under her care, signed the victim's name without permission, making the check payable to her mother for $10,000 and depositing it into her mother's bank account. Under the plea agreement, the aide will serve two months in jail and get three years' probation.

http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-long-island-senior-center-aide-attempting-steal.

***Foster Care Services Agency Settles Charges of Billing Medicaid for Care of Absent Children*—February 5, 2014**—A Manhattan-based foster care services agency was alleged to have billed Medicaid for the care of children prior to their admission and after they were discharged. In the settlement, the agency will pay back $170,775 plus an additional $85,387 in penalties under the New York State False Claims Act. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-250k-settlement-ny-foundling-hospital-overbilling-medicaid.

***Nursing Home Aide Arrested for Injuring Resident and Failing to Seek Medical Help*—February 4, 2014**—A Certified Nurse's Aide at a Genesee County nursing home allegedly caused a 100-year-old nursing home resident suffering from dementia to fall from her wheelchair by moving her without the assistance of another staff member in violation of the individual care plan. The fall resulted in a laceration and pain, but the aide allegedly failed to seek medical assistance for the resident. The aide has been charged with an E felony count of Endangering the Welfare of an Incompetent or Physically Disabled Person. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nursing-home-aide-who-injured-resident-and-failed.

***Payor Settles Charges of Failing to Offer Continuation Coverage to Young Adults and Wrongfully Denying Claims for Medical Treatment*—January 29, 2014**—The payor allegedly violated New York's Age 29 Law, which requires health insurers to offer continuation health coverage to children of plan members until they turn 30 years old, by failing to send statutorily required letters to more than 8,000 of its members and failing to notify almost 1,000 members that their coverage had been terminated. The settlement requires the payor to reinstate health coverage to the young adults whose coverage was terminated and to pay approximately $90,000 in denied claims and a $100,000 civil penalty. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-emblemhealth-failing-offer-continuation-coverage.

***Physician Arrested on Charges of Selling Narcotic Prescriptions to Medicaid Recipient*—January 27, 2014**—An emergency room doctor was charged with selling prescriptions for Lortab to a Medicaid recipient who then returned half of the dispensed tablets to the doctor. The doctor allegedly never provided a medical examination or treatment for the hydrocodone-dependent Medicaid recipient. He was charged with a C felony for criminal sale of a prescription for a controlled substance. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-doctor-who-illegally-sold-prescriptions.

***Rochester Man Pleads Guilty to Posing as Optometrist and Ophthalmic Dispenser*—January 16, 2014**—A Rochester man admitted to fraudulently billing Medicaid and private health insurers more than $115,000 for optometrist and ophthalmic dispensing services without having obtained a valid New York State license. He was charged with various criminal and civil counts and is scheduled to be sentenced in the criminal case in June in Monroe County. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-conviction-rochester-man-who-earned-more-115k-posing.

***Health Care Insurer Settles Claims for Wrongfully Denying Mental Health Treatment Claims*—January 15, 2014**—Cigna Corporation agreed to reprocess and pay $33,000 for hundreds of claims for nutritional counseling for eating disorders and other mental health conditions to members who were denied benefits in violation of Timothy's Law, which requires health insurance companies to provide mental health benefits on par with other medical benefits. Cigna will also eliminate its three-visit cap for mental health conditions and pay a $23,000 civil penalty. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-health-care-insurer-wrongfully-denying-mental.

***Nurse's Aide Pleads Guilty to Abusing Elderly Nursing Home Resident*—January 14, 2014**—A nurse's aide at a rehabilitation and nursing center in Albany accepted a class E felony charge for twisting an elderly patient's arm behind her head and breaking her arm. The nurse is expected to be sentenced to 30 days in jail and five years' probation. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-nurse-who-abused-elderly-patient.

***New York Joins in $40 Million Kickback Settlement with Medical Supplier*—January 9, 2014**—The federal lawsuit by all 50 states and the U.S. government alleged civil violations under federal and state false claims acts for unlawful marketing and kickbacks to promote sales of the supplier's surgical preparation solution, Chloraprep, for non-FDA approved "off-label" use. New York will collect more than $2 million plus interest. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-40m-settlement-resolving-fraud-allegations-against-health.

***Rochester Home Health Agency Settles Charges It Overbilled Medicaid for Inflated Hours and Work by Uncertified Aides*—January 9, 2014**—The agency will refund $2.5 million for more than 6,500 hours of services provided by uncertified home health aides and billing for non-patient care services such as country club dues, advertising costs, marketing salaries, company vehicles and interest expense on business loans. The agency also self-disclosed the unwitting submission of false timesheet claims for inflated hours by home health aides. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-25-m-settlement-rochester-home-health-agency-defrauding.

***Pharmaceutical Manufacturer Sued, and Pharmacy Settles Charges, Relating to Kickback Scheme*—January 8, 2014**—The AG sued Novartis in federal district court alleging that the manufacturer paid kickbacks to a New York pharmacy that placed thousands of calls to Medicaid transfusion patients to induce them to continue using the blood medication Exjade despite harmful side effects. The pharmacy will pay $15 million to reimburse Medicare and Medicaid for excessive prescriptions nationally, including $895,000 relating to New York Medicaid recipients. The complaint alleges that Novartis used rebates, discounts and its control of Exjade prescriptions to pay kickbacks to BioScrip and the two other pharmacies in its closed network for the drug, rewarding whichever pharmacy kept patients on the drug the longest. New York and eight other states sued under New York's false claims act and other statutes. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-lawsuit-against-pharmaceutical-giant-novartis-and-related-15.

***Owners and Manager of Bronx Home Health Care Agency Arrested for Failure to Pay Workers*—January 8, 2014**—The trio face felony charges related to scheme to defraud for failing to pay 62 home health care aides for all the hours they worked. They also face tax fraud and other charges for allegedly not providing workers' compensation insurance, failing to file quarterly tax returns, and failing to pay all of their unemployment insurance taxes. The AG also obtained a civil forfeiture order to seize up to $95,767.96. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-bronx-home-health-care-agency-owners-and-manager-who.

***Nurse Sentenced to Two Years Prison for Charging Medicaid for Services Double Billed or Not Worked*—January 7, 2014**—A licensed practical nurse providing home care for a disabled Bronx boy pleaded guilty to larceny and will pay $939,000 in restitution for billing over a seven-year period for hours that she did not work or that were paid by a private insurance policy. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-two-year-prison-term-licensed-practical-nurse-nyc-home-care.

***North Country Provider Settles MFCU Investigation for $455,000 in Medicaid Overpayments*—December 17, 2013**—A personal care aide and certified home health services agency based in Potsdam agreed to refund overpayments it received from 2005 to 2012, stemming from incorrectly completed cost reports that inflated its reimbursement rate. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-north-country-medicaid-provider.

***Assistant Manager of Disability Services Center Arrested for Stealing Money From Disabled Residents*—December 17, 2013**—A former employee of a center for individuals with disabilities in Schoharie was charged with larceny and falsifying business records for allegedly using residents' personal allowance funds to buy herself more than $1,000 worth of cell phones, calling cards, and iTunes gift cards. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-former-assistant-manager-disability-services-center.

***AG Settles with Two Utica Hospitals, Resolving Competition Concerns and Allowing Merger*—December 11, 2013**—Faxton-St. Luke's Healthcare and St. Elizabeth Medical Center entered into a settlement with the Attorney General to resolve concerns that a proposed merger of the two acute care facilities would adversely affect competition in the healthcare market in Utica. The two facilities, both of which have suffered significant financial losses as independent entities, agreed not to engage in exclusionary conduct with physicians and health plans, to guarantee payors the right to maintain current rates for five years, and to allow ongoing monitoring by the Attorney General. The settlement also ensures that the merger between one secular and one Roman Catholic hospital will not affect the current level of and access to reproductive health services. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-utica-hospitals-address-competitive-concerns.

***College Health Insurer Settles Charges of Overcharging Student Health Plans*—December 3, 2013**—Markel Insurance Company agreed to refund $2.75 million and pay a $990,000 penalty in response to allegations its health and accident policies failed to meet minimum loss ratios requiring plans to pay at least 65 cents on medical care for every dollar of premium. The insurer also allegedly paid improper broker bonuses conditioned on the brokers' keeping loss ratios below the legal minimum. http://www.ag.ny.gov/press-release/ag-schneiderman-and-DFS-superintendent-lawsky-announce-375m-settlement-insurer-for-overcharging.

***Payor Settles Charges of Improper Denials for $3.1 million*—November 28, 2013**—The insurer will refund overpayments for out-of-pocket expenses made by members or absorbed by providers after required deductibles were met. The payor stated that the accounting errors resulted from a software glitch. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-3-million-settlement-excellus-bluecross-blueshield-requiring.

***Mother and Son Charged with Filing False Medicaid Claims in Nursing Home Scheme*—November 14, 2013**—The owner of a Manhattan-based nursing agency and her employee son were arrested for allegedly submitting falsified claim forms doctored to conceal that nurses routinely exceeded the limit of 16 hours per shift by working up to 24 to 48 hours straight. Allegedly, these violations of Medicaid regulations resulted in improper claims of more than $300,000. http://www.ag.ny.gov/press-release/ag-schneiderman-

announces-arrests-mother-and-son-operating-nursing-agency-filed.

***Albany Head Shop Owner Fined $14,000 and Agrees to Remove Mislabeled Designer Drugs*—November 8, 2013**—The owner of a head shop in Albany is barred by a consent order and judgment after an undercover investigation uncovered the sale of synthetic drugs in violation of New York's labeling laws. In 12 other lawsuits by the AG, judges have also granted temporary restraining orders similarly banning the sale of synthetic drugs by 16 other New York head shops. http://www.ag.ny.gov/press-release/ag-schneiderman-secures-permanent-ban-sale-mislabeled-designer-drugs-and-penalty-owner.

***Michigan Man Pleads Guilty to Grand Larceny for Obtaining Medicaid Payments with Illegally Obtained Medical License*—October 24, 2013**—Man billed Medicaid for physician's services, sentenced to one year of incarceration and $21,000 in restitution, plus $300,000 in settlement of a civil suit. When he applied for a New York medical license, he allegedly misrepresented having completed his undergraduate and residency training. He then enrolled as a Medicaid provider having falsely represented that there were no proceedings pending that could result in the revocation of his medical license, notwithstanding a pending proceeding before the State Board for Professional Medical Conduct which ultimately revoked his license. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-and-300k-settlement-case-michigan-man-who.

***Former Disabled-Services Employee Pleads Guilty to Fraudulent Billing*—October 23, 2013**—A former Medicaid service coordinator who submitted a fake college diploma to obtain his job that required an associate's degree or registered nurse qualification pleaded guilty to one count of petit larceny and was sentenced to three years of probation and will pay $14,934.30 in restitution for salary and benefits received. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-former-disabled-services-employee-fraudulent.

***Long Island Ambulette Company Owner Pleads Guilty to Stealing $348k From Medicaid*—September 23, 2013**—An ambulette company billed for more than 2,500 transportation services not provided and more than 4,000 trips by untrained and improperly licensed drivers. The owner and nine employees pleaded guilty in the scheme involving falsified records, and one other faces charges. The owner received five years' probation and will pay a $348k fine. MFCU is seeking six figures in a civil enforcement action against the owner. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-owner-long-island-ambulette-company-who-stole.

New York State Office of the Medicaid Inspector General Update

Compiled by the Editor

Budget Testimony from Medicaid Inspector General James Cox—February 4, 2014—http://www.omig.ny.gov/latest-news/753-2014-budget-testimony.

Governor Cuomo Announces $851 in Medicaid Recoveries—February 3, 2014—http://www.omig.ny.gov/latest-news/752-record-recoveries.

Brooklyn Pharmacy Denied Medicaid Enrollment—December 12, 2013—http://www.omig.ny.gov/latest-news/745-brooklyn-pharmacy-denied-enrollment.

Webinar #19—"Governing Body's Role in Program Integrity"—December 11, 2013—http://www.omig.ny.gov/resources/webinars/742-webinar-19-governing-body-s-role-in-program-integrity.

Q and A for Webinar #18—December 9, 2013—http://omig.ny.gov/webinar18-questions-and-answers.

OMIG Finds $496 Million in Medicaid Home Health Error Payments—October 30, 2013—http://www.omig.ny.gov/latest-news/697-496-million.

OMIG Audit Protocols Posted to the OMIG Website as of February 11, 2014—Assisted Living Program, Certified Home Health Agency, Diagnostic and Treatment Center, Durable Medical Equipment, Hospital Outpatient Department (OPD) Emergency Room/Clinic, Hospital Outpatient Department (OPD) Laboratory, Hospital Outpatient Department (OPD) Ordered Ambulatory Other Than Laboratory, Long Term Home Health Care Program, OPWDD Day Habilitation, OPWDD Day Treatment, OPWDD IRA Residential Habilitation, OPWDD Medicaid Service Coordination, OMH Rehabilitation Adult Services, OASAS Inpatient Chemical Dependence Rehabilitation Services, OASAS Outpatient Chemical Dependence Services, OMH Comprehensive Psychiatric Emergency Programs, OMH Rehabilitation Services Family-Based Treatment, Pharmacy, Transportation Ambulette, Transportation Taxi/Livery.

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

Mr. Laks is Of Counsel to Hiscock & Barclay, LLP in its Albany Office, focusing his practice on health care reimbursement, health care networks and affiliations, managed care law, and federal and state statutory and regulatory compliance.

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

In the Law Journals

2011-2012 Survey Of New York Law: Health Law, Kirsten A. Lerch and Stephen F. Johnson, 63 Syracuse L. Rev. 805 (2013).

A Catholic Perspective On The Department Of Health And Human Services Mandate Concerning Contraception, Tom Judge, 15 DePaul J. Health Care L. 33 (2013).

Acquiring The Distressed Health Care Business: Dealing With Government Provider Agreement Liabilities, 33-2 Am. Bankruptcy Institute J. (Feb 2014).

Announcing Remedies For Medical Injury: A Proposal For Medical Liability Reform Based On The Patient Protection And Affordable Care Act, Steven E. Raper, MD, 16 J. Health Care L. & Pol'y 309 (2013).

Challenges to Employed Physicians' Compensation: Direct, Indirect, or Unintelligible Compensation, AHLA, J. Health & Life Sciences Law, Vol. 7, No. 2, Pg. 1, February, 2014.

Characteristics Of Health Professionals In A Mandated Ethics Tutorial After Violating Sexual Boundaries With Patients, S. Michael Plaut, Janet Klein Brown, Mira Brancu, Rebecca C. Wilbur, Katherine Rios, 16 J. Health Care L. & Pol'y 353 (2013).

Closing The Gaps And Loopholes: Analyzing Tax Exemption Of Non-Profit Hospital Joint Ventures After The Affordable Care Act, Shirley S. Pan, 39 Am. J. L. And Med. 671 (2013).

Comment: Delegation And The Destruction Of American Liberties: The Affordable Care Act And The Contraception Mandate, Michael Barone, Jr., 29 Touro L. Rev. 795 (2013).

Euthanasia And Physician-Assisted Suicide: A Comparison Of E.U. And U.S. Law, Stephen Hoffman, 63 Syracuse L. Rev. 383 (2013).

Freedom Of Choice At The End Of Life: Patients' Rights In A Shifting Legal And Political Landscape (Symposium), 58 N.Y.L. Sch. L. Rev. 233 (2013).

- *Introduction*, Peter J. Strauss
- *Right-To-Die Cases: A New York Historical Perspective*, Sol Wachtler
- *Give Me Liberty At My Death: Expanding End-Of-Life Choice In Massachusetts*, Kathryn L. Tucker
- *A New Life For Wrongful Living*, Nadia N. Sawicki
- *The Limits Of Autonomy: Force-Feedings In Catholic Hospitals And In Prisons*, Ann Neumann
- *Advance Directives, Dementia, And Eligibility For Physician-Assisted Death*, Paul T. Menzel
- *Dispute Resolution Mechanisms For Intractable Medical Futility Disputes*, Thaddeus Mason Pope
- *Disability, The End Of Life, And Why The Conversation Is Still So Difficult*, Alicia Ouellette
- *From Schiavo To Death Panels: How Media Coverage Of End-Of-Life Issues Affects Public Opinion*, Sherrie Dulworth
- *Health Justice Denied Or Delayed At The End Of Life: A Crisis Needing Remedial Action*, David C. Leven

Genetic Testing: Legal and Ethical Issues and Duties for Providers. AHLA, J. Health & Life Sciences Law, Vol. 7, No. 2, Pg. 92, February, 2014.

Grand Bargains For Big Data: The Emerging Law Of Health Information, Frank Pasquale, 72 MD. L. Rev. 682 (2013).

Health Reform And The Supreme Court: The ACA Survives The Battle Of The Broccoli And Fortifies Itself Against Future Fatal Attack, Alicia Ouellette, 76 Alb. L. Rev. 87.

"I Hate My Doctor": Reputation, Defamation, and Physician-Review Websites, Sean D. Lee, 23 Health Matrix 573 (2013).

Improving The Quality Of Health Care: Where Law, Accreditation, And Professionalism Collide, Mark R. Chassin, 23 Health Matrix 395 (2013).

Major Trends In Public Health Law And Practice: A Network National Report: Public Health And The Law, James G. Hodge, Jr., Leila Barraza, Jennifer Bernstein, Courtney Chu, Veda Collmer, Corey Davis, Megan M. Griest, Monica S. Hammer, Jill Krueger, Kerri McGowan Lowrey, and Daniel G. Orenstein, 41 J.L. Med. & Ethics 737 (2013).

Medical-Legal Partnerships In The Age Of The Affordable Care Act, Diane M. Goffinet, James A. Teufel, Diane Land, Andrew Weaver, and Woody Thorne, 47 Clearinghouse Rev. 265 (2013).

Nursing Is Not A Lesser Included Profession: Why Physicians Should Not Be Allowed To Establish The Nursing Standard Of Care, Tsvetelina Gerova-Wilson, 16 Quinnipiac Health L.J. 43 (2013).

Professions And Businesses: Physicians, Acupuncture, Physician Assistants, Cancer And Glaucoma Treatment, Respiratory Care, Clinical Perfusionists, And Orthotics And Prosthetics Practice, Andrea Iglesias & Robert Mollohan, 30 Ga. St. U.L. Rev. 215 (2013).

Protection For Psychotherapy Notes Under The HIPAA Privacy Rule: As Private As A Hospital Gown, Stephanie O. Corley, 22 Health Matrix 489 (2013).

Religious Refusals Under The Affordable Care Act: Contraception As Essential Health Care, Colleen Connell, Lorie Chaiten and Richard Muniz, 15 DePaul J. Health Care L. 1 (2013).

Self-Insurance For Small Employers Under The Affordable Care Act: Federal And State Regulatory Options, Timothy Stoltzfus Jost And Mark A. Hall, 68 N.Y.U. Ann. Surv. Am. L. 539 (2013).

The Affordable Care Act And The Medicare Program: Linking Medicare Payment To Quality Performance, Eleanor D. Kinney, 68 N.Y.U. Ann. Surv. Am. L. 567 (2013).

The Good, The Bad, And The Ugly: The Unnecessarily Broad Impact Of Qui Tam Civil False Claims Act Cases On Rural

Health Care Providers, Andrew M. Hyer, 23 Health Matrix 459 (2013).

The Politics Of Information: Informed Consent In Abortion And End-Of-Life Decision Making, Sonia M. Suter, 39 Am. J. L. and Med. 7 (2013).

The Rules of the Fight Must Be Fair: States Should Pass a Uniform Code for Nonprofit Hospital Tax Exemption of Real Property, Lowell R. Mintz, 26 J.L. & Health 415 (2013).

The Stark Physician Self-Referral Law And Accountable Care Organizations: Collision Course Or Opportunity To Reconcile Federal Anti-Abuse And Cost-Saving Legislation?, Benjamin Holland Able, 26 J.L. & Health 315 (2013).

The Union Of Contraceptive Services And The Affordable Care Act Gives Birth To First Amendment Concerns, Evelyn M. Tenenbaum, 23 Alb. L.J. Sci. & Tech. 539 (2013).

Trust Me I'm A Doctor: The Struggle Over Scope Of Practice And Its Effect On Health Care Fraud And Abuse, Gretchen Harper, 15 DePaul J. Health Care L. 237 (2013).

When Privacy Is Not An Option: Codifying The Contours Of Necessary Third Parties In Emergency Medical Situations, Chris Chambers Goodman, 63 Syracuse L. Rev. 399 (2013).

For Your Information

By Claudia O. Torrey

In the Fall 2013 issue of the *Health Law Journal*, this author stated that according to several *Health Affairs* authors[1] (employed at the Centers for Medicare and Medicaid Services),

> health spending growth through 2013 is expected to remain slow due: to the sluggish economic recovery, increases in cost-sharing requirements for the privately insured, and slow growth in public programs (for example, the United States Supreme Court decision making Medicaid expansion under the Affordable Care Act ["ACA"] optional for States). Ironically, health insurance coverage is set to expand via exchanges under the ACA as of October 1, 2013.
>
> In 2014, projected growth in health spending is 6.1 percent with a projection of 6.2 percent per year through at least 2022; the sustained growth based on predictions of both improved economic conditions and an aging population. Time will tell whether or not coverage expansion under the ACA adds to the projected sustained growth in national health spending.

On February 12, 2014, the Department of Health and Human Services released its coverage report regarding enrollees under the Patient Protection and Affordable Care Act.[2] The report revealed 3.3 *million people selecting "health care exchange" plans for the time* period of October 1, 2013 to February 1, 2014. Ironically, just when the country is increasing its numbers of people with health insurance, the United States is experiencing a dearth of primary care physicians amongst a growing aging population![3] A suggested approach to this problem involves the use of the terms telemedicine,[4] telehealth,[5] and eHealth;[6] collectively, these terms are sometimes categorized as "connected health."[7] The marriage of connected health and health care will create a digital learning curve that arguably can be eased by following guidance laid out in the 2001 Institute of Medicine ("IOM") report-—*Crossing the quality chasm: a new health system for the 21st century*.[8] The IOM report called for health care that is safe, effective, patient-centered, timely, efficient, and equitable.

According to Dr. Lee H. Schwamm, the Telehealth Medical Director at Massachusetts General Hospital in Boston, health care has largely been a local and synchronous service. Dr. Schwamm asserts that the future of health care delivery can be distilled down to seven critical strategies: understanding patients' and providers' expectations; untethering telehealth from traditional revenue expectations; deconstructing the traditional health care encounter; being open to discovery; being mindful of the importance of space in which virtual encounters occur; redesigning care to improve value in health care; and being bold and visionary.[9] Relentless innovation is a crucial driver in creating value across all industries, and health care is no exception;[10] the next frontier or "brave new world" of health care will have to tackle the issue of how best to train the next generation of health care providers to utilize technology as part of "good" medicine.

Endnotes

1. *National Health Expenditure Projections, 2012-2022: Slow Growth Until Coverage Expands And Economy Improves*, Cuckler, Gigi A. et al., http://content.healthaffairs.org/lookup/doi/10.1377/hlthaff.2013.0721 (Internet, September 2013).
2. http://aspe.hhs.gov/health/reports/2014/MarketPlaceEnrollment/February2014/ib_2014feb_enrollment.
3. Inglehart, JK. "*Expanding the role* of advanced nurse practitioners—risks and rewards," N. Engl.J. Med. 2013; 368 (20):1935-41.
4. According to the American Telemedicine Association, Telemedicine is the use of medical information exchange from one site to another via electronic communications to improve a patient's clinical health status. American Telemedicine Association, *What is telemedicine?*, available at http://www.Americantelemed.org/learn.
5. Telehealth services allow consumers to access health education and self-management support through the Internet via computers and/or wireless devices. *See* Kvedar,J., Coye, MJ., Everett, W. "Connected Health: A Review Of Technologies And Strategies To Improve Patient Care With Telemedicine And Telehealth," *Health Affairs*, 33, no.2 (2014: 194-99.
6. *Id.* (services accessed mobile wireless technologies).
7. *Id.*
8. National Academies Press, Washington, DC.
9. Schwamm, LH., "Telehealth: Seven Strategies To Successfully Implement Disruptive Technology And Transform Health Care," *Health Affairs*, 33, no. 2 (2014): 200-06.
10. *Id.*

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

"Of Vital Importance": The New York State Task Force on Life and the Law's *Report and Recommendations for Research with Human Subjects Who Lack Consent Capacity*

By Valerie Gutmann Koch and Susie A. Han

American history has been rife with human subjects research (HSR) scandals—particularly those that involve "vulnerable" populations—including several in New York State, such as those that occurred at the Willowbrook State School and the Jewish Chronic Disease Hospital.[1] In response, state and federal laws and regulations were enacted to ensure voluntary informed consent for participants and institutional review board (IRB) oversight of HSR. However, these laws and regulations do not provide any special oversight mechanisms or protections to ensure the ethical and safe inclusion of cognitively impaired adults in research.

Although research involving adults lacking consent capacity is permitted in New York State, until recently it was limited because of uncertainty about who could provide surrogate consent to participation. In 2010, the Family Health Care Decisions Act changed the legal landscape by permitting surrogate consent to health care and potentially opened up the field of research requiring surrogate consent. However, there remain few—if any—rules and little guidance at both the federal and state level to ensure consistently ethical conduct of research involving adults lacking consent capacity. While some institutions and investigators are conducting researching with this population without oversight or guidance, others are taking an extremely conservative approach and are excluding these individuals from research, citing concerns about vulnerability and exploitation. Without safeguards that are both adequate and robust but not overly burdensome, this will remain a challenge to the conduct of ethical research. Thus, IRBs, investigators, and research institutions have appealed to the New York State Task Force on Life and the Law (the Task Force)[2] for guidance on how to conduct research involving this vulnerable population.

Human subjects research plays an essential role in advancing biomedical and behavioral science and strengthening our ability to prevent and treat human diseases and medical conditions. The optimal condition for research involving human subjects is for the participant to provide first-person informed consent. To learn about and seek cures for the broad range of diseases that impair cognition, however, research requires the participation of individuals who cannot themselves provide informed consent. Laws that exclude individuals who lack consent capacity actually disadvantage this population by preventing scientific advances for conditions that cause decisional incapacity. Although concerns about how to conduct research involving individuals unable to give first-person informed consent are valid and important, justice requires the creation of guidance and procedures that will allow these individuals to benefit from scientific advances while ensuring that their interests are protected.

To address this significant inconsistency in the oversight and conduct of research, the Task Force drafted a set of legal and ethical guidance regarding the conduct of research in New York State involving adults who lack consent capacity. This article addresses the development and key content of the guidance, which may serve as a model for research in other states and at the federal level. An underlying goal of the work is to ensure that research protocols are available to all individuals, including this population, so that they may also experience the benefits of research and share its risks and burdens as their non-cognitively impaired peers, while also ensuring the appropriate level of protections. Thus, the report provides guidance and best practices that will assist institutions, researchers, IRBs, and surrogate decision-makers in the ethical conduct and responsibilities of research involving the cognitively impaired. Without such guidance, either research will occur without appropriate protections and safeguards, or important research may not occur.

Methods

At the request of various stakeholders, the Task Force analyzed the legal and ethical implications of research involving adults lacking consent capacity. The Task Force began this endeavor in December 2007 by disseminating a survey to approximately 300 New York IRB chairs and members that requested information about their institutions' practices, if any, for conducting research involving the cognitively impaired, and their views on the regulatory landscape. More than 100 responses provided a detailed and useful qualitative account of research practices in New York, and indicated a need for guidelines to ensure consistently ethical research practices.

Since 2007, the Task Force has devoted itself to examining the issues associated with research involving cognitively impaired adults. It reviewed medical and policy literature on human subjects research, informed consent, surrogate consent, capacity assessment, risk-benefit analysis, research protections, adverse events, and related topics. It conducted extensive legal research of federal and state regulatory standards, including New York's, and case studies pertaining to human subjects research involving the cognitively impaired. It reached out and relied on

testimony from several experts from research institutions, governmental entities, and patient advocacy organizations. The Task Force analyzed previously released reports, recommendations, and draft regulations on human subjects research by the Department of Health and the public comments to these efforts,[3] and stakeholders and other interested parties provided additional perspectives and input on this project. It also took into account the controversial advisory opinion in the case *T.D. v. N.Y. State Office of Mental Health*,[4] in which the court addressed the need for special protections where research includes individuals who lack consent capacity when surrogate consent is used.

In developing these guidelines, the Task Force considered and declined to recommend legislation governing research involving individuals who lack consent capacity. It concluded that because existing law permits research involving this population,[5] no statutory change is needed. The Task Force therefore identified approaches that comply with current federal and state law, including the Common Rule and New York Public Health Law 24-A,[6] to ensure ethical practices in research involving this vulnerable population.

Recommendations

In order to promote a consistently ethical approach by institutions to the protection of this vulnerable population in New York State, the Task Force made a number of important and—in some cases—unique recommendations regarding including individuals who lack consent capacity in human subjects research.[7] This guidance is necessary in order to ensure that this population is able to participate in research (as the law anticipates) with adequate and appropriate safeguards in place.

A. Participant Selection

The Task Force recommends that researchers and IRBs must ensure that there is justification for involving participants who lack consent capacity in research protocols, and in general, that the least burdened populations should be used as research participants wherever possible. Availability, compromised position, or ease of recruitment are insufficient reasons to justify the inclusion of a specific vulnerable group in research. The inclusion of such individuals may be appropriate in research that offers potential benefits to participants when standard clinical approaches are ineffective, unproven, or unsatisfactory, or when research is reviewing a new, improved standard of care that may be more effective for conditions that uniquely affect that specific population. Furthermore, IRBs should pay particular attention to the rationale behind enrolling vulnerable patients for research protocols that do not explicitly study medical conditions that impair consent capacity.

In addition, the Task Force recommends that the institutional setting for research must be scrutinized when choosing the least burdened population. If researchers propose to utilize nursing home residents or institutionalized patients, they should demonstrate why that venue is necessary,[8] because research involving these groups may be seen as increasing the risks and potential harms for an already burdened population.[9]

Where possible, particularly for high risk or no-direct-benefit research, IRBs should require research protocols to include evidence of safety and efficacy data from studies conducted in a non-impaired group prior to inclusion of cognitively impaired individuals. However, in certain circumstances, the potential benefit is unique to the cognitively impaired population, or the characteristics of the non-impaired participants may differ so greatly from the impaired population that such evidence may not be available.

B. Benefits and Risks

The Task Force recommends that, in reviewing proposed research protocols, IRBs consider whether same or similar benefits are available outside the context of research, the intent of the researcher and purpose of the study, the likelihood that all participants will receive the benefit, and the extent or amount of the potential direct benefit.

One of the core functions of an IRB is to review and approve studies that present a reasonable balance of potential benefits to risks. Research protocols can be classified as either *prospect-of-direct-benefit* or *no-direct-benefit* studies, based on the likelihood that the research will result in direct benefits that improve the health or well-being of a participant by procedures or interventions that are outside of standard health care treatment. Prospect-of-direct-benefit research has a reasonable probability of providing the proposed benefit. No-direct-benefit studies have a negligible or nonexistent probability of offering a benefit to participants.

One of the most complex ethical issues in conducting research involving these individuals is the degree of risk to which researchers may ethically expose this population. While upper limits on the level of acceptable risk may be necessary for some HSR studies, bright-line cut-offs are only appropriate in limited circumstances. The Task Force recommends that research should only be approved for individuals who have first explored all available treatment and research options and failed to receive any therapeutic benefit, and for those without any other known treatment or research options available.

In 1977, the National Commission issued a report on research involving children, suggesting a tripartite scheme for classifying research risks.[10] These three classifications are: (1) minimal risk; (2) minor increase over minimal risk; and (3) more than a minor increase over minimal risk. This scheme was incorporated into the federal regulations for research with children[11] and has

been used in numerous expert commission reports and state regulations delineating research risk in all human subjects research.[12] Although the tripartite risk scheme presents difficulties in application, it remains the most recognized and most used method to classify risks levels. The Task Force concluded that these three major risk levels are appropriate for IRBs and researchers to use for research involving individuals who lack consent capacity.

The Task Force recommends that for all human subjects research, the risk level should be minimized wherever possible to achieve the research objective. Although risk may never be eliminated completely in some studies, the Task Force recommends that procedures should be in place to assure an appropriate level of care for participants, including personalized attention to ensure safety and the use of required medical and therapeutic procedures where appropriate.

When research involves vulnerable individuals, the Task Force recommends that it is appropriate for IRBs to establish a lower ceiling for allowable risk or require a more favorable risk-benefit ratio for a protocol to be approved than they would for similar research involving non-vulnerable participants. However, for research that may offer a prospect of direct benefit, an IRB may allow a higher ceiling for allowable risk and allow a less favorable risk-benefit ratio for research.

For research that is categorized as offering no prospect of direct benefit, it may nevertheless be unclear whether the study has more than a negligible prospect of direct benefit or, if more than negligible, how much more; clarity (or its absence) often depends on the current state of available scientific knowledge. In such cases, where research offers no clear prospect of direct benefit, IRBs should determine whether the research is of "vital importance." For research to be considered of vital importance, there must be clear and significant scientific evidence that the use of such a procedure or intervention presents a reasonable opportunity to further the understanding of the etiology, prevention, diagnosis, pathophysiology, or alleviation or treatment of a condition or disorder.[13] The IRB should carefully review the hypotheses of the study and antecedent evidence, such as data from animal studies, analogous research,[14] or toxicity trial results, to evaluate whether the research is vitally important to the research population and will contribute knowledge about the disorder or condition. Furthermore, the IRB should also examine the researchers' therapeutic intent[15] and the purpose of the research study to determine whether the research is of vital importance and should be approved.

The Task Force recommends that it is acceptable for IRBs to require additional safeguards (such as requiring or recommending informed consent monitors (ICMs) and medically responsible clinicians (MRCs)) to ensure the safety and well-being of vulnerable participants. Both the degree of scrutiny by an IRB and the determination of the number and type of additional protections required should be unique to each study, and should be calibrated according to the risk level and the likelihood and significance of any direct benefit.

The Task Force recommends the following approach to oversee risk-benefit ratios for research involving individuals lacking consent capacity:

For research with *minimal risk* and a *prospect of direct benefit* to the participant, IRBs may approve such studies if the risks are reasonable in relation to the prospective benefits.

For research with *minimal risk* and *no prospect of direct benefit* to the participant, IRBs may approve such studies if the research is important to advance the scientific knowledge of a medical condition that affects the research population, and if the risks are reasonable in relation to such importance. Ethical issues related to research with minimal risk, with or without a prospect of direct benefit, are often manageable. IRBs, researchers, surrogate decision-makers, and potential participants should expect to resolve them without severely impeding research or unreasonably risking the participants' welfare, particularly when the beneficial prospect is more certain, or the benefit is expected to be more frequent or more significant.

For research with a *minor increase over minimal risk* and a *prospect of direct benefit* to the participant, IRBs may approve such studies only if the risks are reasonable in relation to the prospective benefits, if the potential benefits are similar to those available in the standard clinical or treatment setting, and if the risk-benefit ratio is favorable to participants. Such ratios are more favorable when the beneficial prospect is more certain or the benefit is expected to be more frequent or more significant. IRBs may recommend the use of ICMs, MRCs, or other additional safeguards.

For research with a *minor increase over minimal risk* and *no prospect of direct benefit* to the participant, IRBs may approve such studies only if the research is vitally important to further the understanding of the etiology, prevention, diagnosis, pathophysiology, or alleviation or treatment of a condition or disorder that affects the research population, and if the risks are reasonable in relation to the research's "vital importance."[16] Furthermore, IRBs may approve such studies only if they require mandatory rigorous procedures and oversight for enrollment and monitoring of participants through the use of safeguards, including an ICM and an MRC.

For research with a *more than a minor increase over minimal risk* and a *prospect of direct benefit* to the participant, IRBs may approve such studies only if the risks are reasonable in relation to the prospective benefits, if the potential benefits are similar to those available in the standard clinical or treatment setting, and if the risk-benefit ratio is favorable to participants. Such ratios are

less favorable when the risk is substantially more than a minor increase over minimal risk. Such ratios are more favorable when the prospect of direct benefit is more certain, or the benefit is expected to be more frequent or more significant. IRBs should require the use of ICMs and MRCs.

For research with *more than a minor increase over minimal risk* and *no prospect of direct benefit* to the participant, IRBs may approve such studies in only two circumscribed circumstances: where the potential participants have a research advance directive *or* in special situations with notification to the Department of Health and use of a special review panel. These two scenarios are addressed in the following subsections.

1. Use of Research Advance Directives (RADs)

The Task Force recommends that IRBs may approve studies in this risk-benefit category if all potential participants have, when they still had capacity, executed legally binding documents such as Research Advance Directives (RADs), which provide an individual's instructions for future research participation should s/he lose consent capacity, that explicitly state that they are willing to participate in this category of research. However, even if all participants have signed RADs, IRBs may approve such studies only if the research is of vital importance to the understanding of the etiology, prevention, diagnosis, pathophysiology, or alleviation or treatment of a condition or disorder that affects the research population and/or those similarly situated. The IRB must determine that such risks are reasonable in relation to the research's vital importance. Such risks are less likely to be reasonable if they are substantially, rather than marginally, more than a minor increase over minimal risk. Furthermore, IRBs may approve such studies only if they require mandatory rigorous procedures and oversight for enrollment and monitoring of participants through the use of safeguards, including an ICM and an MRC.

2. Notification to the Department of Health and Use of a Special Review Panel

Because so few people have RADs, the Task Force concluded that an alternative mechanism for innovative research to be approved in very limited circumstances may be necessary, and thus there are limited circumstances where a research protocol may be considered for approval even where potential participants do not have RADs. The Task Force therefore recommends a second mechanism for IRBs to approve studies with more than a minor increase over minimal risk and no prospect of direct benefit. This alternative approval process consists of several steps: (1) IRB review, (2) Department of Health notification by the IRB and possible referral by the Department to a special review panel, and (3) IRB decision to approve or reject the research protocol.

For a protocol to be considered under this alternative process, the IRB must first examine whether the research is of vital importance to the understanding of the etiology, prevention, diagnosis, pathophysiology, or alleviation or treatment of a condition or disorder that affects the research population, and if the risks are reasonable in relation to the research's vital importance. Such risks are less likely to be reasonable if they are substantially, rather than marginally, more than a minor increase over minimal risk. In addition, as noted above, although this type of research protocol must be labeled as offering no prospect of direct benefit, for some research participants, a remote possibility exists that they (or others similarly situated) may benefit from the research or from the knowledge gained.[17] In such cases, the IRB must consider whether this remote possibility of benefit exists for potential participants, and weigh it against the potential risks of the protocol. Furthermore, the IRB should ensure that the study requires rigorous procedures and oversight for enrollment and monitoring of participants through the use of safeguards, including an ICM and MRC.

If the IRB concludes that the research is of vital importance to either current research participants and/or those similarly situated, that the risks are reasonable in relation to such vital importance, and appropriate safeguards are in place, such as the ICM and MRC addressed above, the IRB should notify the Department of Health. At the discretion of the Department of Health, the Department may: (1) reject the study (and thus the research could not be approved by the IRB), (2) approve the study (whereby the research could be approved by the IRB), or (3) convene a special review panel of experts[18] who will examine the study and issue recommendations to the IRB on whether the study should be approved. If the Department of Health decides that a special review panel must examine the protocol, after the special panel has made its recommendations, the Department should refer the protocol back to the IRB for review and the IRB will make the final determination based on the panel's recommendations.

The special review panel should be comprised of experts knowledgeable about the conditions(s) or population(s) addressed by the research, to ensure that the reviewers are well-informed about the research topic and can provide meaningful commentary to aid in the IRB's decision-making.[19] While the Task Force acknowledges that the use of a special review panel may delay approval or the commencement of the study, this procedural process is important to safeguard participants. Furthermore, because only a small proportion of state-regulated research would fall into this risk-benefit category, the number of protocols that would be referred to a special review panel would likely be small. Thus, use of these panels would acknowledge the need for innovative research using the existing regulatory framework (i.e., respecting the IRB purpose and structure) and would also ensure that unethical research would not be conducted (supporting the IRB's opinion whether the protocol may be approved).

Where a protocol has been referred to a special review panel by the Department of Health, the panelists should be required to provide a written report that will be publicly available, which will include a summary of the panel's reasoning, analysis, and recommendation to the IRB. The recommendations will advise the IRB to either reject or approve the study, and will include any modifications to the protocol. In the final step of this process, the IRB would then review the recommendations and decide to approve or reject the study.

The panelists should also forward their recommendations to the Department of Health for record keeping. The Department of Health should keep the individual panel members' recommendations on file and make them available to the public upon request, which would provide a historical record of the types of research studies considered by these panels. This information may help guide researchers as they design future studies, assist IRBs with their review and oversight process of this type of risk-benefit research, and promote transparency for the general public to maintain confidence in the oversight process of this category of unique research.

C. Consent and Capacity Assessments

Informed consent is a fundamental tenet of ethically and legally acceptable human subjects research because it helps protect individuals from involuntary participation and exposure to risk. The Task Force recommends that, where possible, informed consent should be obtained in a dynamic process, as part of a continued dialogue between the potential participant and the person presenting the research protocol. The information should be presented using methods that are best suited to the capacity level of the target population. Asking detailed questions and having a discussion about the study with a knowledgeable person will help guide a potential participant in making a careful decision about whether research enrollment is appropriate (i.e., first-person decision-making). The focus of the informed consent process should be on this conversation and comprehension, rather than on the technicalities of the consent form. The Task Force recommends that informed consent be obtained, with the use of a neutral discloser, before enrollment in a research study, but should also be re-obtained when circumstances significantly change the potential benefits or risks or harms, or when new scientific information becomes available.

Cognitively impaired adults who do not have the capacity to provide first-person informed consent may nevertheless retain sufficient capacity to understand some of the more basic concepts involved in a research study and provide assent—affirmative agreement—to participate in the proposed research. Therefore, to preserve the autonomy of potential participants who are capable of assent, the Task Force recommends that researchers must seek assent from such participants in addition to informed consent from a surrogate.[20]

The Task Force recommends that where a potential participant is unable to provide or express assent, researchers must look for signs of dissent—the objection or resistance to participate in the study – both at the initiation of the study as well as once the participant is enrolled. Researchers should recognize that for this population, dissent may not be obvious. Furthermore, if signs of dissent are present, the researcher may not enroll or allow continued participation of the individual in the study.

Any participant who enrolls in a research protocol has the freedom to withdraw from the study without prejudice at any time, and this decision to withdraw should be respected. However, participants who have impaired consent capacity may be unable to express their preference to withdraw from the research. The Task Force recommends that researchers develop formal procedures to ensure that appropriate withdrawal mechanisms are available to the research population, that any withdrawal is accomplished with the least risk to the participant, and that any withdrawal, including the reason for it, is properly reported to the IRB.

Consent capacity may be impaired due to medical conditions or illnesses, chronic diseases, medication, or developmental cognitive impairment.[21] Moreover, lack of capacity may be temporary or permanent, depending on the condition. Consent capacity is best understood as occurring along a continuum—it is not simply either present or absent. Although an individual may exhibit a degree of cognitive impairment, it should not be assumed that the person does not retain sufficient capacity to consent or decline to participate in all research studies.[22] Consent capacity has a complicated relationship to clinical diagnosis and is likely to fluctuate over time and may be task-specific. Determining whether a participant has sufficient consent capacity depends not only on the individual, but on the complexity of the research protocol and the risks and benefits associated with that protocol. Thus, the threshold that distinguishes individuals who meet the consent capacity standard varies between research protocols.

Current practices for screening and evaluating consent capacity vary in type[23] and quality.[24] Selection of the best method for assessing consent capacity depends in part on the use researchers will make of the outcome. In cases where researchers seek to exclude all participants who lack consent capacity, briefer screening tools may suffice. For protocols in which researchers intend to enroll impaired individuals who require either remediation or other consent enhancement techniques to meet criteria for consent capacity, a more detailed evaluation tool may be most useful. In addition, proper use of the capacity evaluation tool may also be contingent on the inclusion or exclusion criteria of the research protocol. The Task Force recommends that researchers seeking approval of a study involving the cognitively impaired should provide the IRB with a description of the procedures and

methods to be used for the initial capacity assessment, as well as how capacity will be monitored through the course of the study (if appropriate), and include information about who will conduct the assessment and his/her qualifications.

D. Legally Authorized Representatives

When researchers are unable to obtain first-person informed consent from a potential participant, researchers may—depending on the nature of the study and the risk-benefit ratio—be permitted to enroll an individual using surrogate informed consent or according to a potential participant's RAD. However, neither the federal nor state governments have directly addressed who should act as a research legally authorized representative (LAR) for the cognitively impaired.[25] If the legislature or Department of Health promulgates rules in the future regarding who may consent, different considerations and standards of decision-making should apply to research than to treatment.[26]

The Task Force recognizes that, ideally, an individual should select an LAR before s/he no longer has consent capacity, using a legally binding document, such as a health care proxy or RAD. The Task Force prefers such appointments because it assumes that the appointed LAR has a close relationship with the individual and that a discussion regarding research preferences has taken place. In some cases, a cognitively impaired adult may retain sufficient capacity to choose a research proxy—a research agent—to make research decisions on his/her behalf, but lack capacity to consent to research participation him/herself.[27] Strict procedural mechanisms and safeguards, similar to those used in a health care proxy designation appointed while the individual has consent capacity, should be in place to ensure that an individual's appointment of a research agent using a legally binding document is an unbiased and free choice.[28] The Task Force also recommends the placement of restrictions on who may serve as an LAR to ensure that participants are adequately protected.[29]

Where an RAD has not been previously executed, it may be permissible, in some cases, for individuals lacking consent capacity to be enrolled in a research protocol with the consent of an LAR. Federal law clearly contemplates allowing surrogates to consent to research involving adults who lack consent capacity.[30] An LAR is defined under the Common Rule as "an individual or judicial body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research…."[31] However, federal law defers to the states to establish who may serve as an LAR, looking to their formulations of LAR to determine who may consent to research conducted in that state. Because New York's laws for human subjects research do not provide a research-related LAR hierarchy, the 2010 passage of the Family Health Care Decisions Act (FHCDA) changed the legal landscape by permitting surrogate consent to health care.[32] The surrogate hierarchy contained in the FHCDA thus opened up the field of research requiring surrogate consent in New York State.

While hierarchies are practical for determining who may serve as an LAR, not all LARs are ethical equivalents, particularly when considering research enrollment decisions. Because LARs listed in a hierarchy often will have varying degrees of kinship, intimacy, and understanding of the wishes of the impaired individual regarding research participation, it is important to consider the relationship between the LAR and the potential participant with respect to the type of research and risk level involved. An LAR who has a close relationship with the impaired individual would be the most familiar with whether s/he would choose to participate in research and under what circumstances. Thus, the Task Force recommends that IRBs and researchers consider limiting the classes of LAR(s) who are authorized to provide surrogate consent to research. The riskier the research protocol and more remote the prospect of benefit, the closer (by kinship or intimacy level) the LAR should be to an individual to be imbued with authority to consent to the impaired individual's participation in the study.[33]

When determining whether an individual should participate in research, an LAR should use instructions from an RAD or similar type of advance directive, if such instructions exist; *or* the participant's prior expressed wishes and preferences about research, if known. If there are no prior expressed wishes, the LAR should use either the best interest standard or substituted judgment.

Finally, to prevent undue inducement to consent to research, LARs may never be the true beneficiary of any financial compensation offered.

E. Notice to Participant and Opportunity for Review

The Task Force emphasized the importance of procedures for providing notice to the potential research participant and, if necessary, the LAR, regarding the capacity assessment and opportunities for objection and review. Researchers should provide notice to the potential participant and/or LAR that an assessment will be conducted and the consequences (if any) of a determination of incapacity.

As part of a research protocol, the Task Force recommends that potential participants and/or LARs should be notified of a planned capacity assessment, as well as the results of the assessment and any consequences of a determination of incapacity. Providing notice promotes transparency by alleviating any concerns that an individual might be involved in research without the knowledge of the participant or LAR. It also demonstrates respect for the prospective participant by presenting an opportunity for the individual or his/her LAR to object to either the capacity assessment or the results of the evaluation. When capacity assessments are contested, the most ethical

alternative may be to decline to enroll the individual in the research protocol. However, in some cases, alternatives short of non-enrollment could appropriately deal with any objection, such as a second capacity assessment. Readily available review procedures allow individuals an opportunity to request further information or a second opinion where they or their LARs see fit. Furthermore, steps should be taken during the notification process to ensure that the results of the capacity assessment remain confidential and that the privacy of the individual is respected. Finally, the Task Force recommends that researchers inform patients of whether the results of the assessment will be entered into an individual's medical record.

F. Additional Safeguards for Research Participants Lacking Consent Capacity

Additional protections might sometimes be necessary to safeguard the rights of participants who lack consent capacity, particularly when a study involves a minor increase over minimal risk or more than a minor increase over minimal risk, and when there is no prospect of direct benefit to the participant. The amount and scope of additional safeguards that the Task Force recommends for research with this population depends on the level of risk and the likelihood of direct benefit that the research protocol offers to the research participant. Such protective measures may include, but are not limited to: (1) independent consent monitors; (2) medically responsible clinicians; (3) state multiple project assurances; and (4) additional reporting requirements.

1. Independent Consent Monitors (ICMs)

By commonly accepted definitions, an ICM is an individual not affiliated with the study or research institution, who is designated by an IRB to monitor the informed consent process[34]—for example, when LAR consent is required. In some cases, this safeguard may provide additional protection for potential participants, because an ICM's duties include ensuring that as a witness to the consent process, verification of valid consent is properly obtained.[35] An ICM provides confirmation that adults lacking consent capacity are enrolled in research protocols only when appropriate informed consent procedures are followed. In addition, an ICM may also confirm that LARs understand the goals and risks of the research by observing the informed consent process.[36]

Furthermore, an ICM may provide independent assurance that an adult lacking consent capacity is enrolled in research only when there is sufficient evidence that such participation is consistent with the person's preferences and / or interests. For some research protocols, an ICM may have a more active role as an advocate for the potential participant and LAR during the recruitment process and possibly for the entire research study.[37] The ICM may serve as a resource to help potential participants and LARs understand the potential risks and benefits and decide if enrollment in a research protocol would be appropriate.[38]

The Task Force recommends that the role and responsibilities of an ICM may vary, from monitoring the informed consent process to advocating on behalf of potential and current research participants, and the degree of involvement of the ICM would be determined by an IRB. After reviewing the research protocol and the risk-benefit level involved, an IRB may determine the scope of responsibilities of an ICM.

2. Medically Responsible Clinicians (MRCs)

Depending on the research study and risk level involved, use of an MRC for each participant may be a necessary safeguard to protect cognitively impaired individuals. An MRC is a licensed medical doctor skilled and experienced in working with the research population and is independent from the study. Ideally, this person should be the physician already attending to the participant's health care needs—who is not involved in the research—but an MRC may also be any qualified physician not affiliated with the research study. While the primary role of an MRC is to serve as an advisor to an individual or LAR regarding research participation, additional duties include: (1) confirming that a participant provided assent to be enrolled in the research; (2) observing the individual for possible dissent to continued participation; and (3) monitoring the individual for any signs of harm as a result of research participation.[39] Thus, use of an MRC is an important safeguard for high risk studies because the physician acts as an advocate for cognitively impaired individuals. The MRC serves as a mechanism to assure that the physical and emotional well-being of participants are looked after by an outside third party.

3. Multiple Project Assurances (MPAs)

According to New York law, the consent of the Commissioner of Health is required for all non-federally regulated research involving "incompetent persons [and] mentally disabled persons," regardless of the risk category.[40] However, to streamline the review process, the Task Force recommends that the Department of Health should develop MPAs[41] to ensure a timely and thorough review of research protocols by IRBs. An MPA is an assurance between the Department of Health and a research entity or institution that pledges that all members of the entity or institution will comply with human subjects research policies issued by the state.

The Task Force recommends the use of a state MPA to obviate the need for full case-by-case Commissioner / Department of Health review for research involving cognitively impaired individuals that involves minimal risk or a minor increase over minimal risk, with or without a prospect of direct benefit, and for research that involves more than a minor increase over minimal risk with a prospect of direct benefit. However, for research that involves more than a minor increase over minimal risk,

without a prospect of direct benefit, a state MPA should not be a valid release from review by the Department of Health. In these cases, if an IRB concludes that the research is of vital importance to either current research participants and/or those similarly situated, that the risks are reasonable in relation to such vital importance, and appropriate safeguards are in place, the Department of Health may: (1) reject the study and the research could not be approved by the IRB, (2) approve the study and the research could be approved by the IRB, or (3) convene a special review panel of experts which will review the study and issue recommendations to the IRB on whether the study should be approved, and the IRB will make the final decision to approve or reject the protocol.

4. Reporting Requirements

While most research conducted in the state is federally regulated or overseen, there is a small portion of research that is not under federal purview. The Task Force recommends that research involving individuals unable to provide consent under Public Health Law 24-A should be subject to federal reporting requirements.[42] These reporting requirements will promote accountability and transparency and may include, if appropriate, evaluations of capacity of participants, including the method(s) used to assess capacity; procedures used to identify LARs for surrogate consent to research; and a summary of various risk levels involved in approved protocols. Furthermore, the Task Force recommends that IRBs be required to report to the Department any violations of approved principles and policies which the institution has promulgated.[43]

The Task Force recommends that researchers conducting studies under New York State's law governing HSR that involve individuals unable to provide consent should be subject to federally mandated reporting requirements and provide such documentation to the IRB. Under federal regulations, researchers are required to submit extensive documentation to an IRB as part of the review and approval process.[44] In addition, the Task Force recommends that researchers should disclose relevant information to potential participants and LARs of how the study will be ethically conducted to ensure that the rights and welfare of participants are protected.

Once the study is under way, the Task Force recommends that researchers should provide regular updates on the status of the participant and the general progress of the study to the participant and/or LAR. They should report any substantial concerns regarding an individual's participation to the LAR in ordinary language so that s/he remains fully informed. In addition, the researcher should remind participants and LARs of the availability of the researcher throughout the study to address any questions. Only with full disclosure to participants, LARs, and IRBs of the status and progress of the research can all parties be confident that the study is being conducted in an ethical and safe manner.

The disclosure of adverse events[45] and unanticipated problems[46] that result from research participation promotes transparency and may further protect the welfare of research participants.[47] The Office of Human Research Protections (OHRP) has suggested definitions of "adverse events"—which are not (in all cases) necessarily reportable to the IRB or federal agency—and "unanticipated problems" which must be reported; the definitions overlap but an occurrence might be either an adverse event or an unanticipated problem without being the other. While most adverse events are not unanticipated problems, and only some unanticipated problems are adverse events, only a small proportion of adverse events are unanticipated problems.

Because the severity of any given adverse event may range from minimal to serious, because the natural progression of an illness or condition under study will vary, and because the severity and frequency of anticipated problems inherent to the research will vary, IRBs should determine, based on the research protocol, which events would require immediate action by the researcher or institution. Any reasonable possibility that a protocol may have caused serious or life-threatening harm or death requires immediate reporting and attention by the researcher and IRB to provide any corrective or preventative action.

The Task Force recommends that for both IRBs and researchers, any non-federal research protocol should contain methods for the identification, management, and reporting of adverse events and unanticipated problems that may occur during the course of a research protocol, comparable to those contemplated by the federal Common Rule.[48]

Conclusions

The Task Force's *Report and Recommendations for Research with Human Subjects Who Lack Consent Capacity* are the result of a multi-year effort to respond to appeals for guidance from New York State IRBs, investigators, and research institutions on how to conduct ethical research involving adults who lack consent capacity. Although New York State law governs human subjects research for a subset of research conducted in the state by providing mechanisms for ensuring voluntary informed consent for participants and IRB review of research protocols, it does *not* provide any special oversight mechanisms for research involving this particular population. Despite calls to do so, federal law also does not provide safeguards or special protections for research involving "mentally disabled persons."[49] The absence of such guidelines or regulations may lead to unethical or unsafe research protocols or the dearth of important research into the broad range of diseases that impair cognition.

Thus, an underlying goal of the Task Force's work is to ensure that research protocols are available to all

individuals, including individuals who lack consent capacity, so that they may also experience the benefits, risks, and burdens of research as their non-cognitively impaired peers, while also ensuring the appropriate level of protections. Although the guidelines focus only on the inclusion of these individuals in research in New York State, the recommendations could serve as a model for the development of other policies in other states and at the federal level.

For more information regarding the Task Force's analysis and recommendations, as well as more on the legal implications of research involving adults lacking consent capacity, see the Task Force's full report, *Report and Recommendations for Research with Human Subjects Who Lack Consent Capacity*, at: http://www.health.ny.gov/regulations/task_force/reports_publications/.

Endnotes

1. H.K. Beecher, *Ethics and Clinical Research, New England Journal of Medicine*, 274, no. 24 (1966): 1354-60.
2. Established by Executive Order in 1985, the Task Force is composed of approximately 23 Governor-appointed leaders in the fields of religion, philosophy, law, medicine, nursing, and bioethics. The Task Force develops public policy on issues arising at the interface of medicine, law, and ethics, and has issued influential reports on cutting-edge bioethics issues. *See* http://www.health.ny.gov/regulations/task_force/ for the list of past and current Task Force projects and current members.
3. Among other efforts, the New York State Department of Health commissioned an advisory work group to address the concept of surrogate consent to research, which released a draft report for public comment in 1998. *See* Department of Health Advisory Work Group on Human Subject Research Involving Protected Classes, "Recommendations on the Oversight of Human Subject Research Involving Protected Classes," 1998, at 16, http://www.nysl.nysed.gov/scandoclinks/ocm49377072.htm, accessed January 8, 2013 [hereinafter "1998 New York State Work Group Report"]; *see also* "Ad Hoc Workgroup Convened by the New York Academy of Medicine, Consent for Research with Decisionally Incapacitated Adults," 2004 (on file with the Task Force).
4. The New York State Office of Mental Health promulgated regulations in 1990 governing research with adults lacking consent capacity, but they were struck down because only the Commissioner of Health has the authority to promulgate regulations under Article 24-A. 165 Misc.2d 62, 73 (N.Y. Sup. Ct. 1995), *aff'd*, 228 A.D.2d 95 (N.Y. App. Div. 1996), *aff'd in part*, *rev'd in part*, 91 N.Y.2d 860 (1997).
5. N.Y. Pub. Health Law §§ 2440–2442; Subpart A of 45 C.F.R 46 (The Common Rule). However, similar to the Common Rule, Article 24-A does not provide detailed procedures for the ethical conduct of such research beyond these general provisions.
6. Article 24-A applies to human subjects research conducted in New York state not covered by federal law. Specifically, the provisions of 24-A do not pertain to research "subject to, and which is in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects." N.Y. Pub. Health Law § 2445. This section applies to research that is not subject to federal regulations even if the sponsoring institution submits to the United States Department of Health and Human Services a "multiple project assurance," voluntarily agreeing to comply with federal human subjects research regulations. See *T.D.*, 228 A.D.2d 95.
7. For more information, particularly regarding the justifications for the Task Force's recommendations and the legal implications of research involving adults lacking consent capacity, see the Task Force's full report, *Report and Recommendations for Research with Human Subjects Who Lack Consent Capacity*.
8. Possible justifications may include that these institutionalized settings provide additional oversight and monitoring of participants and the research and that these settings contribute to the overall standardization and integrity of the data.
9. Many of these residents have an additional layer of vulnerability due to their heavy reliance for care on staff members, some of whom may be part of the research study or involved in recruitment, and may therefore be subject to real or perceived coercion by staff to participate.
10. The Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research, "Report and Recommendations: Research Involving Children," 1977, http://bioethics.georgetown.edu/pcbe/reports/past_commissions/Research_involving_children.pdf.
11. 45 C.F.R. §§ 46.103, 46.109, 46.116-17, 46.405.
12. 45 C.F.R. § 46 (Subpart D); "1998 New York State Work Group Report," *supra* note 3, at 14; Office of the Maryland Attorney General, "Final Report of the Maryland Attorney General's Research Working Group," 1998, at A-17 [hereinafter "Maryland Attorney General Report"].
13. Office for Human Research Protections, "Secretary's Advisory Committee on Human Research Protections (SACHRP), Appendix B," http://www.hhs.gov/ohrp/sachrp/sachrpltrtohhssecapdb.html, accessed April 16, 2013.
14. In the context of the report, analogous research includes any previously performed studies with similar characteristics (i.e., research population or cognitive impairment examined) from which findings can be applied to the current study.
15. It may be prudent to separate therapeutic *intent* from therapeutic *benefit*, especially when the extent of potential benefit has not been established. *See* J.J. Fins, "A Proposed Ethical Framework for Interventional Cognitive Neuroscience: A Consideration of Deep Brain Stimulation in Impaired Consciousness," *Neurological Research* 22, no. 3 (2000): 273-78, at 274-275. It may be helpful for IRBs to use such considerations when attempting to establish the permissibility of studies with more than a minor increase over minimal risk in the absence of clear data regarding the study's potential benefit.
16. Federal regulations regarding human subjects research with children permit this type of research protocol if, among other requirements, the IRB determines that the research is "likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition." 45 C.F.R. § 46.406(c).
17. *See* Fins, "A Proposed Ethical Framework for Interventional Cognitive Neuroscience," 274-275.
18. One model for such a review panel is the federal 407 Review Children's Panels under the Common Rule, which examines research protocols involving children that are otherwise not approvable because of their risk level. *See* 45 C.F.R. § 46.407.
19. These experts would not be restricted to those residing in New York State. Instead, panelists would be selected for their knowledge and expertise in the particular area being studied.
20. Some may argue that for individuals not capable of providing informed consent, there is no need to ask them for assent, and that instead use of surrogate consent is sufficient. However, this view ignores the fact that capacity is not an absolute; requiring assent from these participants allows them to retain a measure of control over their ability to make decisions. In addition, in the past, there has been no requirement that impaired participants

assent to research. Instead, impaired participants who objected to a surrogate enrolling them in research could rely upon judicial review to protect their right of refusal. However, judicial review is both time- and resource-consuming and removes the locus of authority from the potential participant. Requiring assent gives potential participants the swift and irrevocable right to decline to participate in research—without negating the option of judicial review if the participant so requests. It also guarantees that the surrogate decision-maker assists the participant in decision-making but does not usurp the participant's authority.

21. Consent capacity is the ability to demonstrate necessary levels of skill in four domains: (1) understanding; (2) appreciating the relevance of the information to oneself; (3) using information in reasoning about a decision; and (4) expressing a choice.

22. S.Y. Kim et al., "Assessing the Competence of Persons with Alzheimer's Disease in Providing Informed Consent for Participation in Research," *American Journal of Psychiatry* 158, no. 5 (2001): 712-17, at 716; C.B. Fisher et al., "Capacity of Persons with Mental Retardation to Consent to Participate in Randomized Clinical Trials," *American Journal of Psychiatry* 163, no. 10 (2006): 1813-20, at 1818-19; V.D. Buckles et al., "Understanding of Informed Consent by Demented Individuals," *Neurology* 61, no. 12 (2003): 1662-66, at 1665.

23. Some researchers use non-standardized tests for assessing capacity, while others use clinical tools, such as the Mini Mental State Exam, which were not designed to assess, and correlate poorly with, consent capacity. E.D. Sturman, "The Capacity to Consent to Treatment and Research: A Review of Standardized Assessment Tools," *Clinical Psychology Review* 25, no. 7 (2005): 954-74, at 964. More reliable methods for evaluating consent capacity have been developed in recent years. These tests fall into two basic categories: they either attempt to provide full assessment of all aspects of capacity yet are time-consuming, or they offer broad and simple assessments but lack detailed information. L.B. Dunn et al., "Assessing Decisional Capacity for Clinical Research or Treatment: A Review of Instruments," *American Journal of Psychiatry* 163, No. 8 (2006): 1323-34, at 1331; J.H.T. Karlawish et al., "Alzheimer's Disease Patients' and Caregivers' Capacity, Competency, and Reasons to Enroll in an Early-Phase Alzheimer's Disease Clinical Trial," *Journal of the American Geriatrics Society*, 50, no. 12 (2002): 2019-24, at 2023; D.V. Jeste et al., "A New Brief Instrument for Assessing Decisional Capacity for Clinical Research," *Archives of General Psychiatry* 64, no. 8 (2007): 966-74, at 968.

24. S.Y. Kim et al., "Variability of Judgments of Capacity: Experience of Capacity Evaluators in a Study of Research Consent Capacity," *Psychosomatics* 52, no. 4 (2011): 346-53, at 351-52 (noting that because capacity assessment is a relatively new field, it may be appropriate to assess whether sufficient resources are available to those conducting assessments in high-stakes situations).

25. The Common Rule defines an LAR as "an individual or judicial body *authorized under applicable law* to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research."

    45 C.F.R. § 46.102 (emphasis added). Thus, the federal government will look to a state's formulation of LAR to determine which, if any, surrogates are authorized to consent to research conducted in that state. The federal government will recognize a state's definition of LAR if it is ensconced in statute, regulation, case law, or other legally binding authority. The Office of Human Research Protections (OHRP), "Human Research Protections Frequent Questions," *Who can be a legally authorized representative (LAR) for the purpose of providing consent on behalf of a prospective subject?* http://answers.hhs.gov/ohrp/questions/7264, accessed visited July 16, 2012. In states that do not provide a definition of or a standard for selecting an LAR, it is arguable that federally funded research involving those who cannot provide informed consent should not occur, except in very limited circumstances (such as where the individual has executed an RAD).

26. *See, e.g.*, M.N. Gong et al., "Surrogate Consent for Research Involving Adults with Impaired Decision Making: Survey of Institutional Review Board Practices," *Critical Care Medicine*, 38, no. 11 (2010): 2146-54, at 2153.

27. S.Y. Kim, "The Ethics of Informed Consent in Alzheimer Disease Research," *Nature Reviews Neurology* 7, no. 7 (2011): 410-14, at 412 (noting that a significant number of Alzheimer's disease patients may be able to appoint an LAR in a "concurrent" rather than advance directive).

28. Such procedures may include a witness(es) and documentation for the appointment. *See* S.Y. Kim, "Preservation of the Capacity to Appoint a Proxy Decision Maker: Implications for Dementia Research," *Archives of General Psychiatry* 68, no. 2 (2011): 214-20, at 215-16 (discussing appointment of a proxy where a person does not retain sufficient enough capacity to consent to the protocol itself).

29. For example, the number of research participants for whom an LAR can serve should be reasonably limited to make certain that his/her duties to them are not compromised. If a physician is appointed as an LAR, s/he should not simultaneously continue to act as the treating physician to the participant because of a potential conflict of interest. In addition, individuals who are involved in the conduct of a particular research study should not serve as an LAR for a participant in the study, although an exception may be made for where a close familial or other relationship exists between the two individuals.

30. 45 C.F.R. § 46.112; 21 C.F.R. § 56.112.

31. 45 C.F.R. § 46.102.

32. N.Y. Pub. Health Law Art. § 29-cc (2010).

33. For research that has no prospect of direct benefit and involves either a minor increase over minimal risk, or more than a minor increase over minimal risk, it is ethically inappropriate to allow for a surrogate appointed through an institutional or judicial mechanism (i.e., a court-appointed guardian with no prior relationship to the potential participant) to provide surrogate consent. Because these court-appointed LARs often do not have a close personal relationship with the impaired individuals, it would be difficult to accurately act upon their wishes and preferences, and a more cautious approach to research enrollment is reasonable. However, it might be acceptable for IRBs to permit these LARs to consent to research that offers a prospect of direct benefit, depending on the risk level of the study, for these cognitively impaired individuals.

34. *See* Nat'l Bioethics Advisory Comm'n, "Research involving Persons with Mental Disorders that may Affect Decisionmaking Capacity Report and Recommendations," Vol. I. (1998): 21 (hereinafter "NBAC Report"); National Institutes of Health, Trans-NIH Bioethics Committee Working Group, "Research Involving Individuals with Questionable Capacity to Consent: NIH Points to Consider" (2009): 9, http://grants1.nih.gov/grants/policy/questionablecapacity.htm; "Maryland Attorney General Report," *supra* note 12, at A-5; D.L. Rosenstein & F.G. Miller, "Ethical Considerations in Psychopharmacological Research involving Decisionally Impaired Subjects," *Psychopharmacology* 171, no. 1 (2003): 92-97, at 94; Committee on Assessing the System for Protecting Human Research Participants, Institute of Medicine, "Responsible Research: A Systems Approach to Protecting Research Participants," Washington, DC (Daniel Federman et al., eds., The National Academies Press, 2002): 164.

35. NBAC Report, *supra* note 34, at 21.

36. "1998 New York State Work Group Report," *supra* note 3, at 22; H.J. Silverman et al., "European Union Directive and the Protection of Incapacitated Subjects in Research: An Ethical Analysis," *Intensive Care Medicine*, 30, no. 9 (2004): 1723-29, at 1727.

37. E.H. Morreim, "By Any Other Name: The Many Iterations of 'Patient Advocate' in Clinical Research," *IRB: Ethics & Human Research*, 26, no. 6 (2004): 1-8, at 5. Research protocols at the

National Institutes of Health / National Institute of Mental Health employ a Clinical Research Advocate, which is a hybrid of a traditional ICM and of an advocate for vulnerable research participants. These Clinical Research Advocates provide assistance to potential and current research participants by overseeing the informed consent process and also assess the surrogate decision-makers who may be involved in the process of informed consent. Mary Ellen Cadman, Presentation, *Human Subjects Protection Unit*, at PRIM&R 2008 (Nov. 18, 2008).

38. The ICM should be familiar with the clinical aspects of the research protocol, understand and be able to answer questions, especially those concerning risk-benefit information, in plain language. This person could also address additional concerns from participants and LARs during the course of the research study and may help a participant and his / her LAR decide whether continued participation is appropriate. For potential participants without consent capacity, an ICM should offer insight to the LAR as to whether or not the individual should be enrolled in a particular study while respecting the difficulty an LAR may face when making difficult decisions concerning the loved one. Ideally, an ICM would have experience serving as a surrogate decision-maker for a person who has had a similar disorder affecting consent capacity. J.F. & F.G. Miller, "Enrolling Decisionally Incapacitated Subjects in Neuropsychiatric Research," *CNS Spectrums* 5, no. 10 (2000): 32-40 (proposing a matrix of individuals and perspectives, which would assist with enrollment decisions).

39. "1998 New York State Work Group Report," *supra* note 3, at 21.

40. N.Y. Pub. Health Law § 2444.

41. A State MPA would be like a Federalwide Assurance (FWA), a document filed with OHRP by an institution, which ensures that all of its human subject research activities, regardless of the funding source, will comply with the federal research protections provided in the Common Rule.

42. Many states require additional oversight and reporting standards beyond the federal standards. At this time, the Task Force recommends that the federal standards serve as minimum standards for research that falls under N.Y. Pub. Health Law Art. 24-A.

43. N.Y. Pub. Health Law § 2444(2).

44. *See generally* 45 C.F.R. §§ 46.109, 46.111, 46.116-17. Common documentation requirements include: (1) evidence of appropriate education training in human subjects research protection; (2) assessment of potential participants' capacity, including information on who conducted the assessments and how decision-making capacity was assessed; (3) procedures for re-evaluating a participant's capacity; (4) privacy protections to protect potential participants' information; (5) procedures by which the health and safety of participants were monitored during the course of the research, including appropriate consultation with the participant's LAR or MRC, if appropriate; (6) unanticipated adverse events involving risk to participants or others; and (7) reasons for withdrawal of a participant from the research study.

45. The Common Rule does not define or use the term "adverse event," nor is there a commonly used definition of the term. FDA regulations use "adverse event," (21 C.F.R. § 312.64), "adverse effect" (21 C.F.R. § 312.55), "adverse experience" (21 C.F.R. § 312.33), "unanticipated problems" (21 C.F.R. § 312.66), and "unanticipated adverse device effect" (21 C.F.R. § 812.3) interchangeably. *See* Health and Human Services (HHS), "Guidance for Clinical Investigators, Sponsors and IRBs: Adverse Event Reporting to IRBs–Improving Human Subject Protection" (Jan. 2009), http: / / www.fda.gov / downloads / RegulatoryInformation / Guidances / UCM126572.pdf.

46. The Common Rule requires IRBs to have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials and to the federal government of, among other things, any unanticipated problems involving risks to participants or others, but it does not define such "unanticipated problems." *See* 45 C.F.R. § 46.103(b)(5).

47. As with many of the topics discussed in the report, although reporting of adverse events and unanticipated problems is an important component of human subjects research, these recommendations are not intended to emphasize the exceptionalism of this population, but to serve as a model for reporting adverse events and unanticipated problems for all research involving human subjects.

48. The Common Rule requires institutions conducting federally funded research or operating under FWAs to establish procedures for adverse event reporting. 45 C.F.R. § 46.103(a) & (b)(5). The IRB assurance must include: "Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval." 45 C.F.R. § 46.103(b)(5). *See also* OHRP, "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events," (2007) http: / / www.hhs.gov / ohrp / policy / adverntguid.html. N.Y. Pub. Health Law Art. 24-A does not require such reporting.

49. 45 C.F.R. § 46.111.

Valerie Gutmann Koch, J.D., is a Visiting Assistant Professor at Chicago-Kent College of Law, Lecturer at the MacLean Center for Clinical Medical Ethics, and Special Advisor to the New York State Task Force on Life and the Law; she is the former Senior Attorney and Consultant to the Task Force.

Susie A. Han, M.A., M.A., is the Deputy Director and Principal Policy Analyst to the Task Force.

Withhold Now and Ask Questions Later—Withholds and Recoveries of Medicaid Overpayments by OMIG

By Robert Tengeler and Linda Clark

Provider Withholds

State Medicaid agencies have a variety of mechanisms to recover overpayments from Medicaid providers following or even during an investigation or audit. The most common procedure is the use of a withholding of Medicaid payments to satisfy the amount of the overpayment, meaning the State keeps all or some portion of Medicaid receipts from a provider's current Medicaid receivables. Generally there are two types of provider withholds.

In the first instance, the State Medicaid agency, the State Department of Health (DOH), upon notice to the provider and no sooner than 20 days after issuance of a final audit report, may commence recoupment through a provider withhold in the amount of the overpayment identified in the report.[1] This procedure is almost always commenced by the state Medicaid auditing entity within DOH, the Office of Medicaid Inspector General ("OMIG"). Where the audit is based on a statistical extrapolation or projection of findings, the OMIG will include a range of dollar findings depending upon the statistical methodology used. The OMIG will generally seek to recover through a withhold the "low point" amount of the overpayment. The low point theoretically represents a conservative projection of findings, reflecting the lower end of the projected dollar findings, which can vary widely depending upon the nature of the findings and the "confidence interval" used, which is typically in the range of 5-10 percent. This means that based on the methodology utilized by the OMIG's statistician, the midpoint amount of the overpayment resulting from the extrapolation of findings would be plus or minus five percent of such amount if *all* of the claims in the universe were actually audited. One needs to view this methodology in terms of a bell curve. The midpoint would be at the top of the curve, and the low point (a lower amount) and high point would be at opposite ends of the curve. It has been the usual OMIG policy to defend the midpoint if the audit reaches the hearing stage, and to settle at the low point amount, theoretically giving the provider the benefit of the statistical doubt if it settles.

The provider has the right to request an administrative hearing to review the OMIG's determination, and such request must be made within 60 days from the date of the final audit report.[2] Unfortunately, a request for a hearing does not stay the withhold unless DOH cannot schedule or OMIG is unable to proceed with the hearing within 90 days from the receipt of a request for the hearing. Any delays occasioned by the provider (including consensual adjournments requested by the provider) cannot be the basis of the stay of a withhold, and the withhold may resume upon commencement of the hearing.[3] It is also possible that a provider may settle the audit after issuance of the final report. In either case, if the amount of the settlement or the amount of the overpayment as determined after hearing is less than the amount that has been withheld, the OMIG will refund the difference to the provider.

It must be noted that the OMIG has the right to recover overpayments from both the audited provider and any affiliate of the provider.[4] An affiliate is defined as "any person having an overt, covert or conspiratorial relationship with another such that either of them may directly or indirectly control the other or such that they are under common control or ownership."[5] The historical rate of recovery through a withhold under this method has been 10% of Medicaid payments, although there have been many cases where the rate is much higher, with some as high as 100% depending upon the circumstances. Given the tight profit margins under which many providers operate, even a 10% rate of withhold may be onerous. Providers have the ability to request that the OMIG reduce its rate of withhold through a hardship request. This request should be made in writing to the OMIG, and the provider will be required to furnish detailed financial records to support the request for a reduced rate.

The second type of a provider withhold is governed by 18 NYCRR 518.7. Pursuant to this regulation, OMIG has the right to recover overpayments before it has made a final determination (as set forth in a final audit report) regarding the amount of the overpayment. The OMIG may withhold payments upon a determination that a "provider has abused the (Medicaid) program or has committed an unacceptable practice."[6] Abuse is defined as practices by the provider "that are inconsistent with sound fiscal business, medical or professional practices and which result in unnecessary costs to the medical assistance program, which are medically unnecessary or… which fail to meet recognized standards for health care."[7] Unacceptable practices are set forth in 18 NYCRR 515.2 and may consist of preliminary findings or information of an ongoing investigation from a state licensing or law enforcement agency involving fraud, abuse or unprofessional conduct.[8]

Under the Affordable Care Act and as governed by recently amended state regulations, state Medicaid agencies must suspend payments to a provider, in whole or in part, where it is determined that the provider "is the subject of a pending investigation of a credible allegation

of fraud unless the OMIG finds good cause not to withhold payments as set forth in 42 CFR 455.23." A credible allegation of fraud is an allegation that has an indicia of reliability and has been verified by the OMIG, the State Medicaid Fraud Control Unit ("MFCU") or other state or prosecutorial agency. In this situation, the OMIG must make a referral of the matter to the MFCU.[9]

The provider must be furnished with a written notice of withhold within five days after OMIG initiates the withhold, and the regulations define the content of the notice. The provider does not have the right to a formal hearing to review the determination to withhold payments but may within 30 days of the notice submit written arguments challenging the withhold.[10] Additionally, the regulations mandate that the OMIG, when initiating a withhold under 18 NYCRR 518.7, complete various parts of the audit process within mandated periods of time. When the withhold is commenced prior to the issuance of a draft audit report, the report must be issued no later than 90 days from initiation of the withhold. When the withhold is commenced prior to the issuance of a final report, the report must be issued no later than 90 days from initiation of the withhold.[11] Although the regulations are silent as to any remedy for failure to comply with these time requirements, the OMIG will usually suspend the withhold until such time as it issues the required draft or final audit report.

A withhold initiated under 18 NYCRR 518.7 is intended to address situations where a determination has been made that the provider has committed an act of fraud, abuse or other unacceptable practice. In essence, the state agency has determined that a "pre-final determination" withhold is required to "stop the bleeding" of Medicaid payments made to a provider which has allegedly committed these acts before the lengthy audit, investigation or review process has been completed. Although one might question the constitutionality of this action if in fact there is a defined or implied property right of a provider to receive payment for services, both federal and state courts have upheld the regulations upon which this process is based.[12]

In New York, the Court of Appeals addressed this issue in *Medicon Diagnostic Laboratories, Inc. v. Perales.* The Court was vague on whether a specific property right existed for the prompt payment of Medicaid claims and noted that the Appellate Division stated that no such property interest existed. The Court also noted that the "public must be assured that funds which have been set aside (for providing medical services to the needy) will not be fraudulently diverted into the hands of an untrustworthy provider of services."[13] The Court continued by noting that "due process is a flexible constitutional concept" and utilized the balancing test set forth in *Mathews v. Eldridge.*[14] The Mathews test in essence balances any private right (payment of claims) against the interest of the Government (the need for fiscal integrity). The Court referenced the notice and time requirements set forth in state regulations regarding the issuance of draft and final audit reports to the provider (after commencement of a withhold) and upheld the provisions of 18 NYCRR 518.7. As to Medicon's additional claims that the failure to provide a prior notice and prior opportunity to be heard were unconstitutional, the Court held that "the regulations properly balance and adequately protect any property interest petitioners have in reimbursement of their claims."[15]

A withhold initiated under 18 NYCRR 518.7 may be initiated by the OMIG at the request of the MFCU or other state agency. In this situation, the withhold may continue until the agency proceedings or investigation are completed.[16] This process has also been upheld in state court proceedings.[17]

Litigating the Withhold on Behalf of a Provider-Client

A "pre final" withhold initiated under 18 NYCRR 518.7 is required to be based on a finding of fraud or abuse. Accordingly, given the manner in which the OMIG views this situation, it will generally initiate the withhold at a recovery rate of 100% of payments. As can be expected, this will almost always have an obvious effect of forcing a provider to either cease operations or challenge the withhold in court if unsuccessful in the informal review process before the OMIG.

A first consideration is whether to commence a federal or state action. One important consideration revolves around the nature of the withhold. Generally where a withhold is ongoing, it has two parts. The "escrow" consists of the amount already recovered, and the "ongoing withhold" consists of the remaining balance to be recovered. Generally under the Eleventh Amendment to the Constitution, federal courts cannot provide relief to a litigating provider seeking a refund of the escrow portion of the withhold (retroactive relief involving the payment of state funds); the Court may only provide prospective relief. Two leading federal decisions regarding this issue are *Pennhurst State School and Hospital v. Halderman* and *Edelman v. Jordan.*[18]

This concern coupled with the availability of injunctive relief in state courts will usually result in a determination to seek relief in state court. For example, in *Marra's Pharmacy, Inc. v. Sheehan*, No. 4527-11 (Sup. Ct. Albany Co. July 1, 2011), the Supreme Court granted a temporary restraining order enjoining collection or withholding of Medicaid funds where the pharmacy successfully argued that OMIG failed to comply with applicable notice and hearing regulations. Additional arguments made in *Marra's* (and generally applicable to other providers challenging a withhold) included the financial harm to the provider resulting from the withhold—in essence, putting the provider out of business—and a probability of success in challenging the underlying OMIG action.

Civil Proceedings

After completion of the audit process and related proceedings (administrative hearing and / or judicial review), the state agency may also undertake civil proceedings to recover overpayments. This is usually done by the State Attorney General. Under section 145-a(2) of the Social Services Law, the state may file the written final determination of the state Medicaid agency (generally the final audit report) as a lien against the provider. This is permitted only if no related proceeding is pending and the time for initiation of such proceeding (hearing or subsequent Article 78 proceeding) has expired. Additionally, the department may initiate proceedings to intercept state tax refunds due providers who have received Medicaid overpayments. This process mandates the issuance of a written notice and has provisions for an informal review process.[19]

Federal Proceedings

It is worth noting that there are procedures that enable HHS to initiate a withhold of Medicaid payments to recover Medicare overpayments received by a provider.[20] The withhold is permitted for only the federal share of the Medicaid payment (generally 50% of the Medicaid payment). Conversely, HHS may also withhold Medicare payments due a provider to recover Medicaid overpayments.[21]

Endnotes

1. 18 NYCRR 518.8(a).
2. 18 NYCRR 519.4; 519.7.
3. 18 NYCRR 518.8(b).
4. 18 NYCRR 518.6.
5. 18 NYCRR 504.1(d)(1).
6. 18 NYCRR 518.7(a)(1).
7. 18 NYCRR 515.1(b)(1).
8. 18 NYCRR 515.2; 518.7(a).
9. 18 NYCRR 518.7(a)(2).
10. 18 NYCRR 518.7(e).
11. 18 NYCRR 518.7(d).
12. *Medicon Diagnostic Laboratories, Inc. v. Perales*, 74 N.Y.2d 539 (1989); *Tekkno Laboratories v. Cesar A. Perales*, 933 F.2d 1093 (2d Cir. 1991).
13. *Medicon Diagnostic Laboratories, Inc. v. Perales*, 549 N.Y.S.2d 933, at 936.
14. *Medicon Diagnostic Laboratories, Inc. v. Perales*, 549 N.Y.S.2d 933 at 937.
15. *Medicon Diagnostic Laboratories, Inc. v. Perales*, 549 N.Y.S.2d 933 at 937.
16. 18 NYCRR 518.7(d)(4).
17. *Kenmar Surgical Aids, Inc. v. New York State Department of Health*, 697 N.Y.S.2d 468 (Sup. Ct. Albany County 1999).
18. *Pennhurst State School and Hospital v. Halderman*, 465 U.S. 89, 104 S. Ct. 900 (1984); *Edelman v. Jordan*, 415 U.S. 651 (1974).
19. 18 NYCRR Part 520.
20. 42 CFR 447.30; *see also Beverly Enters. v. Miss. Div. of Medicaid*, 808 So. 2d 939, 942 (Miss. 2002).
21. 42 CFR 447.31.

Robert Tengeler is Of counsel to Hiscock & Barclay, LLP with a practice concentrated in health care law. Before retiring as Assistant Medicaid Inspector General in 2006, he directed state agency fraud and abuse and audit activities for both the State Departments of Social Services and Health. He drafted numerous state laws and regulations, was the liaison to the State Medicaid Fraud Control Unit and worked closely with the Attorney General's Office in defending federal and state court cases involving such issues as withholds, the use of statistical sampling in Medicaid audits and provider due process issues related to Medicaid participation and terminations.

Linda Clark is a partner with Hiscock & Barclay with a practice concentrated in commercial litigation including health care matters. Ms. Clark concentrates her practice in the areas of state and federal, commercial, mass tort and class-action/group claim litigation. She has extensive experience representing Fortune 500 and national/global clients as national, regional and local counsel.

Exorcising the Devil from the Details: Covenants Not to Compete and Solicit in New York Physician Employment Contracts

By John Minehan

New York law generally disfavors covenants not to compete or solicit, except in certain particular circumstances, such as the sale of businesses and their good will or where employees have certain skills considered "unique."[1] Unfortunately for New York physicians, and despite the AMA's position that doctors (like lawyers) should not be bound by restrictive covenants stated in AMA Opinion 9.02, both of these exceptions have often been applied to their profession. This article will provide an overview of the case law on this frequently arising (and frequently vexing) issue and will discuss some tactics, techniques and procedures that may be worth considering in light of this law and the factual context of the changing practice of medicine.

A Quick Overview of the Case Law on Physician Covenants Not to Compete

The most frequently cited Court of Appeals cases on this issue hold that covenants not to compete and solicit in physician employment agreements are enforceable in New York State, where such covenants are reasonable as to: 1) geographic extent; 2) scope (including impact on the general public) and 3) duration.[2] Additionally, the *Karpinsky* case holds that where these factors are *not* reasonable, the Court can apply a "blue pencil" to *make* them reasonable.[3]

As usual with a reasonableness standard, the devil is in the details, especially in a profession that has been changing as significantly as the practice of medicine has over the last few decades.

Wrestling with the Details: Some Tactics, Techniques and Procedures

Issues with Geographic Extent

At the most prosaic level, there *is* a difference between "within 5 *miles* of Hospital X" and "within a *5-mile radius* of Hospital X." With the second, all that is required to determine the restricted zone is to take a compass; measure five miles from the legend on a map; place one compass leg on the practice's location; and draw a circle. With the first, at least until the complete triumph of MapQuest and GPS, some lawyer who had been a Soldier, a Marine or, usually best of all, a Boy Scout, would be forced to make tic marks on a sheet of paper, measuring a road distance of five miles on a road map.

However, a five-mile *radius*, although it is easier to work with, may have little to do with where patients *actually come from*, the heart of the interest the contract seeks to protect.

Most physician's offices and institutional providers are very aware of their catchment area; in fact, they live and die by it. A catchment area in health care is a list of the patients' origins by zip code.[4]

Lawyers often use these data to analyze markets for anti-trust purposes. The same analysis may aid an attorney in drafting a geographically reasonable restrictive covenant.

Catchment areas differ among the various regions of the state and with them the geographic extent of a *reasonable* restrictive covenant. As the *Schwartz* case illustrates, a 15-mile restrictive covenant may make sense in a sparsely populated area of the state, but may not be enforceable in densely populated Westchester.[5]

If no patients come from an area, it is difficult to say that it is geographically realistic to ask a former physician-employee or partner not to practice there. For example, if none of the patients come from north of the Tappan Zee or from Tonawanda or from Brunswick Hills, it will be difficult to enforce a covenant not to compete that precludes someone from practicing there.

On the other hand, if a practice or an institutional provider has concrete plans *to expand* into a region it presently does *not* serve, and the physician-employee or (particularly) partner was aware of this plan, then it would be entirely reasonable to write such a restriction into the physician's contract.

This type of usurpation of a business opportunity or misuse of a confidence or secret *may* be actionable even in the absence of a restrictive covenant.[6] However, in addition to a strong paragraph limiting the use of information garnered during the scope of employment after termination, contracts with newly made physician-partners[7] of a practice should include such areas clearly targeted for expansion. While a restrictive covenant is difficult to enforce without new consideration, such a change in status provides an ideal time to review these provisions.[8]

The opposite is also true. Under the principle in the *Last* case, restrictive covenants are *not* enforceable based on services rendered in a facility (in *Last*, an office of a faculty practice plan) which has been *closed*.[9] Simply put, there is no longer an interest there to protect. This raises questions.

An attorney representing a physician bound by a restrictive covenant based upon an office likely to be closed may simply advise the client to do nothing until *after* that office closes. Given this, should physician-employees intentionally be moved around between offices of a practice, to potentially make restrictive covenants more enforceable (especially ones with common contractual language that reads something like "within 5 miles of any facility where physician has rendered services for practice" or should physician employees be left in one place to develop a more robust practice with stronger ties to a patient base? Would moving physicians around, however, be seen, as in *Schwartz*, as making a physician unable to practice in a too-wide geographic area for the covenant to be enforceable? This is a practice management decision, but not one without legal implications.

Issues with Scope

A given physician may have more than one specialty or, especially, sub-specialty. As with *Rifkinson-Mann*, it may aid enforcement of a restrictive covenant if the restrictive covenant only enjoins *one* of these specialties or sub-specialties.[10] Obviously, the restricted specialty or sub-specialty should be the one the physician served in (or served most in) during the term of employment.

This could also raise issues in terms of usurpation of a corporate opportunity. A physician may have been hired *because* of (for example) a certain sub-specialty the physician holds, even though the practice or institutional provider does not have the modality *now*. The physician may receive a better offer and may attempt to argue that any restriction on practice in this sub-specialty is too broad in scope to be enforceable. If the plans are sufficiently concrete, this sub-specialty should probably *also* be included in the restriction, so long as it is otherwise available to the public.

Additionally, thought should be given to *not* restricting a physician-employee from venues that *do not* compete with the employer. For example, if veterans form a negligible part of the patient base of a practice, then allowing a former physician-employee or partner to practice at VA Hospitals or clinics within the geographically restricted area may make sense. These kinds of logical exceptions could make a restrictive covenant seem more reasonable to a court in terms of scope.

Issues with Duration

There is less case law on what constitutes a reasonable duration for a restrictive covenant in a physician's employment contract than on the other factors. In fact, indefinite durations, in limited geographic areas, have been upheld.[11] Most restrictive covenants I have seen are of five years or less, often one year.[12]

Equity

Restrictive covenants are often enforced through injunction, a form of equity. For this reason, the practice or institutional provider seeking to enforce a restrictive covenant needs to have "clean hands." If the practice or institutional provider breached the contract first, courts are loath to enforce them.[13] As in *United Calendar Manufacturing*, a restrictive covenant will likely not be enforced if the contract itself is illegal.[14]

In the same way, restrictive covenants are not enforced based on *other kinds* of breaches of the employment contract, such as failure to return equipment.[15]

In practice, however, this can be a dangerous game for a defendant if it is *not* clear that the proponent of the restrictive covenant is in breach or the contract is illegal.

BDO Seidman and Managed Care: Do Physicians Really Develop Patients and Are Their Services Unique?

In 1999, the Court of Appeals decided the *BDO Seidman* case, 93 NY2d 382, 712 N.E.2d 1220, 690 N.Y.S.2d 854, which held that a director (the step below a partner) of an accounting firm had a right to solicit clients he had originated before or during his time with the BDO Seidman firm and BDO Seidman clients whose files he had not worked during his time at the firm, but **not** those he had been introduced to by the firm, who had been developed by the firm, despite a covenant against solicitation. To date, the holding in *BDO Seidman* has been applied mainly in lower court cases in the context of controversies over covenants not to compete or solicit in physician employment contracts.[16]

This raises an important question: do physicians, especially in a managed care environment, develop patients in the same way that accountants or other professionals develop clients or customers? Obviously, where a practice is acquired, precedents involving the sale of businesses outside of the practice of medicine could be invoked: the purchasing physicians have purchased the good will of the practice and it is theirs to lose.

However, where patients covered by managed care plans often pick their physicians simply because: 1) that practice participates (as it is often described, "pars") in that plan; and 2) the office is conveniently located, can it be said that any physician ever develops a patient in the sense the Court of Appeals meant in *BDO Seidman*? One of the continuing issues in practice management is how to quickly credential new physician-employees, who are just leaving residency programs, with payors. How can these physicians be said to develop patients if a practice or institutional provider can only bill for a small part of their services (generally with private pay, Workers' Compensation and Medicare patients) until they are credentialed with payors? If physicians' services are, at least to this extent, fungible, how can any restrictive covenants in physicians' employment contracts be enforced on the grounds that their services are "unique?"

Changes in the business side of medicine may ultimately decide these issues. Given the popularity of Preferred Provider Organizations (PPOs), where members of a plan can engage a physician outside a plan by paying a premium, it may be said that *these* patients see *that* physician as providing unique services. That physician can probably be said to have "developed" that client in the sense implied by the Court in *BDO Seidman*. In the same way, the patients of a physician in a concergerie or "cash-only" practice, where, for example, well-heeled patients may pay an annual fee for access to a physician and pay in cash for services rendered, may well be said to "develop" their patients in the way described in *BDO Seidman*.[17]

Functionally, a practice which employs physicians who often treat patients "outside the network" under PPO plans may need more carefully worded covenants not to solicit patients than those that do not. In the same way, covenants not to solicit may need to be more carefully worded in cash only or concergerie practices, as well.

Conclusion

The general standard for enforceable covenants not to compete or solicit in physicians' employment contracts in New York State is easily stated: physicians' services are unique and restrictive covenants must be reasonable in terms of duration, geographic extent and scope. However, in a state as geographically and economically diverse as ours, and in a profession changing as rapidly as the practice of medicine, drafting enforceable restrictive covenants is far harder than stating the standard. The devil is in the details. The foregoing was some attempt at exorcising the devil from those details.

Endnotes

1. *See, e.g., Diamond Match Co. v. Roeber*, 106 N.Y. 473, 13 N.E. 419 (1887); *Purchasing Assoc., Inc. v. Weitz*, 13 N.Y.2d 267 (1963); *Reed Roberts Assoc. v. Strauman*, 40 N.Y.2d 303, 307, 386 N.Y.S.2d 677, 679 (1976) (holding that professionals' services are unique) (1976); *Columbia Ribbon & Mfg. Co. v. A-1-A Corp.*, 42 N.Y.2d 496, 499, 398 N.Y.S.2d 1004, 1006 (1977) (stating that restrictive covenants are disfavored); *Weiser LLP v. Coopersmith*, N.Y.S.2d, 2008 WL 2200233 (1st Dep't May 29, 2008) (stating that restrictive covenants are enforceable with sales of businesses).
2. See *Gelder Medical Group v. Weber*, 41 N.Y.2d 680, 363 N.E.2d 573 (1977); *Karpinski v. Ingrasci*, 228 N.Y.2d 45.
3. *Karpinski v. Ingrasci*, 28 N.Y.2d 45, 320 N.Y.S.2d 1 (1971).
4. Jason Shafrin, Defining a Hospital Catchment Area, Healthcare Economist, 11/23/10, healthcare-economist.com/2010/11/23/defining-a-hospital-catchment-area/.
5. *See Michael I. Weintraub, M.D., P.C. v. Schwartz*, 131 A.D.2d 663, 665, 516 N.Y.S.2d 946, 948 (2d Dep't 1987) *compare Metropolitan Medical Group, P.C. v. Eaton*, 154 A.D.2d 252, 254, 546 N.Y.S.2d 90 (1st Dep't 1989) (remanding validity of a 20-mile geographic restriction to the trial court as a question of fact).
6. *See, e.g., North Atl. Instruments Inc. v. Haber*, 188 F.3d 38, 47-48 (2d Cir. 1999), *accord McRoberts Protective Agency, Inc. v. Lansdell Protective Agency*, 61 A.D.2d 652, 403 N.Y.S.2d 511 (1st Dep't 1978).
7. I use the term "partner "for consistency, but this would be equally applicable to new physician-members of a PLLC or new physician-shareholders in a PC.
8. *But see Gazzola-Kraenzlin v. Westchester Medical Group*, 10 A.D.3d 700, 782 N.Y.S.2d 115 (2d Dep't 2004) (holding that continued employment past termination date in an employment contract was consideration for enforcing a restrictive covenant).
9. *See Last v. New York Ins. Of Tech*, 219 A.D.2d 620, 631 N.Y.S.2d 397 (2d Dep't 1995), *accord Penny W. Budoff v. Jenkins, M.D., P.C.*, 143 A.D.2d 250, 532 N.Y.S.2d 149 (2d Dep't 1988), *app. den*., 73 N.Y.2d 810, 537 N.Y.S.2d 494, 534 N.E.2d 333 (1988) (holding that the restrictive covenant applied to location of practice upon employee's termination, rather than hiring, where location changed during term of employment); *Horne v. Radiological Health Services, P.C.*, 83 Misc.2d 446, 371 N.Y.S.2d 948, *aff'd*, 51 A.D.2d 544, 379 N.Y.S.2d 374 (2d Dep't 1975) (stating that closing of practices by defendant in a certain area had opened them up for the plaintiff to practice).
10. *See Rifkinson-Mann v. Kasoff*, 226 A.D.2d 517, 641 N.Y.S.2d 102, 103 (2d Dep't 1996) (holding that a restrictive covenant that only restricted one of a neurologist's specialties was reasonable), *compare Penny W. Budoff, M.D., P.C.*, 143 A.D.2d 250, 532 N.Y.S.2d 149 (2d Dep't 1988), *app. den*., 73 N.Y.2d 810, 537 N.Y.S.2d 494, 534 N.E.2d 333 (1988) (holding that "family practice" services rendered in a women's health practice and in a family practice setting were substantially similar).
11. *See, e.g., Horne v. Radiological Health Services, P.C.*, 83 Misc.2d 446, 371 N.Y.S.2d at 959, *aff'd*, 51 A.D.2d 544, 379 N.Y.S.2d 374 (2d Dep't 1975).
12. *See, e.g., Arnold Leiboff, M.D., P.C. v. Pelaez*, 249 A.D.2d 497, 671 N.Y.S.2d 336 (2d Dep't 1998) (upholding a 2-year duration); *Bollengier v. Gulati*, 233 A.D.2d 721, 650 N.Y.S.2d 56 (3d Dep't 1996) (upholding a 2-year restricted period, where there were other vascular surgeons in the area and Dr. Gulati's practice was very established); *Novenstern v. Mt. Kisco Medical Group*, 177 A.D.2d 623, 576 N.Y.S.2d 329 (2d Dep't 1991) (upholding a 3-year restrictive covenant); *Finger Lakes Chiropractic, P.C. v. Maggio*, 269 A.D.2d 790, 703 N.Y.S.2d 632 (finding a 5-year restrictive covenant reasonable).
13. *See Millet v. Slocum*, 4 A.D.2d 528, 167 N.Y.S.2d 136 (3d Dep't 1957); *I. Edward Brown, Inc. v. Astor Supply Co*., 4 A.D.2d 177, 164 N.Y.S.2d 107; *Cornell v. T.V. Development Corp*., 17 N.Y.2d 69, 215 N.E.2d 249 (1966).
14. *See United Calendar Manufacturing v. Huang*, 94 A.D. 2d 176, 463 N.Y.S.2d 497 (2d Dep't 1983) (refusing to enforce a restrictive covenant in an employment contract between a business corporation and a doctor), *compare Prime Medical Assoc. v. Ramani*, 5 Misc.2d 311, 781 N.Y.S.2d 450 (Sup. Ct 2004) (refusing to uphold restrictive covenant where prohibited by immigration law, which neither plaintiff nor defendant followed).
15. *See In re Long Island Gastrointestinal Disease Group*, 251 A.D.2d 330, 673 N.Y.S.2d 738 (2d Dep't 1998) (holding that enforcement of a restrictive covenant is not an appropriate remedy for failure to return a vehicle leased by a practice while the practice was winding up).
16. *See Orchard Park Community Health Center v. Blasco*, 8 Misc.3d 927, 800 N.Y.S.2d 277 (Sup. Ct. 2004), *compare Awwad v. Capital Region Otolaryngology Head & Neck Group, L.L.P*., 18 Misc.3d 1111(A), 856 N.Y.S.2d 22 (Table) (2007).; *James V. Aquavella, M.D., P.C.*, 13 Misc.3d 1234(A) (Sup. Ct. 2006).
17. Although the issue would still remain, as with BDO Seidman, whether the physician developed the client absent substantial input from the practice.

John Minehan is Of Counsel to Minard Law, PLLC in Highlands, NY. He received his law degree (*cum laude*) from Albany Law School (1999), his MBA (Health Administration) from the Graduate Management Institute, Union College (1999) and his undergraduate degree from the Virginia Military Institute (*Distinguished in General Merit*) (1984).

ICD–10 and the Expansion of Admissible Evidence Under the "Medical Treatment" and Business Record Exceptions

By James G. Fouassier

The reader should be familiar with the application of the "business record exception" to the hearsay rule, recognized at common law and codified in New York in CPLR 4518.[1] An essential requirement of the exception is a finding by the court that the record "was made in the regular course of business and that it was the regular course of business to make it, at the time of the act, transaction, occurrence or event, or within a reasonable time thereafter…."[2] Consequently, a notation in a document that in its entirety may present as a "business record" may not be admissible if it were not the regular job of the recorder to record such information in a timely manner.

A medical record such as a patient's hospital chart, while meeting the definition of a "business record," is subject to some additional elements both of the common law and statute. Therefore, the admissibility of statements contained in a medical record now is considered in light of the common law "medical treatment" exception. CPLR 4518(c) provides that any hospital records are admissible and are *prima facie* proof of the facts therein contained if properly certified or authenticated by the hospital. At the same time any statement made for the purpose of obtaining or facilitating medical treatment, whether or not memorialized in writing, also is admissible as a "medical treatment" exception. The rationale behind the admissibility of "medical treatment" is that a declarant will be motivated to be completely truthful (thus presumably making the statement more reliable) by his or her immediate need for medical care.[3] The exception applies only if it pertains directly to the treatment sought or is reasonably relevant to the determination of a diagnosis or condition. Unless it is determined to be so relevant, statements as to how an injury arose or who inflicted it will not be admitted.

Notwithstanding the logical impression that CPLR 4518(a) and the "medical treatment" exception constitute discrete exceptions to the hearsay rule, the criteria for a finding of admissibility under the "medical treatment" exception are not disregarded or ignored simply because the statement happens to appear in a "medical record." As held by the Court of Appeals in the seminal case of *Williams v. Alexander*, 309 NY 283 [1955], hospital records fall within the business records exception when they "reflect acts, occurrences or events that relate to diagnosis, prognosis or treatment or are otherwise helpful to an understanding of the medical or surgical aspects of [a patient's] hospitalization. (*Id.*, 309 NY at 287; citations omitted). More recently, in a decision relying heavily on *Williams*, the Court of Appeals held to be properly admitted at trial certain statements concerning the factual backgrounds of an assault and robbery. *People v. Oldalys Ortega* and *People v. Maurice Benston*, decided *sub nom*. *People v. Ortega*, 15 NY3d 613 [2010]. In *Benston*, the medical record contained the complainant's statements referring to a history of abuse and incidents of domestic violence; to the defendant being a former boyfriend; and also to the existence of some kind of "safety plan." The trial court ordered redacted any references to a history of abuse and prior complaints but allowed references to the incident of domestic violence, and to a weapon, to go to the jury. The Appellate Division affirmed, finding that the trial court properly exercised its discretion in allowing references to the effect that the victim "was diagnosed as having been subjected to domestic violence involving a former boyfriend. (70 AD3d 479 [1st Dept 2010]). In *Ortega*, the medical record reported that the victim claimed that he was kidnapped and forced to smoke "a white substance" from a pipe. When the defendant later was apprehended the record was offered and admitted at trial. The Appellate Division affirmed. (64 AD3d 422 [1st Dept 2009]).

Judge Lippman, writing for the Court, found that knowing how a patient was injured may be "helpful" to an understanding of the medical aspects of his or her case. Sometimes information is germane to the diagnosis and treatment of psychological illness or injury. Sometimes it is "helpful" in the development of an appropriate discharge plan. Referring to the facts in *Benston*, the Court held that:

> The inquiry in each case before us remains whether the statements at issue were relevant to diagnosis and treatment…. The references to "domestic violence" and to the existence of a safety plan were admissible under the business records exception. Not only were these statements relevant to complainant's diagnosis and treatment, domestic violence was a part of the attending physician's diagnosis in this case…. Developing a safety plan…can be an important part of the patient's treatment. (15 NY3d at 619).

Similarly, with reference to *Ortega*, the Court held that:

> …the statement that complainant was "forced to" smoke a white, powdery substance was relevant to complainant's diagnosis and treatment…. In addition, treatment of a patient who is the victim of

> coercion may differ from a patient who has intentionally taken drugs. (15 NY3d at 620).

The absence in the majority opinion of any significant discussion of whether it is the "regular" duty of the reporter to report and the transcriber to include medically relevant statements in this kind of "business record" suggests that what may have been two distinct exceptions to the hearsay exclusion rule now have become conflated into a redefined "business records" exception.[4] This point was not lost on Judge Smith who, in a concurring opinion, went to great lengths to draw out the continuing distinction between the "business record" exception and the "medical treatment" exception.

Judge Smith begins his analysis by observing that the majority opinion and the Appellate Division cases cited therein "ignore a gap in their logic: the business records exception makes the records themselves, but not hearsay contained within the records, admissible." (15 NY3d at 620; citations omitted). Notwithstanding the inclusive language of CPLR 4518(c), apparently, Judge Smith writes that hearsay cannot be transformed into non-hearsay simply because a business routinely relies upon it and integrates it into its own records. How is this to be reconciled? By recognizing and applying the separate but valid exception for statements made for purposes of medical diagnosis and treatment. Why is it necessary explicitly to recognize this exception? Although the Federal Rules of Evidence, in rule 803(4), does so, and there is some support in New York case law for the exception, Judge Smith finds that the leading treatises on New York evidence (both Richardson and Fisch)[5] suggest that the exception has not been adopted in New York. Arguing that a "broad" understanding of what is relevant to diagnosis and treatment is essential, Judge Smith finds that the majority is adopting the "medical diagnosis and treatment" exception as a matter of law and simply should say so. (15 NY3d at 621.)[6]

More recently, and in a manner which Judge Smith might argue continues to conflate the different exceptions, the Second Department held in the context of a *Kendra's Law* proceeding[7] that statements in the respondent's medical record to the effect that his hospitalizations were caused by his failure to take his medications "were admissible under the business record exception to the hearsay rule because the diagnoses were relevant to his treatment, and could be used to develop a discharge plan that would ensure his safety." *Matter of Anthony H. [Karpati*], 82 AD3d 1240, 1241 [2011].

Somewhere along the way a consideration of the fundamental reason for hearsay exclusion exceptions was lost: is the statement *reliable*?

* * * * * * *

Anyone even remotely familiar with hospital chart documentation, coding, billing or medical claims submission has heard of the International Classification of Diseases, or "ICD." As summarized by Wikipedia:

> The International Classification of Diseases (also known by the abbreviation ICD) is the United Nations-sponsored World Health Organization's "standard diagnostic tool for epidemiology, health management and clinical purposes." The ICD is designed as a health care classification system, providing a system of diagnostic codes for classifying diseases, including nuanced classifications of a wide variety of signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease. This system is designed to map health conditions to corresponding generic categories together with specific variations, assigning for these a designated code, up to six characters long. Thus, major categories are designed to include a set of similar diseases.
>
> The International Classification of Diseases is published by the World Health Organization (WHO) and used worldwide for morbidity and mortality statistics, reimbursement systems, and automated decision support in health care. This system is designed to promote international comparability in the collection, processing, classification, and presentation of these statistics. As in the case of the analogous (but limited to mental and behavioral disorders) Diagnostic and Statistical Manual of Mental Disorders (DSM, currently in version 5), the ICD is a major project to statistically classify health disorders, and provide diagnostic assistance. The ICD is a core statistically-based classificatory diagnostic system for health care related issues of the WHO Family of International Classifications (WHO-FIC).

For more than thirty years the United States has employed a version of the ninth revision of ICD, known as the International Classification of Diseases, Clinical Modification (ICD-9-CM). This adaption was created by the U.S. National Center for Health Statistics (NCHS) and is used in assigning diagnostic and procedure codes associated with inpatient, outpatient, and physician office utilization specific to the United States. The ICD-9-CM is based on the ICD-9 but provides for additional morbidity details (hence additional and different documentation requirements). It is updated annually on October 1st.[8]

In 1992, the World Health Organization implemented the tenth revision of ICD. It has taken all these years for ICD-10 finally to be adopted here in the U.S. and it will be effective as of October 1, 2014. As explained in a very helpful fact sheet recently published by the American Medical Association,[9] the ICD-10 code sets are not a simple update of ICD-9. The ICD-10 code sets have fundamental changes in structure and concepts that make them very different from ICD-9. The revisions address one concern of the drafters: the lack of specificity of the information conveyed in the codes. Currently coding consists of three to five characters that will allow up to 13,000 coding combinations. Coders long ago recognized that this limited the number of conditions and procedures that could be coded, especially if there were significant differences in procedures occasioned by comorbidities and complications. Under ICD-10, the character length increases to seven, resulting in approximately 68,000 code combinations. This increase in "granularity" obviously allows for the coding of many more detailed diagnoses that previously were more generally lumped together. To make matters more complicated the "clinical modifications" specifically adopted in the U.S. (hence, ICD-10 *CM*) include much more detail than required by the international version, and in addition have separate sections for medical procedures, not just diagnoses. The U.S. ICD-10 CM has some 68,000 diagnosis codes and 76,000 procedure codes.

Particularly relevant to the subject of this article is that in addition to coding for diseases, injuries, symptoms and abnormal findings, ICD-10 also requires coding elements for complaints, social circumstances, and external causes of an injury or disease (requiring documentation, for example, of the location where an injury took place and the activity being undertaken at the time, to just mention a few additional elements). This reflects the social objectives of the WHO drafters. Reimbursement issues generally were, and remain, irrelevant to the WHO drafters. Their goal was not just to classify diseases and other health problems recorded on many types of health and vital records (including death certificates and health records) but also to develop data and statistics for epidemiological, quality and consumer safety purposes as well as the generation of a variety of mortality and morbidity statistics by WHO member nations. In particular it is intended that the data will allow these users sensibly and reasonably to allocate scarce resources.

The United States, however, is the only country in the world that uses ICD as a driver for health care *payment*. Here, hospitals and other clinicians cannot bill for their professional services, and insurers and other payers of all kinds cannot adjudicate and pay claims, without coding based on the ICD. Determining the ICD appropriate to a diagnosis or procedure depends upon the documentation contained in a medical record such as a hospital chart. Upon the correct coding of medical and hospital claims will turn the payment or denial of billions of dollars of health care services each year, and the proper coding of those claims, in turn, depends on proper and full documentation of all information subject to coding.

One way to understand the differences in documentation requirements for ICD-9 and ICD-10 is to examine a hypothetical.[10] The coded claim prepared under ICD-10 and submitted by Mrs. Smith's doctor looks like this:

S06.0x1A	Concussion with loss of consciousness of 30 minutes or less, initial encounter
G44.311	Acute post traumatic headache, intractable
M54.2	Cervicalgia
M99.01	Segmental and somatic dysfunction of cervical region
W20.8xxA	Struck by falling object (accidentally), initial encounter
Y93.g3	Activity, cooking and baking
Y92.010	Place of occurrence, house, single family, kitchen

These codes were assigned by trained medical record coders based upon the documentation in the medical records. The documentation contains the following narrative:

> Mrs. Smith presented at her doctor after having a kitchen shelf fall on her three days ago, resulting in a concussion together with cervicalgia. She was cooking dinner at the home she shares with her husband. She did not seek treatment at that time. She states that the people that put up the shelf missed the stud by about two inches. Her daughter, who was present, told her she was unconscious for about four minutes. Mrs. Smith still evidences cephalgias, primarily occipital, extending up into the bilateral occipital and parietal regions. Headaches come on daily and without warning, and last for long periods of time. Patient reports that NSAIDS are of no effect. She denies any changes to taste, smell or vision. Patient demonstrates tenderness across the superior trapezius.

Unlike the situation under ICD-9, ICD-10 requires that the external cause of the injury or illness be specified. The falling shelf is what caused the injury so it actually must be recited for the claim to be properly coded. The activity of the patient must be documented, hence

"cooking dinner." Documentation also must include the location of the injury; an injury occurring in the home must specify the actual room (here, the kitchen).

The reader may wish to examine a web resource presented by *ICD10Data.com* at http://www.icd10data.com/ICD10CM/Codes/V00-Y99/Y90-Y99/Y92- listing all of the possible "Y.92" coding for "Place of Occurrence of the External Cause" for an appreciation of the scope of the task providers and their coders will face under ICD-10. By my count there are some 200 possibilities, ranging from "bathroom" and "driveway" to "oil rig" and even "courthouse."

Is any of this newly required documentation admissible? To conflate both exceptions in the manner evidenced by *Ortega* and FRE 803(4) and apparently approved in cases such as *Williams*, the question becomes whether the recording of the information in the medical record is undertaken for purposes of medical diagnosis or treatment or the necessary description of medical history, past or present symptoms, pain or the inception or general character of the cause or external source thereof *insofar as reasonably pertinent to diagnosis or treatment*. The resolution is fact specific and must be determined on a case by case basis in the context of the claim. At the same time ICD-10 mandates that the documentation be placed in the record by the clinician; thus it is being recorded in the regular course of the hospital's business and it is in the regular course of such business that the clinician makes such a record. Why should it not be admissible independent of any finding that it is pertinent to the treatment of the patient? It may be reliable even if not pertinent. Conversely, a statement which, *prima facie*, appears to be relevant or pertinent to treatment in fact may not be; a court may not be competent to make such a determination in the absence of expert testimony (which is not always employed) and testimony may be conflicting or contradictory.

The answer, I submit, is that we follow the admonition of Judge Smith in *Ortega* and preserve as separate and distinct the "medical treatment" and "business record" exceptions. Statements contained in a hospital record which satisfy the requirements of CPLR 4518(a) should be admitted without consideration of relevance to treatment, with the weight of the evidence then being left to the trier of fact. No longer do we qualify the application of the business record exception by the extraneous finding that "regular course of business" must mean "medically necessary for treatment." This common sense approach will allow the information contained in the hospital or other clinical record, now mandated by ICD-10, to be admitted under the criteria established by CPLR 4518, and allow the trier of fact to determine what weight, if any, the evidence should be afforded (CPLR 4518[a]).[10]

****

In the *Williams* case (*supra*) the hospital record contained the following information that was provided by a pedestrian injured when struck by the defendant's car: "I was injured when the defendant's car was struck from behind by a truck and was pushed into me." At the trial of the action the defendant offered the pedestrian-plaintiff's statement in support of the defense that the defendant was fully stopped at the time the truck struck him in the rear, propelling him forward into the pedestrian. While the statement also may have been admissible as a party admission, a separate exception to the hearsay rule, the question for the court was whether the statement is admissible from the hospital record. The inquiry then became whether the statement was necessary for the diagnosis or treatment of the patient. In *Williams* the court found that it was not, and thus did not pertain to the business of the hospital; therefore it was not a "business record" that could be admitted under the business records exception.

Findings in other civil cases are to the same effect. In *Sermos v. Gruppuso*, 95 AD 3d 985, 944 NYS2d 245 (2012), a plaintiff sued the homeowners after he sustained injuries from falling into a swimming pool after tripping over a loose board in the owners' backyard. The Second Department held, inter alia, that that notations in the hospital record upon which the homeowners relied were not germane to the plaintiff's diagnosis or treatment and would not have been admissible at trial for their truth under the business records exception to the hearsay rule. Similarly, in a negligence action against New York City and the Transit Authority for injuries sustained by a rider getting off a bus, summary judgment for the City was reversed on the ground that the trial court improperly admitted the history portion of the plaintiff's medical record, because the entry, which contained information relating to how the accident occurred, was not admissible as a business record under CPLR 4518 in that it was not germane to plaintiff's diagnosis or treatment. *Gunn v. City of New York*, 104 AD2d 848, 480 NYS2d 365 (2d Dept 1984). A hospital triage report containing conflicting information on whether a plaintiff's injuries were caused by fall from a negligently maintained fire escape or a jump from a window to escape the fire was deemed inadmissible under the business record exception because the cause of the plaintiff's injuries was not germane to her diagnosis or treatment. *Quispe v Lemle & Wolff, Inc.*, 266 AD2d 95, 698 NYS2d 652 (1st Dept 1999).

In criminal cases the results have been the same. In *People v. Johnson*, 70 AD3d 1188, 896 NYS2d 199 (2010), the Third Department held that it was reversible error for the trial court to admit into evidence the defendant's emergency room medical records without redacting two notations in the treating physician's report that defendant was intoxicated, because the prosecution failed to demonstrate that intoxication was relevant or germane to the medical diagnosis or treatment of the defendant's

broken clavicle. Also in a criminal context (prosecution for second degree murder and related offenses) a victim's emergency room records stating that he was shot in a drive-by shooting were held inadmissible under the business records exception as irrelevant to the victim's diagnosis and treatment. *People v. Townsley*, 240 AD2d 955, 659 NYS2d 906 (3d Dept 1997), *app. denied sub nom, People v. T-Rock*, 90 NY2d 943, 664 NYS2d 762 (1997).

Under ICD-10 protocols, much if not most of these objectionable statements would be required to be documented in the hospital records. Separate and distinct rules respecting the admissibility of information contained in a hospital record and statements that are relevant to "medical treatment" would have allowed admission of the statements.

The advent of ICD-10 provides our courts with a new opportunity to review admissibility of hospital records with an emphasis on determining reliability, leaving to the trier of fact a determination of weight and value. Since ICD-10-CM does not become effective until October 1, 2014, it may be some time until a court has occasion to address this issue. The consequences for the personal injury bar, I submit, will be dramatic.

Endnotes

1. Rule 4518. Business records. (a) Generally. Any writing or record…made as a memorandum or record of any act, transaction, occurrence or event, shall be admissible…if the judge finds that it was made in the regular course of any business and that it was the regular course of such business to make it, at the time of the act, transaction, occurrence or event, or within a reasonable time thereafter…. All other circumstances of the making of the memorandum or record, including lack of personal knowledge by the maker, may be proved to affect its weight, but they shall not affect its admissibility. The term business includes a business, profession, occupation and calling of every kind.
2.. *Id.* New York is in the minority in allowing declarations of body condition to be admissible as a distinct exception only if made to a treating physician (unless the declarant now is deceased, thus invoking a different exception). *Query* if the declaration would be admissible if the non-treating clinician, or even a clerk, dutifully and regularly records it in the medical record ? *See infra.*
3. *See also* Rule 803(4) of the Federal Rules of Evidence:

   > The following are not excluded by the hearsay rule, even though the declarant is available as a witness:
   >
   > (4) STATEMENTS FOR PURPOSES OF MEDICAL DIAGNOSIS OR TREATMENT. Statements for purposes of medical diagnosis or treatment and describing medical history, or past or present symptoms, pain, or sensations, or the inception or general character of the cause or external source thereof insofar as reasonably pertinent to diagnosis or treatment.

4. *Williams* predates the adoption of the CPLR by some eleven years. Since the drafters presumably would reconcile case law in codifying common law rules of evidence it is curious that CPLR 4518(c) does not expressly set out the limitation that the "facts contained" therein must be germane to diagnosis or treatment. Was this a tacit acknowledgment that New York had yet to adopt "medical treatment" as a distinct exception to the hearsay exclusion?
5. Prince, *Richardson on Evidence*, section 8-610 [11th Ed]; Fisch, New York Evidence, secs 995-996 [2d Ed.].
6. Interestingly, in a separate concurring opinion Judge Pigott, although finding the error harmless, declines to apply such a "broad" understanding of relevance:

   > …[I]n my view, the majority in *Benston* interprets the business records exception too broadly by concluding that the "diagnosis" of domestic violence and references to a "safety plan" were properly admitted as part of the victim's diagnosis and treatment. While I recognize that domestic violence differs materially as an offense from other types of assault, the admission of this evidence can be error. A blanket rule allowing statements made by the complainant at the time of admission to the hospital can be just as harmful to a complainant's interests in some cases as its application here was to the defendant. (15 NY3d at 623). Apparently Judge Pigott, like the majority, also failed to perceive a distinction between the "business records" and the "medical diagnosis and treatment" exceptions.

7. Mental Hygiene Law section 9.60.
8. http://www.ama-assn.org/ama1/pub/upload/mm/399/icd10-icd9-differences-fact-sheet.pdf.
9. *American Association of Professional Coders (AAPC)* website; http://www.aapc.com/icd-10/icd-10-documentation-example.aspx.
10. CPLR 4518(a): "…All other circumstances of the making of the memorandum or record, including lack of knowledge by the maker, may be proved to affect its weight, but they shall not affect its admissibility."

James G. Fouassier is the Associate Director of Managed Care for Stony Brook University Hospital, SUNY and a member of the Health Law Section. His opinions are his own and may not reflect those of Stony Brook University Hospital, the State University of New York or the State of New York. He may be reached at james.fouassier@stonybrookmedicine.edu.

Health Care Institution Litigation*

By William A. Escobar and Antonia F. Giuliana

I. Introduction

§ 85:1 Scope note

Health care has become a dominant sector of the economy with increasing government funding, regulations, and attention from legislators, prosecutors, plaintiffs' lawyers, and whistleblowers. The litigation challenges confronting health care institutions have grown and include: (i) litigating complex cases simultaneously in numerous jurisdictions; (ii) dealing with statutory schemes with double or treble damages, civil penalties, criminal exposure, and the threat of exclusion from government funded programs; and (iii) trying cases before jurors that are invested in the issues as consumers and taxpayers.

Health care spending within government funded programs, such as Medicaid, continues to increase dramatically.[1] New York's Medicaid program incurred costs of $46 billion in 2008 alone.[2] Three years earlier, New York Medicaid paid more than a million claims per day at a cost of $44.5 billion,[3] which was almost one half of New York State's $105.5 billion total executive budget for the 2005-2006 fiscal year.[4]

The Government Accountability Office in Washington D.C. estimates that 10.5% of Medicaid spending is due to improper payments.[5] Such allegedly improper payments can serve as the basis for civil claims against health care providers and institutions under a variety of statutory and common law theories. Potential liability for providers and health care institutions arises in situations in which a plaintiff (either the government, a qui tam relator, or both) alleges that a defendant has submitted or caused to be submitted false or fraudulent claims for payment to Medicaid or another government funded health care program. Both the federal and state governments have enacted and strengthened statutes that authorize the government and private citizens to file civil actions for treble damages and penalties against health care institutions that are accused of submitting such allegedly false claims.[6] As a result, investigations and litigation in the health care arena have proliferated in recent years.

New York State has been very active in pursuing recoveries for health care fraud and abuse, especially against large health care institutions. In 2007, New York led the nation in reporting state health care fraud and abuse recoveries, accounting for $136 million of the $308 million national total.[7] In 2008 and 2009, New York State reported recovering $533.5 million in civil damages and settlements for health care fraud and abuse.[8]

In response to the upward spiraling costs of government funded health care programs, New York has ramped up its efforts to combat fraud by enacting broad statutes which will be increasingly used against participants in the health care sector. In April 2007, the state enacted the New York State False Claims Act which contains qui tam provisions that authorize and encourage private citizens to commence civil actions on the state and local government's behalf for health care fraud discovered by those individuals.[9] Moreover, the emergence of expansive theories of liability under the false claims acts have led to an increased use of the statutes in health care litigation, especially against deep pocket defendants.[10]

This chapter discusses the claims that are typically asserted against health care institutions in state false claims actions[11] and the parties that are typically involved in such litigation.[12] This chapter also discusses the strategic considerations that defense counsel should take into account when litigating a state false claims action[13] and examines the key statutory schemes and causes of action under New York law.[14] This chapter concludes with a discussion of representative cases brought against health care institutions under the recently enacted New York State False Claims Act.[15]

§ 85:2 State government funded health care programs in New York

The Medicaid program, created in 1965, is a state administered program, jointly funded by the federal government, that pays for medical assistance for certain low-income individuals and families.[16] Under Medicaid, each state establishes its own eligibility standards, benefit packages, payment rates, and program administration in accordance with certain federal statutory and regulatory requirements.[17] In New York, local Departments of Social Services administer New York's Medicaid program, under the oversight of the Department of Health, Office of Medicaid Management.[18] Medicaid providers submit claims for payment to New York State or its fiscal intermediary.[19] The New York Medicaid program is funded through federal, state and county monies. While the proportion of costs for which the federal government is responsible for differs from state to state, federal monies fund 50% of the New York Medicaid program's annual expenditures.[20]

Elderly Pharmaceutical Insurance Coverage Program (EPIC) is a New York State program that helps more than a quarter million senior citizens pay for their prescription drugs to the extent they are not covered by Medicare or other insurance.[21] Most enrollees have Medicare Part D or other drug coverage and use EPIC to lower their drug costs even more by helping them pay the deductibles and co-payments required by their other drug plans.[22]

II. Parties

A. The Potential Plaintiffs

§ 85:3 Overview

New York has been a leader among the states in pursuing and reporting recoveries for health care fraud and abuse.[23] The two agencies largely responsible for these recoveries are the New York State Attorney General Medicaid Fraud Control Unit and the recently established New York Office of the Medicaid Inspector General. A number of recoveries were due to qui tam lawsuits filed by private citizens under the New York False Claims Act.

§ 85:4 The New York State Attorney General Medicaid Fraud Control Unit (NYMFCU)

In 1995, the New York Medicaid Fraud Control Unit (the New York Medicaid Fraud Control Unit or NYMFCU) became part of the Office of the New York State Attorney General.[24] NYMFCU's mission is to conduct a statewide program for investigation and prosecution of health care providers and institutions that are accused of defrauding the Medicaid program.[25] In 2008, NYMFCU was named Medicaid Fraud Control Unit of the year by the federal government based on NYMFCU's return of investment of approximately $6.64 for every federal dollar expended.[26]

Three divisions of NYMFCU are responsible for qui tam actions and complex civil fraud investigations. The Civil Enforcement Division of NYMFCU handles complex civil fraud investigations using the New York State False Claims Act, SSL § 145-b, and the Executive Law, and initiates actions for civil remedies.[27] The Special Projects Division joins and takes a leading role in nationwide teams investigating health care institutions operating in states across the country.[28] The False Claims Act section shares responsibility with the Special Projects Division for investigating and, when appropriate, superseding or intervening in qui tam civil actions filed pursuant to the False Claims Act.[29]

In 2008, NYMFCU opened 439 Medicaid fraud investigations and resolved 347. Of these, 164 investigations were resolved as a result of civil actions.[30] At the end of 2008, NYMFCU had 559 open fraud investigations, of which 109 are qui tam complaints asserting claims for health care fraud and abuse under the New York False Claims Act, which went into effect on April 1, 2007.[31] As of the end of 2008, 17% of NYMFCU's open investigations docket consisted of qui tam actions filed pursuant to the New York's new False Claims Act.[32]

NYMFCU has become an active participant in the National Association of Medicaid Fraud Control Units (NAMFCU), which assigns teams to represent states in nationwide investigations.[33] Of the six national settlements concluded in 2008, NYMFCU was a member of three of the NAMFCU teams and staffed these teams with attorneys, auditors, investigators, and information technology specialists. New York State's share of these settlements totaled $157.5 million.[34] NYMFCU has stated that it plans to continue focusing on large providers and industry-wide investigations.[35]

§ 85:5 The New York Office of the Medicaid Inspector General (NY-OMIG)

In November 2006, New York State established the Office of the Medicaid Inspector General (the "New York Office of the Medicaid Inspector General" or the "NY-OMIG")[36] as an independent entity to tackle the issue of fraud, waste and abuse within New York State's Medicaid program and to recover improperly expended Medicaid funds.[37] The NY-OMIG works cooperatively with NYMFCU, the New York State Comptroller, federal prosecutors, state district attorneys, the Welfare Inspector General, and the special investigative units maintained by each health insurer operating within the state.[38] State law and federal regulations require the NY-OMIG to refer all cases of suspected provider fraud to the NYMFCU.[39]

One of the NY-OMIG's duties is to pursue civil and administrative enforcement actions against those who are accused of engaging in fraud, waste or abuse or other illegal or inappropriate acts within the Medicaid program.[40] The NY-OMIG has the authority to initiate or participate in civil proceedings, including actions at law

or in equity in order to recover any overpayments where the action or proceeding would be in the best interests of the program.[41]

The NY-OMIG has broad discretionary power to impose several different sanctions against individuals or entities, including but not limited to, Medicaid providers, based on its investigative activities.[42] Sanctions include censure, exclusion, or conditional or limited participation in the Medicaid program.[43] A sanction may be imposed upon a finding that an individual or entity has committed an "unacceptable practice" under the regulations.[44] In addition to sanctions, the NY-OMIG may impose monetary penalties in certain circumstances.[45] The NY-OMIG's final determinations involving sanctions, penalties, and/or overpayments are issued pursuant to a Notice of Final Agency Action or Final Audit Report.[46] Both notices are subject to administrative review, and if necessary, judicial review.[47]

Administrative review of certain NY-OMIG final determinations is performed in a hearing by an administrative law judge. In 2008, 52 administrative hearings were requested to challenge the final determinations of the NY-OMIG. In 2008, four cases were resolved by stipulation of settlement, 12 hearing requests were withdrawn, and nine hearing decisions were issued.[48] In addition, a defendant may seek judicial review of NY-OMIG final determinations by initiating a proceeding in the New York State Supreme Court pursuant to Article 78 of the Civil Practice Law and Rules.[49] During 2008, 20 Article 78 proceedings were filed. At the conclusion of the reporting period, six proceedings were closed. Of the six closed proceedings, three cases were dismissed and three cases were affirmed.[50]

§ 85:6 Qui tam plaintiffs (also known as relators or "whistleblowers")

"Qui tam" is a shortened form of the Latin phrase "qui tam pro domino rege quam pro se ipso in hac parte sequitur" which means "who as well for the king as for himself sues in this matter."[51] Qui tam provisions in the federal and state false claims acts permit a private citizen to commence a civil action on behalf of the government.[52] Today, qui tam actions are commonly known as "whistleblower" lawsuits. The purpose of qui tam provisions in false claims acts is to encourage private citizens who are aware of fraud committed against the government to come forward and report the matter to the authorities, especially when that person is at some individual risk in coming forward.[53] Qui tam provisions achieve this purpose by rewarding and protecting private citizens that come forward by permitting them to share in any recovery that is ultimately gained.[54]

A qui tam plaintiff does not suffer any injury, but instead brings the suit in the name of the government and has standing to sue through a potential assignment of the government's damage claim.[55] The typical qui tam action is "filed by an insider at a private corporation who discovers his employer has overcharged under a government contract."[56] However, qui tam actions, especially those in the health care field, have not been restricted to such classic examples. Relators can be corporations, partnerships, non-profit organizations, unincorporated associations, individuals, or groups of individuals, although the most common relator is an employee or former employee of the defendant corporation.[57]

The financial rewards available to whistleblowers make qui tam litigation very attractive to relators and their counsel, especially in actions against large health care institutions where a single judgment or settlement can exceed tens, if not hundreds, of millions of dollars. The relator's "cut" in such cases is typically between 15-30% of the proceeds recovered in the action.[58] Because relators' counsel typically provide their services on a contingency basis for qui tam litigation, there is a significant financial incentive for counsel to become involved in such matters. Indeed, qui tam litigation is a growing specialty area for plaintiffs' firms.

The number of qui tam actions alleging claims for health care fraud under the federal False Claims Act (the federal FCA) and the New York State False Claims Act (the NY-FCA) has increased significantly in recent years. As of October 2009, 985 qui tam health care cases alleging claims under the federal FCA were pending.[59] As of the end of 2009, in New York State, NYMFCU reported 535 active fraud investigations, of which 133 were qui tam actions under the NY-FCA.[60]

B. The Potential Defendants

§ 85:7 Overview

The most common corporate defendants in civil actions for health care fraud and abuse brought under New York State law are the providers that submit claims for reimbursement, including hospitals and hospices, home health care agencies, managed care organizations, and pharmacies. Recently, there has been an effort to expand the scope of health care fraud and abuse litigation by filing actions against entities that do not submit claims and do not receive payment from government programs, including drug manufacturers and companies that provide support services to health care institutions.

§ 85:8 Hospitals and hospices

Hospitals and hospices typically submit claims for reimbursement under government sponsored health care programs. Hospitals and hospices have been targets of qui tam complaints in New York State.[61] A plaintiff may allege, for example, that a hospital knowingly presented, or caused to be presented, false claims to Medicaid for reimbursement for drugs or services by not actually rendering the services or drugs for which it claimed reimburse-

ment, submitting a claim based on a false certification, or using improper codes to bill for drugs or services actually dispensed resulting in higher reimbursement.[62]

§ 85:9 Home health care agencies

Every month, more than 150,000 New York residents receive some sort of Medicaid-reimbursed home health care services. In 2007, New York Medicaid incurred $3.8 billion in home health care costs throughout the state.[63] Medicaid-reimbursed home health care involves a myriad of services, programs, and employment arrangements involving skilled nurses, home health aides, and personal care aides. Due to state initiatives designed to improve care and reduce costs by emphasizing home care rather than institutional care, the number of Medicaid recipients receiving home health care has grown significantly.[64] Accordingly, home health care agencies have been subject to heightened scrutiny by the state in recent years. A recent initiative by the NYMFCU called "Operation Home Alone" targeted health care fraud in the home health care industry and resulted in a number of civil settlements and criminal convictions.[65]

§ 85:10 Managed care organizations

Managed care organizations have state contracts to arrange for health care services to be provided to Medicaid patients under a capitation system. "Capitation" means that health care providers are paid a set amount by New York Medicaid for each enrolled person assigned to that provider for a certain period of time, whether or not that person seeks care. Since 1996, New York Medicaid payments to managed care organizations rose from approximately $1 billion to over $7 billion in 2007, as such entities are playing an expanded role in providing health care to uninsured New York residents.[66] Because Medicaid pays managed care organizations on a capitation basis, managed care organizations make money based on the number of beneficiaries they can recruit. As a result, managed care organizations are susceptible to allegations of enrollment fraud.[67]

§ 85:11 Substance abuse clinics

Substance abuse clinics that provide Medicaid services are typically required to submit annual cost reports. Clinics that allegedly submit "inflated" cost reports or cost reports that include "non-allowable" costs may be sued under the state false claims acts.[68] NYMFCU has been aggressive in pursuing fraud and abuse claims against substance abuse clinics and has filed civil actions against not only against substance abuse clinics and their operators, but also, in at least one instance, against the accounting firm and accountant that certified the clinic's allegedly inflated cost reports that were submitted to Medicaid.[69]

§ 85:12 Retail pharmacies

Retail pharmacies that provide drugs to Medicaid beneficiaries submit claims for reimbursement to Medicaid. One of the most clear cut examples of health care fraud and abuse that is actionable under New York law occurs when a pharmacy charges Medicaid for drugs that were never provided to a patient.[70] Retail pharmacies also may be susceptible to allegations that they have used improper codes to bill Medicaid for drugs actually dispensed to patients resulting in a higher reimbursement than they would have received had they used the proper billing codes.[71]

§ 85:13 Entities that do not submit claims and do not receive payments

Potential defendants in civil actions for health care fraud and abuse extend beyond those entities that submit claims and receive payment. Even non-health care entities are at risk. For example, in 2008, the New York Attorney General reached a $1 million settlement with an accounting firm that certified a clinic's allegedly **"**inflated**"** cost reports that were sent to Medicaid.[72] In addition, pharmaceutical manufacturers have become increasingly popular targets under the state false claims acts. In 2008 and 2009, two-thirds of the $533.5 million in civil recoveries for health care fraud and abuse in New York State came from settlements with pharmaceutical manufacturers.[73] Although pharmaceutical manufacturers do not typically submit claims for reimbursement under government sponsored programs such as Medicaid and EPIC, plaintiffs have alleged theories of indirect liability to hold manufacturers liable under the false claims acts. As discussed below in **§§** 85:45 to 85:49, by asserting expansive theories of liability under the false claims acts, plaintiffs have brought civil claims against drug manufacturers based on alleged off-label marketing, **"**marketing the spread**"** between the government reimbursement rate and a provider's acquisition cost for a particular drug, failure to pay appropriate Medicaid rebates, and other related activities.

Endnotes

1. Medicaid spending for all states was approximately $350 billion in 2007. See Presentation by Senate Committee on Investigations and Government Operations, Jan. 7, 2010, Jim Sheehan, New York Medicaid Inspector, available at www.omig.state.ny.us/data/ (follow "Medicaid Inspector General James G. Sheehan's presentation before the New York Senate Committee on Investigations and Government Operations, Chaired by Senator Craig Johnson (D-Nassau), on January 7, 2010 in New York City." hyperlink). The Centers for Medicare and Medicaid Services reports that Medicaid spending increased 4.7% in 2008 and 9.9% in 2009. From 2009 through 2019, Medicaid spending growth rates are projected to average 7.5%. As a result of rapid growth in government spending, the public share of total health care spending is expected to rise from 47% in 2008, exceed 50% by 2012, and reach 52% by 2019. CMS, Recession Expected to Impact Growth in National Health Expenditures Over the Next Several Years (Feb. 4, 2010), http://www.cms.hhs.gov/apps/media/fact_sheets.asp (follow "February 04, 2010" hyperlink).
2. See Presentation by Senate Committee on Investigations and Government Operations, Jan. 7, 2010, Jim Sheehan, New York Medicaid Inspector, available at www.omig.state.ny.us/data/

(follow "Medicaid Inspector General James G. Sheehan's presentation before the New York Senate Committee on Investigations and Government Operations, Chaired by Senator Craig Johnson (D-Nassau), on January 7, 2010 in New York City." hyperlink).

3. Michael Luo & Clifford J. Levy, As Medicaid Balloons, Watchdog Force Shrinks, New York Times, July 19, 2005, at A1 available at http://www.nytimes.com/2005/07/19/nyregion/19medicaid.html.
4. State of New York, Executive Chamber, 2005-06 New York State Executive Budget, at 5, available at http://www.budget.state.ny.us/pubs/archive/fy0506archive/fy0506littlebook/lb0506.pdf.
5. GAO, Improper Payments: Progress Made but Challenges Remain in Estimating and Reducing Improper Payments, April 22, 2009, available at http:/www.gao.gov/new.items/d09628t.pdf.
6. See §§85:17 to 85:23.
7. New York State Office of the Medicaid Inspector General (OMIG) 2007 Annual Report, at 8, available at http://www.omig.state.ny.us/data/images/stories/annual%20report%202007.pdf; OMIG 2008 Annual Report, at 4, available at http://www.omig.state.ny.us/data/images/stories/annual_report_2008.pdf.
8. New York State Medicaid Fraud Control Unit (NYMFCU) 2008 Annual Report, at 2-3, available at http://www.ag.ny.gov/media_center/reports/MFCU%202008%20annual%20report%20final.pdf; New York State Medicaid Fraud Control Unit ("NYMFCU") 2009 Annual Report, at 1, available at http://www.ag.ny.gov/media_center/2010/apr/mfcu_2009.pdf.
9. N.Y. Fin. Law §§187 to 194.
10. See §§85:7, 85:13.
11. See §§85:17 to 85:33.
12. See §§85:3 to 85:13.
13. See §§85:14 to 85:16.
14. See §§85:17 to 85:33.
15. See §§85:34 to 85:49.
16. U.S. ex rel. Romano v. New York-Presbyterian Hosp., Medicare & Medicaid 302375, 2008 WL 904730, at *1 (S.D. N.Y. 2008). There are several state government funded health care programs in New York. This section, however, only discusses the programs under which claims are most frequently brought against large health care institutions and providers in New York, specifically Medicaid and EPIC.
17. U.S. ex rel. Romano v. New York-Presbyterian Hosp., Medicare & Medicaid 302375, 2008 WL 904730, at *1 (S.D.N.Y. 2008).
18. See New York State Medicaid Program, Information For All Providers General Billing (Dec. 10, 2008), at 6, available at http://www.emedny.org/ProviderManuals/AllProviders/PDFS/Information_for_all_providers-general_billing.pdf.
19. See New York State Medicaid Program, Information For All Providers General Billing, at 6 (Dec. 10, 2008), available at http://www.emedny.org/ProviderManuals/AllProviders/PDFS/Information_for_all_providers-general_billing.pdf.
20. NYMFCU 2008 Annual Report, at 4.
21. New York State Department of Health, Elderly Pharmaceutical Insurance Coverage (EPIC) Program, http://www.health.state.ny.us/health_care/epic/ (last visited Mar. 2, 2010).
22. New York State Department of Health, Elderly Pharmaceutical Insurance Coverage (EPIC) Program, http://www.health.state.ny.us/health_care/epic/ (last visited Mar. 2, 2010).
23. See §85:1. See also OMIG 2007 Annual Report, at 8; OMIG 2008 Annual Report, at 4; NYMFCU 2008 Annual Report, at 2-3.
24. NYMFCU 2008 Annual Report, at 4. NYMFCU, previously known as the New York Special Prosecutor for Nursing Homes, Health and Social Services, was originally formed in January 1975 as an independent state agency. In May 1978, after Congress passed legislation establishing the state Medicaid fraud control unit program, the Office of New York Special Prosecutor for Nursing Homes, Health and Social Services was renamed and reorganized as New York's Medicaid Fraud Control Unit. See NYMFCU 2008 Annual Report, at 4.
25. NYMFCU 2008 Annual Report, at 5.
26. NYMFCU 2009 Annual Report, at 5.
27. NYMFCU 2008 Annual Report, at 5.
28. NYMFCU 2008 Annual Report, at 5-6.
29. NYMFCU 2008 Annual Report, at 6.
30. NYMFCU 2008 Annual Report, at 9.
31. NYMFCU 2008 Annual Report, at 9.
32. NYMFCU 2008 Annual Report, at 2.
33. In large, complex cases against health care institutions, the NAMFCU will typically appoint a team consisting of several state Medicaid Fraud Control Units that collaborates and works jointly with the Department of Justice and state prosecutors to investigate allegations of health care fraud and abuse occurring in multiple states or nationwide. See NYMFCU 2008 Annual Report, at 18; see also NYMFCU 2009 Annual Report, a 5.
34. NYMFCU 2008 Annual Report, at 2.
35. NYMFCU 2008 Annual Report, at 2.
36. The NY-OMIG was created, at least in part, in response to criticism from the federal government. The Centers for Medicare and Medicaid Services ("CMS") issued a June 2006 report, stating that it "does not believe that New York's oversight of Medicaid program integrity is commensurate with the risk incurred by its Medicaid program, the largest in the country." OMIG 2007 Annual Report, at 54.
37. See 2006 N.Y. Laws 442; Pub. Health Law §30; see also New York State Office of the Medicaid Inspector General, 2008 Annual Report, at Executive Summary. According to the OMIG's 2008 Annual Report, it began 3,281 investigations in 2008 and completed 2,366. It also referred 88 cases to the New York State Attorney General for potential prosecution as criminal cases and referred 531 cases to other state agencies (the vast majority of those (496) were referred to local social services districts for investigation at the local level). The NY-OMIG excluded 660 providers from participating in New York's Medicaid program in 2008 and terminated 39. See OMIG 2008 Annual Report, at Executive Summary.
38. See OMIG 2008 Annual Report, at 3; see also Pub. Health Law §31.
39. See Pub. Health Law §32(7); 42 C.F.R. §455.21.
40. See OMIG 2008 Annual Report, at 2.
41. Pub. Health Law §§30, 31; OMIG 2008 Annual Report, at Executive Summary.
42. OMIG 2008 Annual Report, at 58.
43. See 18 NYCRR §515.3(a).
44. 18 NYCRR §§515.1 to 515.2.
45. 18 NYCRR §§516.1 to 161.5.
46. OMIG 2008 Annual Report, at 61.
47. OMIG 2008 Annual Report, at 61.
48. OMIG 2008 Annual Report, at 62.
49. OMIG 2008 Annual Report, at 61. See generally Chapter 102, "CPLR Article 78 Challenges to Administrative Determination" (§§102:1 et seq.) for discussion of Article 78 Proceedings.
50. OMIG 2008 Annual Report, at 62.
51. Black's Law Dictionary 1282 (8th ed. 2004).

52. 31 U.S.C.A. §3730(b)(1) (2000) ("A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government."); N.Y. Fin. Law §190(2)(a) ("Any person may bring a qui tam civil action for a violation of section one hundred eighty-nine of this article on behalf of the people of the state of New York or a local government.").

53. U.S. ex rel. Dick v. Long Island Lighting Co., 912 F.2d 13, 18, 36 Cont. Cas. Fed. (CCH) P 75930 (2d Cir. 1990) (citing H.R. Rep. No. 660, 99th Cong., 2d Sess. 22 (1986)); U.S. ex rel. Ellis v. Sheikh, 583 F. Supp. 2d 434, 438, 71 Fed. R. Serv. 3d 1414 (W.D.N.Y. 2008).

54. 31 U.S.C.A. §3730(d); N.Y. Fin. Law. §§190(6)(a), 191(1).

55. 31 U.S.C.A. §3730(b)(1) (2000); NY Fin. Law §190; Vermont Agency of Natural Resources v. U.S. ex rel. Stevens, 529 U.S. 765, 773-74, 120 S. Ct. 1858, 1863, 146 L. Ed. 2d 836, 50 Env't. Rep. Cas. (BNA) 1545, 16 I.E.R. Cas. (BNA) 417, 30 Envtl. L. Rep. 20622 (2000).

56. U.S. ex rel. Polansky v. Pfizer, Inc., 2009 WL 1456582, *8 (E.D.N.Y. 2009) (citing U.S. ex rel. Hopper v. Anton, 91 F.3d 1261, 1266, 111 Ed. Law Rep. 676 (9th Cir. 1996)).

57. 1 John T. Boese, Civil False Claims and Qui tam Actions §4.01[B] [1], [2] at 4-14, 4-16 (3d ed. 2010 Supp. 2009-1).

58. N.Y. Fin. Law §190(6)(a).

59. Press Release, Senator Chuck Grassley, More Than a Thousand Fraud Cases Await Government Action (Oct. 7, 2009), available at http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=23563.

60. NYMFCU 2009 Annual Report, at 8.

61. See §§85:37 to 85:40, 85:42.

62. See §§85:36 to 85:39.

63. NYMFCU 2008 Annual Report, at 10.

64. NYMFCU 2008 Annual Report, at 10.

65. NYMFCU 2008 Annual Report, at 9.

66. NYMFCU 2008 Annual Report, at 21.

67. See §85:43.

68. See §85:44.

69. See §85:44.

70. See §85:36.

71. See §85:39.

72. See §85:44.

73. NYMFCU 2008 Annual Report, at 2, 18; NYMFCU 2009 Annual Report, at 1, 13.

The authors gratefully acknowledge the assistance of Jessica K. Shook and David de la Garza Bassett, litigation associates at Kelley Drye & Warren LLP, in the preparation of this chapter.

Book Review

Robert Haig, *Commercial Litigation in New York* (3d Edition 2014)

By Edward S. Kornreich

Health care lawyers are generalists, and often regulatory specialists and transactional attorneys with a smattering of litigation exposure. As such, they frequently have procedural and substantive questions concerning ongoing New York State Court litigation in which their client is involved. The recently issued Third Edition of *Commercial Litigation in New York State Courts* is a welcome source of answers to those questions.

The work is uniquely focused on New York courts, and offers legal analysis on both substantive and procedural issues. Even more important is its discussion of strategies and its practical guidance. The included checklists and forms are very helpful.

While the work is not by any means a primer on health law, as part of its comprehensive scope, it does touch upon health law issues as they need to be known by a general litigator. Moreover, for questions regarding, for example, subpoenas, service of process, venue, statute of limitations, the merits of a motion to dismiss, discovery—including related technology issues—indeed for all the day-to-day litigation issues that health care lawyers frequently face, the work offers straightforward, accurate answers, and is an excellent desktop tool. For example, recently I needed prompt guidance on claims against New York State, and its sovereign and governmental immunity. The treatise offered clear and concise explanations with many useful citations, and I quickly had my answers.

For the more specialized health care litigator, the work contains a number of chapters on conducting a trial, written originally by my late partner, Stephen Kaye, and recently updated by my firm. Steve's insights into trial advocacy are remarkable.

Proceeds from this excellent treatise accrue to the New York County Lawyers' Association. I recommend it highly.

Edward S. Kornreich is a partner in Proskauer Rose, LLP, and is the past longstanding chair of the firm's Health Care Department.

New Officers Elected

At the Health Law Section Annual Meeting in January, the membership elected the following officers. Their terms start June 1, 2014:

Chair:	Margaret (Margie) J. Davino Kaufman, Borgeest & Ryan (NYC)
Chair-Elect:	Kenneth (Ken) R. Larywon Martin, Clearwater & Bell (NYC)
Vice-Chair:	Raul A Tabora, Jr. Bond Schoeneck & King, PLLC (Albany)
Secretary:	Lawrence (Larry) Faulkner ARC of Westchester (Hawthorne)
Treasurer:	Robert (Bob) A. Hussar Manatt, Phelps & Phillips (Albany)

Recent Events

- ***The New York State Task Force on Life and the Law, Current Projects*** was held on April 3, 2014.

  This was a joint meeting of the NYSBA Health Law Section, Committee on Ethical Issues in the Provision of Health Care and New York City Bar Association, Health Law Committee, but was open to other Health Law Section members as well.

  The NYS Task Force on Life and the Law is a multidisciplinary panel that makes policy recommendations on ethical issues in health care and biology.

  The Executive Director, Stuart Sherman, presented on issues recently considered by the Task Force and the Empire State Stem Cell Board, including:

  – research involving adults who lack capacity to consent,

  – allocation of ventilators in an influenza pandemic,

  – changes to the Family Health Care Decisions Act, and

  – the work of Empire State Stem Cell Board.

  The program was held simultaneously at the State Bar Center, One Elk Street, Albany, NY 12207 and at the City Bar Association, 42 W 44th Street, New York, NY 10036.

- ***2014 Annual Meeting.*** The Health Law Section's Annual Meeting was held at the New York Hilton on January 29, and was well-attended. The program covered the latest developments across the range of NY and federal health law topics, including genetics and the law, regulatory update, mobile health apps, the NY health exchange, new managed care entities, payment and reimbursement issues.

  NYS Senate Health Chair Kemp Hannon, and NYS Assembly Health Chair Richard Gottfried described upcoming health legislation. Margaret (Margie) J. Davino of Kaufman, Borgeest & Ryan, LLP, was Program Chair.

- ***Surrogate Health Care Decision Making: Proposed Amendments to the Family Health Care Decisions Act (PHL 2994-a) and to the Health Care Decisions Act for Persons with Mental Retardation (SCPA 1750-b).***

  This joint meeting of the NYSBA Health Law Section, Committee on Ethical Issues in the Provision of Health Care, and New York City Bar Association, Health Law Committee, was held on March 5 at both the NYSBA Bar Center in Albany and the City Bar Association in NYC. The presentations were by Paul Kietzman, General Counsel, NYSARC, Inc. and Robert Swidler, General Counsel, V.P. Legal Services, St. Peter's Health Partners.

Committee Activities

- The E-Health Committee is collaborating with Albany Law School in preparing a white paper and conference on Telehealth and Telemedicine in the fall of 2014. For more information contact Raul A. Tabora, Bond Schoeneck & King, Albany NY.

Scenes from the Health Law Section

ANNUAL MEETING

New York Hilton Midtown

January 29, 2014

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.

E-Health and Information Systems
Charles C. Dunham, IV
Bond Schoeneck & King
111 Washington Avenue
Albany, NY 12210
cdunham@bsk.com

Daniel Meier
Benesch Friedlander Coplan & Aronoff
50 Main Street, Suite 1000
White Plains, NY 10606
rtabora@bsk.com
dmeier@beneschlaw.com

Ethical Issues in the Provision of Health Care
Alice H. Herb
SUNY Downstate Medical Center
450 Clarkson Avenue, Box 116
Brooklyn, NY 10011
aherb217@gmail.com

Lawrence R. Faulkner
ARC of Westchester
265 Saw Mill River Road, 3rd Fl.
Hawthorne, NY 10532
lfaulkner@westchesterarc.org

Health Care Providers and Networks
David A. Manko
Rivkin Radler LLP
926 RXR Plaza
Uniondale, NY 11556-0926
david.manko@rivkin.com

Reginald Bullock Jr.
North Shore-Long Island Jewish Health System
145 Community Drive
Great Neck, NY 11021
rbullock@nshs.edu

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

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

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

Medical Research and Biotechnology
Samuel J. Servello
Moses & Singer LLP
405 Lexington Avenue, 12th Fl.
New York, NY 10174-0002
sservello@mosessinger.com

Alex C. Brownstein
BioScience Communications
250 Hudson Street
New York, NY 10013
alex.brownstein@bioscicom.net

Membership
James F. Horan
New York State Health Department
Bureau of Adjudication
Riverview Center
150 Broadway, Suite 510
Albany, NY 12204-2719
jfh01@health.state.ny.us

Karen L. I. Gallinari
Montefiore Medical Center
15 Wilcox Avenue
Yonkers, NY 10705
kgallina@montefiore.org

Mental Hygiene and Developmental Disabilities
Carolyn Reinach Wolf
Abrams, Fensterman, Fensterman, Eisman, Greenberg, Formato & Einiger, LLP
1111 Marcus Avenue, Suite 107
Lake Success, NY 11042
cwolf@abramslaw.com

Hermes Fernandez
Bond, Schoeneck & King, PLLC
111 Washington Avenue
Albany, NY 12210-2211
hfernandez@bsk.com

Professional Discipline
Barbara A. Ryan
Aaronson Rappaport Feinstein et al
600 3rd Avenue, 6th Fl.
New York, NY 10016
baryan@arfdlaw.com

Publications and Web Page
Robert N. Swidler
St. Peter's Health Partners
5 Cusack
315 S. Manning Blvd.
Albany, NY 12208
robert.swidler@sphp.com

Reimbursement, Enforcement, and Compliance
Melissa M. Zambri
Hiscock & Barclay LLP
80 State Street
Albany, NY 12207-2207
mzambri@hblaw.com

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

Public Health
Julia C. Goings-Perrot
Catania, Mahon, Milligram & Rider, PLLC
1 Corwin Court
P.O. Box 1479
Newburgh, NY 12550
jgoings-perrot@cmmrlegal.com

Publication and Editorial Policy

Persons interested in writing for this *Journal* are welcomed and encouraged to submit their articles for consideration. Your ideas and comments about the *Journal* are appreciated as are letters to the editor.

Publication Policy:
All articles should be submitted to:

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

Submitted articles must include a cover letter giving permission for publication in this *Journal.* We will assume your submission is for the exclusive use of this *Journal* unless you advise to the contrary in your letter. Authors will be notified only if articles are rejected. Authors are encouraged to include a brief biography with their submissions.

Editorial Policy: The articles in this *Journal* represent the authors' viewpoints and research and not that of the *Journal* Editorial Staff or Section Officers. The accuracy of the sources used and the cases cited in submissions is the responsibility of the author.

Subscriptions

This *Journal* is a benefit of membership in the Health Law Section of the New York State Bar Association.

The *Journal* is available by subscription to non-attorneys, libraries and organizations. The subscription rate for 2014 is $150.00. Send your request and check to Newsletter Dept., New York State Bar Association, One Elk Street, Albany, NY 12207.

Accommodations for Persons with Disabilities:
NYSBA welcomes participation by individuals with disabilities. NYSBA is committed to complying with all applicable laws that prohibit discrimination against individuals on the basis of disability in the full and equal enjoyment of its goods, services, programs, activities, facilities, privileges, advantages, or accommodations. To request auxiliary aids or services or if you have any questions regarding accessibility, please contact the Bar Center at (518) 463-3200.

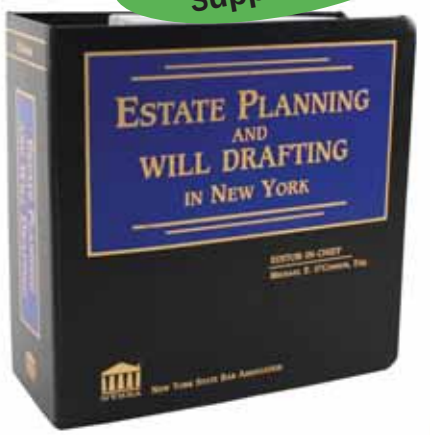
ISSN 1530-3926 ISSN 1933-8406 (online)

NEW YORK STATE BAR ASSOCIATION

Estate Planning and Will Drafting in New York

Section Members get 20% discount* with coupon code PUB2143N

With 2013–2014 Supplement



Editor-in-Chief

Michael E. O'Connor, Esq.
DeLaney & O'Connor, LLP
Syracuse, NY

Key Benefits

- Marital Deduction / Credit Shelter Drafting
- Estate Planning with Life Insurance
- Lifetime Gifts and Trusts for Minors
- Planning for Client Incapacity

Product Description

This comprehensive text provides an excellent overview of the complex rules and considerations involved in estate planning in New York State. Whether your practice incorporates issues surrounding minors, marriage, the elderly, federal and state taxes, this text provides comprehensive guidance to attorneys. With useful practice comments, real-world examples and sample forms this text is also an invaluable practice guide for practitioners who are just entering this growing area.

Contents at a Glance

Book with Forms on CD Prices | PN: 4095C | 2006 (includes 2013–2014 revision)
NYSBA Members $185 Non-Members $220

PN: 50954 (2013–2014 Supplement for past purchasers) | loose-leaf
NYSBA Members $125 Non-Members $150

CD Prices | PN: 60954 | 2013–2014
NYSBA Members $100 Non-Members $120

Discount good until May 31, 2014

To order call **1.800.582.2452**
or visit us online at **www.nysba.org/pubs**

Order multiple titles to take advantage of our low flat rate shipping charge of $5.95 per order, regardless of the number of items shipped. $5.95 shipping and handling offer applies to orders shipped within the continental U.S. Shipping and handling charges for orders shipped outside the continental U.S. will be based on destination and added to your total. Prices do not include applicable sales tax.

Mention code: PUB2143N when ordering.

NYSBA

NEW YORK STATE BAR ASSOCIATION
HEALTH LAW SECTION
One Elk Street, Albany, New York 12207-1002

ADDRESS SERVICE REQUESTED

NON PROFIT ORG.
U.S. POSTAGE
PAID
ALBANY, N.Y.
PERMIT NO. 155