NYSBA WINTER 2012 | VOL.17 | NO. 1

Health Law Journal

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

Inside

NYSBA

HEALTH LAW JOURNAL

WINTER 2012

Vol. 17, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

Table of Contents

Cover artwork:
A Rustic Concert, by Govardhan (1625)

A Message from the Section Chair

Dear Fellow Section Members:

I have much good news to share about our Section's activities.

Programs

Our Section's Fall meeting, which focused on the legal issues arising from the structuring of Accountable Care Organizations (ACO) was a major success, drawing almost 100 attendees. Not only were there outstanding presentations by very distinguished panelists, but the meeting took place just two days after the Department of Health and Human Services issued its final guidance on ACOs, making ours the first-in-the-nation program to analyze the final guidance. Congratulations to program Co-Chairs Margie Davino and Julia Goings-Perrot, and to the panelists who clearly explained and analyzed the complex guidance on such short notice.

Our Annual Meeting, which took place on January 12, 2012, was co-chaired by Robert Hussar and Melissa Zambri. It focused on current fraud and abuse developments, and federal and state enforcement initiatives in this always active area of health care law.

On February 21, 2012, our Section co-sponsored an all-day program on "Legal, Ethical and Mental Health Issues on Today's Higher Education Campus," which was held at Fordham Law School's Lincoln Center Campus. Co-chairs of the program were Health Law Section Members Mary Beth Morrissey, Lawrence Faulkner, and Carolyn Wolf.

Future programs will include one dedicated to the issues affecting in-house counsel at health care providers and companies.

Section Committees

One of my priorities during my tenure as chair has been to streamline our Section's Committee structure and to get inactive Committees active. To that end, the Executive Committee has approved the following consolidations:

Unchanged	Chair/Co-Chair
Executive Committee	Section Chair
Membership	Karen Gallinari
Fraud Abuse and Compliance	Melissa Zambri Robert Hussar
Ethical Issues in the Provision of Health Care	Lawrence Faulkner
In-House Counsel	Reginald Bullock
Public Health and Health Policy	Julia Goings-Perrot

Changes

- The Special Committee on E-Health Information Systems has been made a Standing Committee. It will be chaired by Raul Tabora.
- The Special Committee on Legislative Issues has been made a Standing Committee, and will continue to be chaired by James Lytle.
- The Committee on Hospitals and Health Systems and the Long Term Care Providers Committee have been merged into a new Committee on Institutional Providers.
- The Physicians and Licensed Health Care Professionals Committee and the Professional Discipline Committee, have been merged into a new Committee on Health Professionals chaired by Barbara Ryan.
- The Committee on Payment and Reimbursement, and the Committee on Managed Care, Insurance and Consumer/Patient Rights have been merged into a new Committee on Reimbursement Issues to be co-chaired by Harold Iselin and Ross Lanzafame.
- The Mental Health Issues Committee and the Special Committee on Mental Retardation and Developmental Disabilities have been merged into a new Committee on Mental Health and Developmental Disabilities. It will be co-chaired by Carolyn Wolf and Hermes Fernandez.

Our scholarly and informative *Health Law Journal* will continue under the outstanding editorship of Robert Swidler, and Supraspinatus will continue to be managed by Paul Gillan.

My thanks to all our Committee Chairs and all those who lend their talents and time to our Section. I encourage each and every Section member to join and be active on one or more of our Committees. Not only will you be contributing to the important work of our Section, but you will be able to network with other Section members.

Strategic Planning

Our Section has accomplished a great deal over the years thanks to the hard work and dedication of past Section Chairs, Officers, and Committee Chairs. We have

now grown to 1,300 members, and the time has come for us to undertake some strategic planning for our Section's future. Accordingly, I have asked incoming Chair Ellen Weissman, Chair-Elect Kathleen Burke, and some past Section Chairs to begin the process of developing a strategic plan for the next five years. Once completed, the strategic plan will be presented for consideration by the Executive Committee of our Section. We welcome input and ideas from all Section members during this planning process.

Diversity

The Diversity Challenge of the Health Law Section has developed an Action Plan with three major components:

- outreach to the health law sections of minority bar associations;
- membership marketing materials appealing to a more diverse membership;
- a Summer internship program with 3 slots to encourage minorities to consider health law careers.

Our Diversity Task Force, chaired by Lisa Hayes, working in conjunction with Membership Committee Chair Karen Gallinari, are planning programs and collaborations. Our Section was represented at the Association's "Celebrating Diversity" Reception on Monday, January 23, 2012. This event was part of the Annual Meeting at the New York Hilton. We are offering a free 1-year membership in the Health Law Section to potential new members expressing an interest in health care law.

Also during the Annual Meeting, our Section was a Gold Sponsor of the Edith I. Spivak Symposium of the NYSBA's Committee on Women in the Law, which was held on Tuesday, January 24, 2012.

In sum, great things continue to happen in our Section, but only through the efforts of committed Section members. I encourage all our members to get involved in Section activities.

Francis J. Serbaroli
Chair
Health Law Section

In the New York State Courts

By Leonard M. Rosenberg

Medical Malpractice Claim Dismissed on Ground That Medical Professionals Do Not Owe a Duty to the General Public

Fox v. Marshall, 88 A.D.3d 131, 928 N.Y.S.2d 317 (2d Dep't 2011). Plaintiff, the husband of a murder victim, sued Defendants SLS Residential, Inc. ("SLS"), a substance abuse and mental health facility, and Dr. Mark J. Stumacher, a psychiatrist employed by SLS, for negligence and medical malpractice.

Plaintiff alleged that SLS provided Defendant, Evan Marshall ("Marshall"), a temporary "pass" to leave its facility to visit his mother. Upon arriving at his mother's home, Marshall, who had a history of substance abuse and psychiatric problems, allegedly purchased and consumed cocaine. The next day, Marshall forced his way into the home of decedent, Denice Fox, and then murdered her and dismembered her body. Marshall was arrested and pleaded guilty to murder in the first degree.

Plaintiff sued SLS and Dr. Stumacher, Marshall's treating psychiatrist at SLS, for negligence and medical malpractice. SLS and Dr. Stumacher moved to dismiss the complaint for failure to state a cause of action. Dr. Stumacher asserted that a medical malpractice claim could not be sustained because a physician's duty of care is owed solely to his patient and thus, he did not owe a duty of care to the decedent.

The motion court denied Defendants' motions, holding that SLS may have owed a duty to protect the public from Marshall's actions given evidence that SLS had the ability to control Marshall's actions and had knowledge that Marshall may be a danger to himself and others.

The Appellate Division affirmed the motion court's holding that Plaintiff stated a negligence cause of action against SLS. The court reasoned that

even though SLS is a voluntary in-patient facility, SLS exercised a certain level of authority and control over Marshall. The court found it significant that Marshall needed a facility-issued pass to visit his mother, suggesting a degree of control over his whereabouts, and that SLS was aware of Marshall's psychiatric problems.

However, the Appellate Division ruled that Plaintiff could not sustain a medical malpractice cause of action against Dr. Stumacher. Generally, a medical malpractice claim may not be asserted in the absence of a direct physician-patient relationship, under which the physician owes a duty of care to the patient. Although in limited circumstances courts have expanded this duty of care to a patient's family members, the court held that physicians do not undertake a duty to the community at large. The court noted that if it were to extend the physician's duty of care to the public, medical professionals would be subject to liability to a limitless class of potential defendants. This in turn may affect the medical treatment of mental health patients, as healthcare providers might opt in favor of unnecessary confinement, or be reluctant to undertake treatment at all.

Psychologist Lacks Standing to Force Office of Professional Discipline to Investigate His Complaint Against Another Psychologist

Reisner v. Catone, 33 Misc. 3d 659, 929 N.Y.S.2d 403 (Sup. Ct., New York County 2011). Petitioner, Steven Reisner, a New York licensed psychologist, sought article 78 relief against the Office of Professional Discipline ("OPD") for refusing to investigate Dr. John Leso, another New York licensed psychologist, for his role in assisting the United States military in conducting interrogations of detainees at Guantanamo Bay Naval Base in Cuba.

Reisner alleged that Dr. Leso used his expertise in psychology to harm the health of detainees at Guantanamo Bay while he was a member of the military's Behavioral Science Consultation Team ("the BSCT"). Petitioner demanded that Dr. Leso be investigated and disciplined by the OPD. The OPD responded to Reisner's demand by stating that it had no legal basis for an investigation because Dr. Leso's actions with the BSCT did not involve a therapist-patient relationship, and thus were not subject to state ethical restraints. Reisner commenced an article 78 proceeding challenging the OPD's refusal to investigate Dr. Leso. The OPD cross moved to dismiss the petition, arguing that petitioner lacked standing to sue.

The court noted that standing to challenge a governmental action requires two elements. First, the petitioner must show (1) an "injury-in-fact" and (2) that the alleged injury falls within the "zone of interest" sought to be protected under the relevant statute. Alternatively, a petitioner may obtain standing under the "public interest" doctrine.

The court dismissed the petition, holding that the petitioner did not suffer "injury-in-fact" or as the court described it, injury personal to the party. Petitioner argued that his "injury-in-fact" was OPD's violation of his right to have his complaint investigated. The court found that the New York Education Law does not guarantee every person the right to have every complaint investigated no matter the circumstances or subject of the complaint. Petitioner also failed to show that his alleged injury was within the "zone of interests" sought to be protected under the Education Law. The court found that the purpose of

the Education Law was to protect the welfare of patients seeking professional help, and not to safeguard Petitioner's license, the value and prestige of which he claimed to be diminished by Dr. Leso's conduct.

The court also held that petitioner did not have standing under the public interest doctrine, which is applied narrowly to cases of unprecedented action by a local official. The court stated that there are well-established legal mandates that if contravened by a public official warrant standing in an article 78 proceeding to all affected individuals. However, the OPD's failure to investigate Dr. Leso in this case did not fit within this class of legal mandates.

In a Matter of First Impression, Appellate Division Holds That Supreme Court Has Jurisdiction to Declare the Maternity of a Child in a Gestational Surrogacy Action Without Requiring a Formal Adoption Proceeding

T.V. v. New York State Dept. of Health, 88 A.D.3d 290, 929 N.Y.S.2d 317 (2d Dep't 2011). Plaintiffs, the genetic parents of a child born to a gestational mother under a surrogate parenting contract, sought a judgment declaring that the genetic mother is the legal mother of the child, and directing the New York State Department of Health ("DOH") to amend the child's birth certificate accordingly. The Appellate Division held that the Supreme Court had authority to render a declaratory judgment that a genetic mother is the legal mother of a child born to a surrogate mother.

Plaintiff D.Y.-V. (the "Genetic Mother") and Plaintiff T.V. (the "Genetic Father") were unable to conceive children. Without compensation, Plaintiffs' friend offered to act as the gestational mother of Plaintiffs' child. Prior to the child's birth, Plaintiffs filed an action in the Supreme Court seeking, among other things, a judgment declaring Plaintiffs to be the legal parents of the child, and enjoining the DOH from listing the gestational parents on the child's birth certificate. Shortly after the child's birth, the Supreme Court denied Plaintiffs' motion, and the DOH identified the gestational mother as the child's mother on the birth certificate, but did not identify a father. Thereafter, the Supreme Court held a hearing to determine the issue of paternity and granted an order of filiation, identifying the Genetic Father as the child's legal father and directing that he be named the father on the child's birth certificate.

Plaintiffs then filed an amended complaint setting forth two causes of action: (i) a judgment declaring the Genetic Mother to be child's legal mother and (ii) a judgment declaring Family Court Act §§ 517 and 542 and article 8 of the Domestic Relations Law unconstitutional. In their second cause of action, Plaintiffs alleged that Family Court Act §§ 517 and 542 violated the Genetic Mother's equal protection rights because it permitted the Genetic Father to obtain an order of filiation while denying her that same right. Plaintiffs also alleged that article 8 of the Domestic Relations Law violated the Due Process Clauses of the United States and New York State Constitutions if it was read to presume that the gestational mother was the child's legal mother and to preclude the Genetic Mother from establishing her parental rights.

The DOH moved to dismiss the amended complaint arguing that under Public Health Law § 4130, it was clear that the "woman who actually gives birth to the child is the mother," neither the Family Court Act nor any other provision provides for an order of maternity, Plaintiffs' relief was contingent upon an unenforceable surrogate parenting contract, and that the challenged statutes are not unconstitutional because they serve an important governmental interest in that they provide accurate identification of the birth parents on a child's birth certificate. The DOH also argued that the biological differences between men and women in relation to childbirth cannot be disputed, and "the principle of equal protection does not prohibit Congress or the New York State Legislature from addressing this issue in a manner specific to each gender." In opposition, Plaintiffs argued, among many things, that the statutes as applied violate their fundamental right to privacy, which includes the right to raise children. The Supreme Court granted the DOH's motion to dismiss the complaint for failure to state a cause of action, concluded that the issue should be redressed by the legislature, and held that an alternative remedy exists in the form of an expedited adoption.

In reversing the Supreme Court's decision, the Appellate Division evaluated both the legislative history of surrogate parenting contracts and case law determining the court's authority to make declarations regarding a child's legal parentage.

First, the court noted that the enactment of Domestic Relations Law §§ 122-124, declaring surrogate parenting contracts unenforceable, was based on the New York State "Task Force on Life and the Law" ("Task Force") recommendation that surrogacy contracts be declared void. After the enactment of Domestic Relations Law §§ 122-124, the Task Force issued an updated summary on surrogate parenting contracts, which stated that "if both the genetic mother and the birth mother agree, after the child is born, that the genetic mother should be recognized as the child's sole legal mother, the law should provide a mechanism for achieving that result efficiently, without the need for a formal adoption proceeding." Based on this updated summary, the court concluded that because Domestic Relations Law §§ 122-124 was enacted based on the Task Force's recommendations, the Supreme Court erred in holding that it lacked the authority to issue a maternity order to the Genetic Mother without first conducting a formal adoption proceeding.

The court also relied on *Arredondo v. Nodelman*, 163 Misc. 2d 757, 622 N.Y.S.2d 181 (Sup. Ct., Queens County 1994) and *Doe v. New York City Bd. of Health*, 5 Misc. 3d 424, 782 N.Y.S.2d 180 (Sup. Ct., New York County 2004), in which both courts found that the

Supreme Court had the authority to determine the identity of the child's legal mother in a gestational surrogacy action. In these cases, like the case at hand, all parties agreed that the genetic parents would be the legal parents of the children and that the genetic parents' names should appear on each child's birth certificate. Given these factual similarities, the court held that the Supreme Court has the authority to declare the Genetic Mother the legal mother of the child. Specifically, the court held that there is neither a provision in the Domestic Relations Law that prohibits the Supreme Court from issuing an order of maternity nor a provision that limits the parties to a formal adoption proceeding. In addition, the court determined that the fact that article 5 of the Family Court act addresses only "Paternity Proceedings" rather than maternity proceedings does not deprive either the Family Court or the Supreme Court of jurisdiction. Finally, the court held that although *Doe* and *Arredondo* involved determinations made by the New York City Department of Health and Mental Hygiene, an agency exempt from Public Health Law article 41, such distinction is irrelevant as the process adopted by the City of New York and the State of New York are largely the same. The court also relied on *Matter of H.M. v. E.T.*, 14 N.Y.3d 521, 904 N.Y.S.2d 285 (2d Dep't 2010), which involved a Family Court proceeding to determine whether a female is a child's parent for purposes of support obligations.

The court determined that parents are not required to go through a formal adoption proceeding to seek the issuance of a new birth certificate. Public Health Law § 4130, which requires a birth certificate to be filed within five days of the child's birth, permits the amendment of the birth certificate upon submission of a "judgment, order or decree relating to parentage." Accordingly, a plain reading of the statute establishes that an order or decree relating to adoption is not required to issue a new birth certificate. In reaching this decision, the court criticized the Supreme Court's suggestion that adoption of the child was a suitable alternative remedy because it not only ignores the lengthy, intrusive adoption process that the parents would have to endure but also ignores the "biological link" between the genetic mother and child.

Further, the court noted that a classification burdening the exercise of a fundamental right, such as the right to conceive and raise one's children, must be strictly scrutinized. Accordingly, the court held that Plaintiffs stated a valid cause of action that the applicable provisions of the Domestic Relations Law and Family Court Act were unconstitutional based on an impermissible gender-based classification between parents after the child's birth.

Family Practitioner Who Provided Mental Health Services Held Liable for Medical Malpractice on Basis of Consensual Sexual Relationship with Patient

Dupree v. Giugliano, 87 A.D.3d 975, 929 N.Y.S.2d 305 (2d Dep't 2011). Plaintiff sued physician for medical malpractice on the basis of the consensual sexual relationship they engaged in while she was under his medical care. The Suffolk County Supreme Court, upon a jury verdict, entered judgment for patient. Finding that the defendant's conduct departed from good and accepted medical practice, the jury awarded plaintiff damages for past mental distress, future mental distress, loss of past financial support and punitive damages, in the sum of $416,500. The trial court denied defendant's motion to set aside the verdict on the ground that the sexual relationship was not part of any medical treatment he provided to plaintiff, and therefore could not support a malpractice verdict.

Patient sought treatment from the defendant, a family practitioner, for symptoms that he diagnosed as depression and panic attacks. The defendant prescribed an anti-depressant medication, and recommended that she seek counseling from a psychiatrist or psychologist. Plaintiff returned to defendant's office once or twice per month, at which times she discussed with the defendant her symptoms and the "stressors…in her life," and the defendant reassured her, giving her advice as to how to work through her panic attacks.

During and after the course of such treatment, defendant and plaintiff became sexually involved with each other for a period of approximately nine months. After the sexual relationship began, and concurrently with it, the plaintiff was also treated by a therapist whom the defendant had recommended. Plaintiff disclosed to that therapist that she was having an affair, but she did not disclose that the affair was with the defendant. After the plaintiff and defendant mutually ended the affair, plaintiff disclosed the affair to her husband, who consequently initiated divorce proceedings.

The Appellate Division held that credible evidence at trial established that the plaintiff sought and obtained treatment from the defendant for mental health issues, and that, during and after receiving mental health treatment from defendant, plaintiff and defendant engaged in a sexual relationship. In affirming the trial court's ruling, the majority relied on the testimony of the plaintiff's expert that because of the particularly sensitive nature of the relationship between a mental health provider and a patient, including the emotional dependence of the patient on the provider, a sexual relationship between the patient and the provider is very likely to harm the patient. The majority concluded that a sexual relationship between a mental health provider and a patient is accordingly a departure from the standard of care, whether it is characterized as part of the treatment or independent of it, and it is a departure even when it takes place after the treatment has ended. The Court found that plaintiff's sexual relationship with the defendant had an impact upon the plaintiff's level of trust and openness with her other therapist and held that the doctor exploited the "eroticized transference"

in which the doctor becomes, for the patient, "a very sexually charged figure."

A lengthy dissent questioned the majority's decision and reasoning. The dissent concluded that plaintiff's evidence failed to demonstrate that defendant had committed acts of medical malpractice by engaging in a sexual relationship with plaintiff, particularly in light of plaintiff's testimony that the consensual sexual relationship was unrelated to any medical treatment she received from the defendant.

The dissent noted that the ruling was inconsistent with prior decisions of the Court, and that there is "no authority for the proposition that conduct committed by physicians not providing mental health services constitutes malpractice only when it constitutes or is substantially related to treatment, whereas physicians providing mental health services can commit malpractice even when their conduct does not constitute treatment or bear a substantial relationship to treatment."

The dissent also argued that "it cannot reasonably be maintained, however, that any conduct committed by a doctor that interferes with a patient's treatment, no matter how unrelated to treatment or the practice of medicine, constitutes a departure from accepted medical practice." In support, the dissent provided examples from case law, including a case involving intentional sexual assault of a patient by a physician, which conduct the Second Department previously held did not constitute medical malpractice.

District Court Applies Federal Privilege to Medical Peer Review Records in Federal Tort Claims Act Suit

Francis v. United States, 2011 WL 2224509 (S.D.N.Y. 2011). Plaintiffs, administrator of the estate of her deceased son, and in her individual capacity, brought a medical malpractice and wrongful death action in state court against several physicians and health care institutions. Pursuant to the Federal Tort Claims Act ("FTCA"), the United States removed the action from state to federal court, and substituted the United States for several of the defendants. Plaintiffs sought, among other things, an order compelling the United States to produce quality assurance documents and other records withheld on the basis of privilege. The District Court denied Plaintiffs' motion holding that a federal privilege protects medical peer review materials from disclosure in a medical or dental malpractice action.

The court concluded that the practitioner narratives, which were created in response to the United States Department of Health and Human Services' request for information to determine whether the action should be defended by the United States, were prepared in anticipation of litigation and were therefore protected under the work product doctrine. The court further held that Plaintiffs failed to demonstrate substantial need for the narratives or inability to obtain their substantial equivalent given that the narratives were prepared using information already disclosed to Plaintiffs and Plaintiffs were free to depose the authors of the narratives.

As to whether the quality assurance documents were privileged, the court recognized that there is no consensus as to whether a federal peer review privilege exists in the context of medical or dental malpractice. To determine whether the circumstances of the action call for a recognition of such privilege, the court considered three factors: (i) whether the privilege serves private and public interests; (2) the evidentiary benefit that would result from denial of the privilege; and (3) recognition of the privilege among the States. Applying these factors, the court found that a privilege for medical peer review records is warranted.

First, the court found that such privilege would serve private and public interests by encouraging increased candor and self-evaluation in the peer review process and improving the quality of care. Next, the court held that because Plaintiffs are in possession of nearly all the decedent's records and they may procure an expert to assess the quality of care the decedent received, the quality assurance records are not the only avenue Plaintiffs have to establish their claims against Defendant. Acknowledging that there is unanimous State recognition of the medical peer review privilege, and concluding that such privilege would further federal policy, the court held that it is appropriate to recognize a federal privilege in medical and dental malpractice actions. In support of this conclusion, the court held that although the Health Care Quality Improvement Act of 1986, which provided qualified immunity to peer review participants, did not create a privilege for peer review documents, the Patient Safety and Quality Improvement Act of 2005 provides broad protection to peer review materials. The court also found that recognizing a medical peer review privilege would further Congress' intent to promote peer review to improve quality of care.

Finding that a peer review privilege applies, the court held that only the quality assurance review documents containing self-examining statements are privileged. Accordingly, the court held that the report of the decedent's care and plan of correction, which contain self-evaluative analysis, are protected under the privilege but the chronologies which contain no such analysis are not.

Hospital That Acquired Assets of Another Hospital Pursuant to Berger Commission Mandate Has Standing to Intervene In *Cy Pres* Proceeding Concerning Trust Assets of Acquired Hospital

In re Trustco Bank, 33 Misc.3d 745, 929 N.Y.S.2d 707 (N.Y. Sur. Ct. 2011). Pursuant to the Berger Commission Report, St. Clare's Hospital in Schenectady County, New York was required to surrender its license to operate as a hospital, and to execute an Asset Transfer Agreement with Ellis Hospital and the Ellis Hospital Foun-

dation, Inc. ("Ellis"). Pursuant to this agreement, Ellis assumed the sole responsibility of providing hospital and other health care services previously provided by St. Clare's Hospital, and became the sole remaining hospital in Schenectady County.

Trustco Bank commenced a *cy pres* proceeding pursuant to EPTL 8-1.1(c) to determine whether St. Clare's Hospital's relinquishment of its license to operate as a hospital rendered impractical or impossible the administration of the subject charitable trusts according to their literal terms. St. Clare's Hospital of Schenectady, N.Y. Foundation, Inc. (hereinafter "St. Clare's") sought an order rejecting a Notice of Appearance filed by Ellis. St. Clare's argued that Ellis did not have a cognizable legal stake in the *cy pres* proceeding sufficient to confer standing as a party and at best was a potential beneficiary. The Attorney General, in support of St. Clare's motion, argued that his office has sole standing to represent potential beneficiaries, and that the issue of standing was premature because the court had yet to determine whether to exercise its *cy pres* powers over the Trust Agreement.

The Court disagreed that it must first decide whether *cy pres* applies before reaching the issue of standing. The Court reasoned that a potential beneficiary has as much of a tangible stake in the Court's determination of whether to apply its *cy pres* power as it has in the Court's determination of how to apply that power. The Court recognized that Ellis, which was not named as an interested party in the underlying Petition, filed a Notice of Appearance as if it were a named party with standing to appear. The Court noted that the proper procedure would have been to file a motion to intervene, which Ellis did not do. However, because Ellis had sought intervenor status as an alternative remedy, the Court found that the issue of Ellis' standing to appear in the proceeding had been properly raised.

In deciding the issue of Ellis' standing, the court relied on *Alco Gravure v. The Knapp Foundation,* 64 N.Y.2d 458, 490 N.Y.S.2d 116 (1st Dep't 1985). In *Alco Gravure*, the Court of Appeals held that the general rule is that one who is merely a possible beneficiary of a charitable trust, or a member of a class of possible beneficiaries, is not entitled to sue for enforcement of the trust (only the Attorney General has the statutory power and duty to represent the beneficiaries of any disposition for charitable purposes). There is an exception, however, when a particular group of people has a special interest in funds held for a charitable purpose, as when they are entitled to a reference in the distribution of such funds and the class of potential beneficiaries is sharply defined and limited in number.

The Court found that Ellis had a unique, contractual relationship with St. Clare's that set it apart from all other potential chartable beneficiaries, and therefore was entitled to a preference in the distribution of the trust funds. The Court reasoned that Ellis had acquired St. Clare's Hospital's assets and had assumed its hospital services pursuant to the Berger Commission's mandate and the Asset Transfer Agreement. The Court found that under the *Alco Gravure* exception, such facts gave Ellis standing to appear and participate in the proceeding as an interested party, with the right to file a responsive pleading, participate in discovery, make motions and participate during trial as if Ellis were originally listed as an interested party in the Petition. The Court acknowledged, however, that Ellis lacked standing to commence a *cy pres* proceeding unless it were named trustee or in possession of the subject disposition.

No Private Right of Action for Consequential Damages Is Implied from the Reimbursement Provisions of Public Health Law § 2807

Signature Health Center, LLC v. State, 2011 WL 6222203 (3d Dep't 2011). Signature Health Center, LLC ("Signature") was approved by the Department of Health (DOH) to operate as a licensed diagnostic and treatment center, and provided services to Medicaid recipients under the DOH's Medicaid program. After receiving a reimbursement rate per patient visit based on its projected costs, Signature sought two subsequent rate adjustments that were approved by DOH and certified by the Division of Budget. The DOH, however, did not publish the revised rates and refused to reimburse Signature in accordance with them. Signature commenced an article 78 proceeding that resulted in an order requiring the DOH to publish the revised reimbursement rates and make all payments due in accordance with those rates. DOH did so, and paid approximately $3 million in retroactive reimbursement. Signature then sued the State, seeking consequential damages arising from the DOH's delay in publishing and paying the revised reimbursement rates.

The Court of Claims examined the issue in light of the Court of Appeals' recent decisions in *McLean v. City of New York*, 12 N.Y.3d 194, 878 N.Y.S. 238 (1st Dep't 2009) and *Dinardo v. City of New York*, 13 N.Y.3d 872 (2009), and concluded that the State could not be liable for failure to perform a ministerial act unless it owed a special duty to the claimant. The Court of Claims determined that such a duty existed because Public Health Law § 2807, which governs the reimbursement of Medicaid expenses incurred by participating providers, implicitly created a private cause of action for the benefit of Medicaid treatment providers. On the issue of damages, however, the Court of Claims found that Signature had failed to prove that its alleged lost profits resulted directly from the delayed reimbursement, and denied the claims for consequential damages based upon a failure to proof. Signature appealed.

The Appellate Division examined whether a special duty exists between the State of New York and Signature by virtue of Public Health Law § 2807, such that the State may be liable for improper withholding of Medicaid reimbursement payments. To form a special relationship through the breach of a statutory duty, the govern-

ing statute must authorize a private right of action. The Appellate Division noted that since Public Health Law § 2807 does not expressly confer upon Medicaid providers the right to seek civil damages for a violation of its provisions, recovery may be had only if a private right of action can be implied. Such a private right of action can be implied when (1) the plaintiff is one of the class for whose particular benefit the statute was enacted; (2) recognition of a private right of action would promote the legislative purpose of the governing statute; and (3) to do so would be consistent with the legislative scheme.

The Appellate Division found that although Medicaid providers are a class for whose benefit the reimbursement provisions of Public Health Law § 2807 was enacted, "permitting a private action for consequential damages would not promote the legislative purpose of that statutory provision and would be inconsistent with the overall legislative scheme."

The Court reasoned that the legislative intent of the statute was to control the spiraling cost of Medicaid services and that to "permit Medicaid providers to bring a private right of action for recovery of consequential damages—including lost profits—against the [State of New York] for its negligent failure to provide reimbursement would therefore contravene the key cost containment purpose of the statute." Further, the Court recognized that since "the Legislature has established procedures for judicial review of DOH's administrative rate-setting determinations and payment of reimbursement rates, it is fair to infer that had it intended to create a private right of action against governmental agencies, it would have specially done so." The Court also noted that as there is no authority in the Medicaid statutes for the recovery of interest for delayed or wrongfully withheld reimbursement payments, the Legislature could not have intended to permit recovery of consequential damages based on wrongfully withheld reimbursement payments.

Court Directs Psychiatric Clinic to Provide OPMC with Records of Physician's Inpatient Psychiatric Treatment

In re the Application of State Bd. for Professional Medical Conduct v. Payne Whitney Psychiatric Clinic, 2011 WL 3235991 (Supreme Court, New York County, July 21, 2011). Petitioner, the State Board for Professional Medical Conduct ("OPMC"), sought an order, pursuant to Mental Hygiene Law, directing disclosure by respondent Payne Whitney Psychiatric Clinic ("Payne Whitney") of a certified copy of the treatment records of a physician, licensed to practice medicine in New York, who had been treated at Payne Whitney's inpatient psychiatric unit.

The Public Health Law requires the OPMC to investigate all complaints of professional misconduct it receives. Accordingly, the OPMC sought the physician's treatment records, which are also generally confidential pursuant to the Public Health Law, as part of its investigation of allegations that the physician has a psychiatric condition that impairs his ability to practice medicine, and which would constitute professional misconduct.

Mental Hygiene Law ("MHL") § 33.13(c)(1) requires that the records of facilities licensed or operated by the Offices of Mental Health, Mental Retardation and Developmental Disabilities not become public records, and not be released except pursuant to a court order requiring disclosure upon a finding by the court that the interests of justice significantly outweigh the need for confidentiality. However, MHL § 33.13(c)(8) provides that such medical records can be disclosed to the OPMC if requested in the exercise of its statutory function, power and duties. However, when the subject of inquiry is a patient, the information may only be released, pursuant to a court order, upon a finding that the interests of justice significantly outweigh the need for confidentiality.

OPMC argued that the interests of justice "significantly outweigh the need for confidentiality," in accordance with the requirements of Mental Hygiene Law § 33.13(c)(1), because it expected the treatment records to reflect that the physician has a psychiatric condition that impairs his ability to practice medicine. In support, OPMC submitted certain documents to the Court *in camera*.

The physician opposed the OPMC petition as premature and unwarranted, and argued that he should be given an opportunity to be interviewed first, so as to provide an explanation of the issues under investigation. The physician submitted an attorney affirmation and his own affidavit stating that he was "duly discharged from Payne Whitney" and that he is "not mentally impaired nor in need of medical treatment for mental impairment," and questioned the necessity and effectiveness of the mental health treatment he was receiving.

The court concluded, based on the information submitted by OPMC *in camera*, that it was clear that the "interests of justice significantly outweighed the need for confidentiality," and the treatment records of the physician should be disclosed to the OPMC in order for the OPMC to fully comply with its obligation to investigate the impairment allegations.

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

The Medicaid Redesign Team's Final (?) Report

Introduction and Overview: For what may be the last time, the Medicaid Redesign Team (MRT) met in Albany on December 13 to finalize recommendations that comprised the second phase of Governor Cuomo's Medicaid Redesign effort. Over 100 recommendations were made by various Work Groups and adopted by the MRT, which formed the basis of a written report by the MRT that was forwarded to the Governor in January.

The meeting culminated a nearly year-long effort to overhaul the State's Medicaid program, which included a massive production of reports and analyses by the MRT members and Work Groups, aided by Department of Health and Executive Chamber staff: an undeniably extraordinary and impressive undertaking, whatever may be the ultimate outcome of the MRT's policy recommendations. Given the success of the policy undertaking, there remains some possibility that the MRT may continue, at least in some fashion, even following the completion of its assigned tasks.

The recommendations, organized by the reporting Work Groups, may be reviewed at the Department's website (http://www.health.ny.gov/health_care/medicaid/redesign), along with the final report. I thought it might be helpful to place these recommendations in some context.

The implementation time frame: While the first phase of the MRT recommendations were primarily oriented to short-term recommendations that were to be implemented either in the 2011-12 or 2012-13 fiscal years, the second phase of the MRT recommendations have been generally more focused on the longer-term, often with implementation schedules that might

extend over several—and, in some cases, many—years. As a result, the MRT and the Cuomo Administration have also made clear that these recommendations will not only be subject to careful scrutiny by the Governor before being advanced by the Administration, but may also be subject to a sequencing process that may defer some recommendations for longer term implementation.

Although the first phase of recommendations were largely adopted in their entirety and immediately included as amendments to his 2011-12 Executive Budget proposal, it is not expected that each of these recommendations will be embraced by the Administration, either in the short or longer term. Certain recommendations, including those within the purview of the Benefit Design and Affordable Housing Work Groups, carry budgetary commitments that may be difficult to reconcile with the State's current fiscal status. Still other elements of the recommendations—including, for example, the scope of practice recommendations contained in the recommendations of the Workforce Flexibility Work Group—may face stiff uphill battles in the Legislature, which will have its own say with regard to those recommendations that require statutory change. Other proposals, including the broad new federal waiver discussed below, will be contingent upon the approval of the federal government.

In short, it should *not* be assumed that the inclusion of a recommendation within the MRT report guarantees its implementation—or even necessarily its support by the Administration.

The pursuit of a new federal waiver: If the centerpiece of the MRT's first phase was the enactment of a two-year global cap on Medicaid spending, the major recommendation of this second phase is a new 1115 waiver that would allow New York to implement the Medicaid Redesign work plan and to manage both Medicaid and Medicare spending in a manner that will reduce costs, enhance quality and improve the coordination of care. The waiver will encompass the elements of the existing Federal-State Health Reform Partnership (F-SHRP) and the New York Partnership Plan waivers and will be designed to slow the growth of Medicaid spending in New York and to allow the State to invest a portion of the anticipated $18.3 billion in federal Medicaid and Medicare savings achieved through the first phase of MRT recommendations to enhance health care quality, access and care coordination. The waiver will not address the care system administered by the Office for People with Developmental Disabilities (OPWDD), which will be submitting a different but consistent waiver to address the unique complexity of services provided within that system.

Continued emphasis on care coordination: The recommendations continue to emphasize the need to coordinate care through variously configured care management organizations that would be responsible for the care needs of identified populations. Much of the debate on the future approaches to long term care and behavioral health care focused on the nature of the care coordination models that might be implemented to manage care for the respective populations: while a transition period is contemplated, the recommendations generally envision that entities would, at least eventually, assume financial risk for these populations

and be responsible for providing, in the longer term, fully integrated care. State officials have repeatedly expressed their intention to provide care management in some form (including but not limited to HMOs) to all Medicaid patients and to phase out "fee-for-service" Medicaid. The stated goal is to transform the Medicaid program to deliver care coordination in one form or another, in conjunction with a variety of improved reimbursement systems such as shared savings or capitation.

Among the more ambitious proposals are the recommendations likely to be advanced for integrating care for the dual-eligibles—those eligible for both Medicaid and Medicare. The recommendations include a proposal that would allow the State to receive a per member, per month payment from Medicare for New York's dual eligibles, which would then be "sub-capitated," along with State Medicaid dollars, to managed care organizations or other care coordination entities, such as Accountable Care Organizations (ACOs).

While the overall direction of these recommendations strongly embraced care coordination, the MRT was also open to alternative approaches to care coordination, including provider-based approaches. In addition, some of the recommendations in the Benefit Design and Health care Disparity areas still contemplated a strong role for State government in administering the Medicaid program, including new scrutiny of the effectiveness and outcome of particular health interventions—clearly signaling that a reliance on care coordination would not necessarily result in the complete delegation of care management responsibilities to care coordination entities.

New scrutiny of health care facility governance: The report of the Brooklyn Work Group made recommendations that would significantly strengthen the State's ability to oversee the operation of health care facilities through, for example, the appointment of a temporary operator for facilities that present a danger to their patients. Recommendations may also be advanced to allow the Department to replace board members who are not fulfilling their obligations. The Department of Health has elsewhere voiced its concerns over various models of hospital affiliations and governance, which it believes may lessen accountability for the quality and prudent fiscal management of facility operations. Coupled with the Administration's ongoing review of not-for-profit compensation practices, these initiatives could signal a more contentious era in State oversight of not-for-profit health care and human service providers and their governance.

Preparing for federal health reform: Not surprisingly, a number of the recommendations also address the steps the State will have to take to implement federal health reform, including aggressive implementation of health home and patient-centered medical home initiatives, as well as rethinking the role of local governments in the administration of the Medicaid program. Among the recommendations of the MRT Work Group on Program Streamlining is the enactment of legislation to establish the Health Benefit Exchange in New York—an issue that was stalled in the Legislature last year and that may be among the more immediate proposals advanced by the Administration in the coming legislative session.

The future of the MRT: Whether the MRT, as currently constituted, will continue to operate beyond this calendar year remains to be seen. The issuance of its final report on this second phase of its work will complete the task assigned by the Governor to the MRT. As noted, the success of the effort, however, may encourage the Administration to convene a similar stakeholder group to assist the Administration in the construct of the federal waiver request, which may also benefit from a disparate but consensus-oriented sounding board like the MRT.

Whether the MRT will entirely fulfill its mission will, moreover, depend on the massive implementation effort that will be left to the State Department of Health and other relevant state agencies over the coming years. Following its implementation, the Medicaid program may be deemed to have been sufficiently reformed to satisfy state policy makers or, perhaps more likely, a new generation of political and administrative leaders will again decide to tackle the massive task of redesigning Medicaid all over again.

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

In the New York State Agencies

By Francis J. Serbaroli

Changes in Methodology for Appeals

Notice of Adoption. The Office for People With Developmental Disabilities amended section 686.13 of Title 14 NYCRR to increase appeal thresholds and to limit grounds for appeals. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Efficiency Adjustment for HCBS Waiver Respite Services (A)

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-10.5 of Title 14 NYCRR to implement an efficiency adjustment by modifying the price methodology for HCBS waiver respite services. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Efficiency Adjustment for Residential Habilitation Services Delivered in Supervised IRAs and Supervised CRs (A)

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 635-10.5(b) and 671.7(a) of Title 14 NYCRR to implement an efficiency adjustment by modifying the supportive IRA price methodology. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Reimbursement Methodology for Group Day Habilitation Services and Supplemental Group Day Habilitation Services (A)

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 635-10.5 and 671.7 of Title 14 NYCRR to modify reimbursement for prices in supervised IRAs and supervised CRs effective July 1, 2011. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Reimbursement Methodology for Group Day Habilitation Services and Supplemental Habilitation Services (A)

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-10.5(c) of Title 14 NYCRR to modify the reimbursement methodology for group day habilitation services effective July 1, 2011. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Efficiency Adjustment for HCBS Waiver Community Habilitation Services (A)

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-10.5(ab) of Title 14 NYCRR to implement an efficiency adjustment by modifying the fee schedule for HCBS waiver community habilitation. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Reimbursement of Clinic Treatment Facilities ("Article 16 Clinics")

Notice of Adoption. The Office for People With Developmental Disabilities amended Part 679 of Title 14 NYCRR to effect a new reimbursement methodology for clinic treatment facilities and to achieve consistency with other State agencies. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Personal Services Surpluses Adjustment for Prevocational Services

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-10.5(e) of Title 14 NYCRR to modify reimbursement methodology for prevocational services effective July 1, 2011. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Limits on Reimbursement of Group Day Habilitation, Supplemental Group Day Habilitation, and Prevocational Services

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-10.5(c)(7) and (e)(8) of Title 14 NYCRR to impose stricter limits on reimbursement of services per person per day. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Reimbursement of ICF/DDs

Notice of Adoption. The Office for People With Developmental Disabilities amended section 681.14 of Title 14 NYCRR to modify reimbursement methodology and make associated changes. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Efficiency Adjustment for HCBS Waiver Supported Employment Services

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-10.5(d) of Title 14 NYCRR to implement an efficiency adjustment by modifying the fee schedule for HCBS waiver-supported employment services. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Reimbursement of Specialty Hospitals

Notice of Adoption. The Office for People With Developmental Disabilities amended section 680.12 of Title 14 NYCRR to modify the

reimbursement methodology for Specialty Hospitals and make associated changes. Filing date: June 14, 2011. Effective date: July 1, 2011. *See* N.Y. Register June 29, 2011.

Sexually Transmitted Disease (STD) Reporting and Treatment Requirements

Notice of Adoption. The Department of Health amended section 2.10 and Part 23 of Title 10 NYCRR to add reporting of cases or suspected cases or outbreaks of communicable disease by physicians, list and reporting of STDs. Filing date: June 21, 2011. Effective date: July 6, 2011. *See* N.Y. Register July 6, 2011.

Children's Camps, Swimming Pools, Bathing Beaches

Notice of Adoption. The Department of Health amended Subparts 6-1, 6-2 and 7-2 of Title 10 NYCRR to incorporate PHLs, including a new day camp definition, and amend standards for swimming and camp cabins. Filing date: June 21, 2011. Effective date: July 6, 2011. *See* N.Y. Register July 6, 2011.

Changes to Prescribed Uses of Health Care Adjustment/Health Care Enhancement Funds

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 635-10.5, 671.7, 679.6, 680.12, 681.14, 686.13 and 690.7 of Title 14 NYCRR to allow providers to exercise broader discretion in the allocation of these funds. Filing date: June 21, 2011. Effective date: July 6, 2011. *See* N.Y. Register July 6, 2011.

January 2011 Ambulatory Patient Groups (APGs) Payment Methodology

Notice of Adoption. The Department of Health amended subpart 86-8 of Title 10 NYCRR to refine the APG payment methodology. Filing date: June 22, 2011. Effective date: July 13, 2011. *See* N.Y. Register July 13, 2011.

Provider Allocation of OPWDD Funding

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities amended sections 635-10.5, 671.7 and 681.14 of Title 14 NYCRR to delay implementation of a restriction on allocation of resources while OPWDD conducts impact assessments. Filing date: July 1, 2011. Effective date: July 1, 2011. *See* N.Y. Register July 20, 2011.

Qualified Health Information Technology Entities

Notice of Proposed Rulemaking. The Department of Health proposed amending section 504.9 of Title 18 NYCRR to broaden the definition of a Service Bureau to include Qualified Entities. *See* N.Y. Register September 14, 2011.

Willowbrook Case Services Add-On to the Rate for Intermediate Care Facilities (ICF/DD)

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended and proposed permanent amendment to section 681.14 of Title 14 NYCRR to establish a mechanism to pay for case management services for ICF/DD residents who are members of the Willowbrook Class. File Date: September 1, 2011. Effective Date: September 1, 2011. *See* N.Y. Register September 14, 2011.

Medicaid Estate Definition

Notice of Emergency Rulemaking. The Department of Health amended section 360-7.11 of Title 18 NYCRR to expand the estate definition for Medicaid recovery purposes to include assets that pass outside of an individual's probate estate. File Date: September 8, 2011. Effective Date: September 8, 2011. *See* N.Y. Register September 28, 2011.

Accreditation of General Hospitals and Diagnostic and Treatment Centers

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 405.1, 700.2, 720.1 and 755.2; renumbering of sections 751.11 to 751.12; and adding new section 751.11 to Title 10 NYCRR to update accreditation provisions for general hospitals and diagnostic and treatment centers. *See* N.Y. Register September 28, 2011.

Medicaid Benefit Limits for Enteral Formula, Prescription Footwear, and Compression Stockings

Notice of Proposed Rulemaking. The Department of Health proposed amending Parts 505 and 513 of Title 18 NYCRR to establish Medicaid benefit limitations on coverage of enteral formula, prescription footwear, and compression stockings. *See* N.Y. Register September 28, 2011.

Observation Unit Operating Standards

Notice of Proposed Rulemaking. The Department of Health proposed amending section 405.19 of Title 10 NYCRR to provide operating standards for observation units. *See* N.Y. Register September 28, 2011.

Per-Patient Spending Limits for Certified Home Health Agencies (CHHA)

Notice of Adoption. The Department of Health amended section 86-1.13 of Title 10 NYCRR to control over-utilization of CHHA services. The change will apply an average annual per-patient spending limit. File Date: September 20, 2011. Effective Date: October 5, 2011. *See* N.Y. Register October 5, 2011.

HCBS Waiver Monthly Community Habilitation Services

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amend-

ing sections 635-10.4, 635-10.5 and Subpart 635-12 of Title 14 NYCRR to establish Monthly Community Habilitation as a new HCBS waiver service. *See* N.Y. Register October 12, 2011.

Municipal Public Health Services Plan—Radioactive Material and Radiation Equipment

Notice of Emergency Rulemaking. The Department of Health amended Part 40 of Title 10 NYCRR to establish funding for certified counties to inspect radiation equipment and the NYCDOHMH to conduct licensing and inspections. File Date: September 29, 2011. Effective Date: September 29, 2011. *See* N.Y. Register October 19, 2011.

Audits of Institutional Cost Reports (ICR)

Notice of Emergency Rulemaking. The Department of Health amended Subpart 86-1 of Title 10 NYCRR to impose a fee schedule on general hospitals related to the filing of ICRs sufficient to cover the costs of auditing the ICRs. File Date: October 3, 2011. Effective Date: October 3, 2011. *See* N.Y. Register October 19, 2011.

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. File Date: October 4, 2011. Effective Date: October 4, 2011. *See* N.Y. Register October 19, 2011.

Distributions from the Health Care Initiatives Pool for Poison Control Center Operations

Notice of Proposed Rulemaking. The Department of Health proposed amending section 68.6 of Title 10 NYCRR to revise the methodology for distributing HCRA grant funding to Regional Poison Control Centers (RPCCs). *See* N.Y. Register October 19, 2011.

Implementation of Medicaid Fee Reductions in Various OMH-Licensed Programs

Notice of Adoption. The Office of Mental Health amended Parts 512, 588 and 591 of Title 14 NYCRR to reduce rates for various non-State-operated programs consistent with the 2011-2012 enacted State budget File Date: October 3, 2011. Effective Date: October 19, 2011. *See* N.Y. Register October 19, 2011.

Hospital Quality Contribution

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 86-1 of Title 10 NYCRR to collect thirty million dollars annually for the Medical Indemnity Fund. *See* N.Y. Register October 26, 2011.

Reduction to Statewide Base Price

Notice of Proposed Rulemaking. The Department of Health proposed amending section 86-1.16 of Title 10 NYCRR to impose a reduction to the statewide base price as an interim measure. *See* N.Y. Register October 26, 2011.

Medicaid Managed Care Programs

Notice of Proposed Rulemaking. The Department of Health proposed repealing Subparts 360-10, 360-11, sections 300.12, 360-6.7; and adding 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. *See* N.Y. Register October 26, 2011.

Requirements Pertaining to the Investigation and Review of Serious Reportable Incidents and Abuse Allegations

Notice of Adoption. The Office for People With Developmental Disabilities amended Part 624 of Title 14 NYCRR to reduce conflicts of interest in the investigation and review of serious reportable incidents and abuse allegations. File Date: October 11, 2011. Effective Date: November 1, 2011. *See* N.Y. Register October 26, 2011.

Requirements for Training of Employees, Volunteers, Family Care Providers, and Board Members in the OPWDD System

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 633.8 and 633.99 of Title 14 NYCRR to require annual training in positive relationships, abuse/ incidents and safety and security procedures in some situations. File Date: October 11, 2011. Effective Date: November 1, 2011. *See* N.Y. Register October 26, 2011.

Provisions for Medical Director Coverage in Article 16 Clinics

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending section 679.3 of Title 14 NYCRR to scale medical director coverage to the size of the clinic. *See* N.Y. Register October 26, 2011.

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

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 63 of Title 10 NYCRR to increase HIV-testing and to promote HIV-positive persons entering into treatment. *See* N.Y. Register November 2, 2011.

Managed Care Organizations (MCOs)

Notice of Proposed Rulemaking. The Department of Health proposed amending section 98-1.11 of Title 10 NYCRR to specify approval standards for asset transfers or loans proposed by MCOs. *See* N.Y. Register November 2, 2011.

Potentially Preventable Negative Outcomes

Notice of Proposed Rulemaking. The Department of Health proposed

adding section 86-1.42 to Title 10 NYCRR to deny additional reimbursement for hospital acquired conditions. *See* N.Y. Register November 2, 2011.

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

Notice of Adoption. The Office of Mental Health Part amended 578 of Title 14 NYCRR to amend reimbursement methodology for eligible pharmaceutical costs for RTFs and freeze rates of payments effective July 1, 2011. File Date: October 17, 2011. Effective Date: November 2, 2011. *See* N.Y. Register November 2, 2011.

Carbon Monoxide Detector Use in Residential Programs

Notice of Adoption. The Office of Mental Health Part amended Parts 594 and 595 of Title 14 NYCRR to conform to non-discretionary statutory requirements regarding the use of carbon monoxide detectors in OMH-licensed housing. File Date: October 17, 2011. Effective Date: November 2, 2011. *See* N.Y. Register November 2, 2011.

Implementation of 1.1% Medicaid Fee Reductions for Operating Rates of Continuing Day Treatment Programs

Notice of Adoption. The Office of Mental Health Part amended Part 588 of Title 14 NYCRR to reduce rates for Continuing Day Treatment Programs consistent with the 2011-2012 enacted State Budget. File Date: October 17, 2011. Effective Date: November 2, 2011. *See* N.Y. Register November 2, 2011.

Public Water Systems

Notice of Adoption. The Department of Health amended Subpart 5-1 of Title 10 NYCRR to incorporate mandatory regulations (Federal Ground Water Rule) to increase protection against microbial pathogens in ground water. File Date: October 21, 2011. Effective Date: November 9, 2011. *See* N.Y. Register November 9, 2011.

Methodology to Determine the Allowable Costs of Continuing Lease Arrangements

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending sections 635-6.3 and 635-99 of Title 14 NYCRR to modify the method of determining allowable costs of continuing lease arrangements. *See* N.Y. Register November 9, 2011.

Requirements Pertaining to the Investigation and Review of Serious Reportable Incidents and Abuse Allegations

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed a consensus rulemaking to amend section 624.5(c)(1)(iii) of Title 14 NYCRR to clarify the effective date of recently promulgated regulations. *See* N.Y. Register November 9, 2011.

Authority to Collect Pharmacy Acquisition Cost

Notice of Emergency Rulemaking. The Department of Health amended section 505.3 of Title 18 NYCRR to establish a requirement that each enrolled pharmacy report actual acquisition cost of a prescription drug to the Department. File Date: October 27, 2011. Effective Date: October 27, 2011. *See* N.Y. Register November 16, 2011.

Clinic Treatment Programs

Emergency and Proposed Rulemaking. The Office of Mental Health amended Part 599 of Title 14 NYCRR to clarify existing regulation and enable providers to seek reimbursement for certain services using State-only dollars. File Date: November 1, 2011. Effective Date: November 1, 2011. *See* N.Y. Register November 16, 2011.

Operation of Psychiatric Inpatient Units of General Hospitals

Notice of Adoption. The Office of Mental Health amended section 580.6(b)(4) of Title 14 NYCRR to prohibit commingling of adults and children receiving services in groups in hospitals licensed by the Office of Mental Health. File Date: October 26, 2011. Effective Date: November 11, 2011. *See* N.Y. Register November 16, 2011.

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

Notice of Proposed Rulemaking. The Office of Mental Health proposed a consensus rulemaking to amend Part 577 of Title 14 NYCRR to freeze rates of payments to freestanding psychiatric centers licensed under Mental Hygiene Law Article 31 effective January 1. 2012. *See* N.Y. Register November 16, 2011.

Chemical Analyses of Blood, Urine, Breath or Saliva for Alcoholic Content

Notice of Adoption. The Department of Health amended Part 59 of Title 10 NYCRR to update technical standards for blood and breath alcohol testing conducted by law enforcement. File Date: November 22, 2011. Effective Date: December 7, 2011. *See* N.Y. Register December 7, 2011.

NYS Newborn Screening Panel

Notice of Adoption. The Department of Health amended section 69-1.2 of Title 10 NYCRR to add severe Combined Immunodeficiency (SCID) and eliminate testing for hyperammonemia/ornithinemia/citrullinemia (HHH). File Date: November 22, 2011. Effective Date: December 7, 2011. *See* N.Y. Register December 7, 2011.

Amendment to Limitations of Operating Certificates

Notice of Proposed Rulemaking. The Department of Health proposed amending section 401.2 of Title 10 NYCRR to allow Public Health Law article 28 facilities to operate at sites not designated on their operating certificate during an emergency. *See* N.Y. Register December 7, 2011.

Hospital Temporary Rate Adjustments

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.31 of Title 10 NYCRR to no longer require that a merger, acquisition or consolidation needs to occur on or after the year the rate is based upon. File Date: November 23, 2011. Effective Date: November 23, 2011. *See* N.Y. Register December 14, 2011.

October 2011 Ambulatory Patient Groups (APGs) Payment Methodology

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 86-8 of Title 10 NYCRR to refine the APG payment methodology. *See* N.Y. Register December 14, 2011.

Medicaid Benefit Limits for Enteral Formula, Prescription Footwear, and Compression Stockings

Notice of Emergency Rulemaking. The Department of Health amended Parts 505 and 513 of Title 18 NYCRR to impose benefit limitations on Medicaid coverage of enteral formula, prescription footwear, and compression stockings. File Date: December 2, 2011. Effective Date: December 2, 2011. *See* N.Y. Register December 21, 2011.

Potentially Preventable Negative Outcomes

Notice of Emergency Rulemaking. The Department of Health added section 86-1.42 to Title 10 NYCRR to deny additional reimbursement for hospital acquired conditions. File Date: December 6, 2011. Effective Date: December 6, 2011. *See* N.Y. Register December 21, 2011.

Limitation of New Enrollment to the Healthy NY High Deductible Plan Pursuant to Section 4326(g) of the Insurance Law

Notice of Emergency Rulemaking. The Department of Financial Services added section 362-2.9 (Regulation 171) to Title 11 NYCRR to mitigate large premium increases for current enrollees in Healthy NY by limiting new enrollees to the high deductible plan. File Date: December 7, 2011. Effective Date: December 7, 2011. *See* N.Y. Register December 28, 2011.

Provider Allocation of OPWDD Funding

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 635-10.5, 671.7 and 681.14 of Title 14 NYCRR to repeal a provision that restricts providers' abilities to allocate revenues to administrative expense. File Date: December 12, 2011. Effective Date: December 28, 2011. *See* N.Y. Register December 28, 2011.

Behavior Management—Modifying or Controlling Maladaptive or Inappropriate Behavior

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending section 633.16; and amendment of Parts 81, 624, 633 and 681 of Title 14 NYCRR to establish requirements for interventions used in the OPWDD system to modify or control maladaptive or inappropriate behavior. *See* N.Y. Register December 28, 2011.

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. File Date: December 14, 2011. Effective Date: December 14, 2011. *See* N.Y. Register January 4, 2012.

July 2011 Ambulatory Patient Groups (APGs) Payment Methodology

Notice of Adoption. The Department of Health amended Subpart 86-8 of Title 10 NYCRR to refine the APG payment methodology. File Date: December 20, 2011. Effective Date: January 4, 2012. *See* N.Y. Register January 4, 2012.

Visitation and Inspection of Facilities

Notice of Proposed Rulemaking. The Office of Mental Health proposed adding Part 553 to Title 14 NYCRR to create a new updated part which reflects the agency's expectations regarding visitation and inspection of facilities. *See* N.Y. Register January 4, 2012.

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 Chair of the Health Law Section. The assistance of Whitney M. Phelps, Of Counsel, and Caroline B. Brancatella, Associate, of Greenberg Traurig's Health and FDA Business Group in compiling this summary is gratefully acknowledged.

New York State Fraud, Abuse and Compliance Developments

Edited By Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions

Compiled by Eugene M. Laks

SBV Pharmacy, Inc. *(DOH administrative hearing decision dated June 24, 2011, James F. Horan, Administrative Law Judge)*. The ALJ sustained recovery for Medicaid overpayments of claims paid for pharmacy services provided after the Medicaid beneficiary had died. The pharmacist was unaware that the beneficiary had died and engaged in no wrongdoing. The ALJ held, however, the payments must be returned by the pharmacy.

Dumont Masonic Home *(DOH administrative hearing decision dated July 14, 2011, John Harris Terepka, Administrative Law Judge)*. The ALJ sustained the OMIG audit offset of the nursing home provider's investment income from the sale of securities in Board restricted funds against interest expenses claimed by the provider in determining reimbursable capital costs. The funds were not restricted by the donors. In addition, interest on working capital loans was disallowed as the facility had cash on hand to meet working capital needs without borrowing.

Niagara Pharmacy *(DOH administrative hearing decision dated July 20, 2011, John Harris Terepka, Administrative Law Judge)*. The OMIG audited a sample of the pharmacy provider's claims and extrapolated the disallowance to the universe of claims over a four year period. The ALJ sustained disallowances because the prescribers' Medicaid identification numbers appearing on the claim form, including hospital identification numbers, did not reflect the correct identification numbers of the actual prescribers. Regarding the potential for correction of submitted claims to reflect the correct prescriber number

under Medicaid policy and procedures, the ALJ noted that the prescriber had not availed itself of such opportunity. Claims disallowed as billed in excess of prescribed quantity were partially affirmed. Disallowances also were affirmed where the supervising physician was not identified on prescriptions written by physician's assistants, there was an improper refill of a prescription and/or the pharmacy billed for the wrong item.

The provider did not challenge the validity of the random sample nor the statistical sampling methodology in general. The provider did challenge the OMIG extrapolation methodology as inaccurate because the OMIG did not identify and offset underpayments. The ALJ held that the purpose of OMIG audits did not include identification of underpayments. The ALJ also rejected the argument that an uneven distribution by date in the audit disallowances invalidated the extrapolation over the four year audit period. The ALJ further sustained the application of the midpoint extrapolation of the sample disallowance remaining following hearing to determine the restitution owed to the Medicaid program by the provider, rather than the low point of a selected statistical confidence interval.

Odd Fellow & Rebekah Rehabilitation and Health Care Center, Inc. *(DOH administrative hearing decision dated July 28, 2011, John Harris Terepka, Administrative Law Judge)*. This was an audit of the nursing home facility's base year cost report for 2000-2001, applied in the calculation of the 2000-2005 Medicaid rates, as a substantially changed institution with extensive renovation and new construction. The ALJ sustained the OMIG audit determination that the provider had improperly classified various employee salaries and fringe benefits to various cost centers in the facility cost report, resulting in increased reimbursement through avoidance of ceilings and other limiting factors in the Medicaid rate calculation methodology. Disallowance of costs not attributable to the cost reporting period, costs not related to services provided to Medicaid patients, certain capital costs under previous Article 28-A financing and working capital interest on funds borrowed by the provider from funds in its own accounts without adequate documentation were sustained.

New York State Attorney General Press Releases

Compiled by Charles Z. Feldman

Pharmaceutical Pays New York $2.5 Million to Resolve Multi-State Anti-Kickback Investigation—5/4/2011—EMD Serono, Inc. was charged with paying health care professionals for activities such as attending advisory and consultancy meetings, speaking engagements, and charitable events for the purpose, at least in part, of inducing those professionals to prescribe Rebif, a drug manufactured by EMD Serono. New York State netted $2.5 million from the settlement.

New York State Office of the Medicaid Inspector General Update

Compiled by Marie A. Butchello

- Press Release—December 7, 2011—following an investigation commenced by OMIG, a Washington Heights physician was convicted of Medicaid fraud for prescribing Human

Immunodeficiency Virus (HIV) medications to his patients, although they did not have the virus, and billing the cost of the drugs to Medicaid.

- Press Release —December 1, 2011 —Brooklyn Physician and Wife Indicted for Illegally Collecting Medicaid —the physician and his wife allegedly lied on a Medicaid application enabling the wife to receive Medicaid health benefits. OMIG began its investigation following an anonymous tip on the Fraud Hotline.
- OMIG continues to issue periodic Compliance Alerts. In July 2011, OMIG issued two compliance alerts to assist providers with Alert 2011-06, Effectiveness Review Checklist, which details the types of documentation OMIG will expect to see during a compliance review. Alert 2011-07, Effectiveness Review Process, sets forth through its several exhibits the process a provider can expect when undergoing a compliance effectiveness review.
- OMIG Compliance Webinar #14: Certification for 2012: What Every Provider Needs to Know About Changes to the OMIG Certification Process, November 14, 2011. This Webinar is still available on OMIG's website.
- OMIG Compliance Webinar #13: The Federal Care Act Section 6402 and Credible Allegations of Fraud, September 7, 2011. Topics include the possible suspension of all government payments under Medicaid pending resolution of allegations. This Webinar is still available on OMIG's website.
- OMIG Compliance Webinar #12: Preventing, Addressing, and Reporting Abuse and Neglect in the Care and Treatment of Individuals with Developmental Disabilities, July 15, 2011. Topics include the recently strengthened regulatory framework governing abuse prevention and reporting and the impacts on provider compliance programs. This Webinar is still available on OMIG's website. Attorneys can earn CLE credit.
- OMIG Compliance Webinar #11: Medicaid and Dental Issues, June 29, 2011. This Webinar is still available on OMIG's website. Attorneys can earn CLE credit.
- OMIG Compliance Webinar #10: Responding to Medicaid Inspector General Audits and Compliance Reviews of Home Health and Personal Care Services: The Law, Regulation, and Process of Medicaid Audits, May 25, 2011. This Webinar is still available on OMIG's website. Attorneys can earn CLE credit.

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. Feldman is an associate in the Albany Office of Hiscock & Barclay, LLP, practicing in the areas of health care compliance and civil litigation, including professional malpractice and personal and premises liability.

Ms. Butchello is an associate in the Buffalo Office of Hiscock & Barclay, LLP, practicing in the Firm's Health Care & Human Services Practice Area. She focuses her practice on counseling a variety of health care providers with respect to regulatory compliance, fraud and abuse, governmental audits and investigations and transactional matters.

In the Journals

Compiled by Melissa Ann Dizon and Nicholas A. Battaglia

- *A Next Step in Health Care Reform: Ensuring the Protection of Employee Rights Under the Family and Medical Leave Act*, April G. Dawson, 56 St. Louis U. L.J. 1 (2011).
- *A Veil of Tax Exemption? A Proposal for the Continuation of Federal Tax-Exempt Status for "Nonprofit" Hospitals,"* Jeremy J. Schirra, 21 Health Matrix 231 (2011).
- *AAJ Resources Help Lawyers Represent Nursing Homes Residents*, 47-AUG Trial 48 (2011).
- *Access to Information on Safe Abortion: A Harm Reduction and Rights Approach*, Joanna N. Erdman, 34 Harv. J. L. & Gender 413 (2011).
- *An Ethics Expertise for Clinical Ethics Consultation*, Lisa M. Rasmussen, 39 No. 4 J.L. Med. & Ethics 649 (Winter 2011).
- *Autism Insurance Reform: A Comparison of State Initiatives*, Melissa Stuart, 8 No. 2 Ind. Health L. Rev. 497 (2011).
- *Beyond Religious Refusals: The Case for Protecting Health Care Workers' Provision of Abortion Care*, Steph Sterling & Jessica L. Waters, 34 Harv. J. L. & Gender 463 (2011).
- *Bioethics and the Disposition of Cryopreserved Preembryos*, Olivia Lin, 34-FALL Fam. Advoc. 38 (2011).
- *Blowing Electronic Smoke: Electronic Cigarettes, Regulation, and Protecting the Public Health*, Daniel F. Hardin, 2011 U. Ill. J.L. Tech. & Pol'y 433 (2011).
- *Born by the Woman, Caught by the Midwife: The Case for Legalizing Direct-Entry Midwifery in All Fifty States,* Sarah Anne Stover, 21 Health Matrix 307 (2011).
- *Bringing Smart Pills to Market: FDA Regulation of Ingestible Drug/Device Combination Products,* Matthew Avery & Dan Liu, 66 Food & Drug L.J. 329 (2011).
- *Camera Phones, Patient Privacy and HIPAA: The Growing Problem of Camera Phone Abuse in Health-Care Facilities*, Kimberly R. Silas, 59 La. B.J. 180 (2011).
- *Can Speech by FDA-Regulated Firms Ever be Noncommercial?*, Nathan Cortez, 37 Nos. 2 & 3 Am. J.L. & Med. 288 (2011).
- *CMS Publishes Final Rules on Medicaid RACS*, 25 No. 6 Health Care Collector 5 (2011).
- *Commercial Speech and Off-Label Drug Uses: What Role for Wide Acceptance, General Recognition and Research Incentives?*, Margaret Gilhooley, 37 Nos. 2 & 3 Am. J.L. & Med. 258 (2011).
- *Communitarianism and the Ethics of Communicable Disease: Some Preliminary Thoughts*, Cara M. Cheyette, 39 No. 4 J.L. Med. & Ethics 678 (Winter 2011).
- *Comparing Pre-Gap and Gap Behaviors for Medicare Beneficiaries in a Medicare Managed Care Plan*, Kavita V. Nair, 38 No. 2 J. Health Care. Fin. (Aspen) 38 (2011).
- *Compensating Individual Providers Based on Quality: Practical and Legal Considerations in a Changing Environment*, Bruce A. Johnson & Sara V. Blass, 5 No. 1 J. Health & Life Sci. L. 1 (Oct. 2011).
- *Conflicts over Control and Use of Medical Records at the New York Hospital before the Standardization Movement*, Eugenia L. Siegler & Andrew B. Cohen, 39 No. 4 J.L. Med. & Ethics 640 (Winter 2011).
- *Controlling Health Care Costs Through Public, Transparent Processes: The Conflict Between the Morally Right and the Socially Feasible*, David Orentlicher, 36 J. Corp. L. 807 (2011).
- *Embodied Equality: Debunking Equal Protection for Abortion Rights*, Erika Bachiochi, 34 Harv. J.L. & Pub. Pol'y 889 (2011).
- *Fair Market Value: What's Fair and Is It Commercially Reasonable?*, Gregory D. Anderson & John R. Holdenreid, , 5 No. 1 J. Health & Life Sci. L. 54 (Oct. 2011).
- *Fetal Pain, Abortion, Viability, and the Constitution*, I. Glenn Cohen & Sadath Sayeed, 39 J.L. Med. & Ethics 235 (2011).
- *Focusing on Fraud: The Federal Government Expands Its Use of the False Claims Act to Police Off-Label Pharmaceutical Promotion*, Kristin McCreary Eichel, 8 No. 2 Ind. Health L. Rev. 339 (2011).
- *Fundamental Rights for Women: Applying Log Cabin Republicans to the Military Abortion Ban*, Hillary Hansen, 23 Hastings Women's L.J. 127 (2012).
- *Hospital Tax-Exemption and the Community Benefit Standard: Considerations for Policymaking*, Bobby A. Courtney, 8 No. 2 Ind. Health L. Rev. 365 (2011).
- *Improve Medical Malpractice Law by Letting Health Care Insurers Take Charge*, Kenneth S. Reinker & David Rosenberg, 39 J.L. Med. & Ethics 539 (2011).
- *Insuring Health Care Compliance: The Nexus of Medical Malpractice Litigation and Government Regulation*, D. Scott Jones & Richard E. Moses, 13 No. 4 J. Health Care Compliance 27 (2011).

- *Me and My Body: The Relevance of the Distinction for the Difference between Withdrawing Life Support and Euthanasia*, Andrew McGee, 39 No. 4 J.L. Med. & Ethics 671 (Winter 2011).
- *Mediation and Medical Malpractice: Why Plaintiffs, Hospitals and Physicians Should be at the Table*, Chris Stern Hyman, 66-OCT Disp. Resol. 32 (2011).
- *Medical Abortion and the 'Golden Rule' of Statutory Interpretation*, Kate Greasley, 19 Med. L. Rev. 314 (2011).
- *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, Elliot Sheppard Tarloff, 86 N.Y.U. L. Rev. 1196 (2011).
- *Medical Tourism, Access to Health Care, and Global Justice*, I. Glenn Cohen, 52 Va. J. Int'l L. 1 (2011).
- *Medicare Reporting, Resolving Conditional Payments and Taking Medicare's Interest Into Account for Future Payments*, Daniel J. Santaniello, 30 No. 4 Trial Advoc. Q. 5 (2011).
- *Medicare Set-Asides and Future Damages Considerations in Civil Liability Matters, Lessons Learned Through the Workers' Compensation Set-Aside Process*, Tamela J. White, 78 Def. Couns. J. 429 (2011).
- *Nanotechnology: How Voluntary Regulatory Programs Can Both Ease Public Apprehensions and Increase Innovation in the Midst of Uncertain Federal Regulations*, Katie Miller, 8 No. 2 Ind. Health L. Rev. 435 (2011).
- *No Need for More Regulation: Payors and Their Role in Balancing the Cost and Safety Considerations of Off-Label Prescriptions*, Amy E. Todd, 37 Nos. 2 & 3 Am. J.L. & Med. 422 (2011).
- *No, Physician-Assisted Suicide is Not Legal in Montana*, Senator Jim Shockley, 37-NOV Mont. Law 7 (2011).
- *Nursing Home Quality, Staffing, and Malpractice Paid-Losses*, Mei Zhao, 38 No. 1 J. Health Care Fin. (Aspen) 1 (2011).
- *Nursing the Primary Care Shortage Back to Health: How Expanding Nurse Practitioner Autonomy can Safely and Economically Meet the Growing Demand for Basic Health Care*, Michael B. Zand, 24 No. 2 J.L. & Health 261 (2011).
- *Off the Roads & Out of the Courts: Enter a Technology Fix for Drunk Driving*, Nora J. Pasman-Green, 24 No. 2 J.L. & Health 217 (2011).
- *Off-Label Drug Use and Promotion: Balancing Public Health Goals and Commercial Speech*, Aaron S. Kesselheim, 37 Nos. 2 & 3 Am. J.L. & Med. 225 (2011).
- *Off-Label Prescription Advertising, the FDA and the First Amendment: A Study in the Values of Commercial Speech Protection*, Coleen Klasmeier & Martin H. Redish, 37 Nos. 2 & 3 Am. J.L. & Med. 315 (2011).
- *Organ Conscription: How the Dead Can Save the Living*, David Schwark, 24 No. 2 J.L. & Health 323 (2011).
- *Over Extended: The Role of the Independent Nurse Practitioner Practice in Addressing Problems with Affordability of U.S. Primary Care*, Daniel Marino, 20 Annals Health L. Advance Directive 12 (2011).
- *Oversight Overhaul: Eliminating the Premarket Review of Medical Devices and Implementing a Provider-Centered Postmarket Surveillance Strategy*, Bonnie Scott, 66 Food & Drug L.J. 377 (2011).
- *Perspective on Economic Critiques of Disability Law: The Multifaceted Federal Role in Balancing Equity and Efficiency*, Elizabeth Burleson, 8 No. 2 Ind. Health L. Rev. 335 (2011).
- *Physician, Heal Thyself: Discretion and the Problem of Excessive Prosecutorial Caseloads, A Response to Adam Gershowitz and Laura Killinger*, Josh Bowers, 106 Nw. U. L. Rev. Colloquy 143 (2011).
- *Physician's Duty to Inform Patients of New Medical Discoveries: The Effect of Health Information Technology*, Mark A. Rothstein, 39 J.L. Med. & Ethics 690 (2011).
- *Privatization of Hospitals: Meeting Divergent Interests*, Thomas P. Weil, 38 No. 2 J. Health Care Fin. (Aspen) 1 (2011).
- *Protecting Scientific Integrity: The Commercial Speech Doctrine Applied to Industry Publications*, Joanna K. Sax, 37 Nos. 2 & 3 Am. J.L. & Med. 203 (2011).
- *Reconsidering Law and Policy Debates: A Public Health Perspective by John G. Culhane*, James G. Hodge, Jr., 39 J.L. Med. & Ethics 704 (2011).
- *Reforming Pharmaceutical Industry-Physician Financial Relationships: Lessons from the United States, France, and Japan*, Marc A. Rodwin, 39 No. 4 J.L. Med. & Ethics 662 (Winter 2011).
- *Reporting and Returning Medicare and Medicaid Overpayments*, Brooke Robertson, 13 No. 5 J. Health Care Compliance 51 (2011).
- *Retiree Medical Benefits Litigation—Theories of Recovery and Key Issues*, Alan M. Sandals, ST027 ALI-ABA 193 (2011).
- *Stem Cell Based Treatments and Novel Considerations for Conscience Clause Legislation*, Lucas Mlsna, 8 No. 2 Ind. Health L. Rev. 471 (2011).

- *Structuring the Offering of Physician Interests in a Multi-Specialty Ambulatory Surgery Center to Comply with the Anti-Kickback Law*, Mark J. Zafrin, , 5 No. 1 J. Health & Life Sci. L. 58 (Oct. 2011).
- SYMPOSIUM: *Commercial Speech and Public Health*, introduction by Jonathan H. Adler.
  - *Health Related Claims, The Market for Information, and the First Amendment*, 21 Health Matrix 7 (2011).
  - *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, Lars Noah, 21 Health Matrix 31 (2011).
  - *Commercial Speech, Drugs, Promotion and a Tailored Advertisement Moratorium*, Margaret Gilhooley, 21 Health Matrix 97 (2011).
  - *The Food & Drug Administration v. The First Amendment: A Survey of Recent FDA Enforcement*, Gerald Masoudi and Christopher Pruitt, 21 Health Matrix 111 (2011).
  - *Hidden Truth: The Perils and Protection of Off-Label Drug and Medical Device Promotion*, Gregory Conko, 21 Health Matrix 149 (2011).
  - *Discourse Norms as Default Rules: Structuring Corporate Speech to Multiple Stakeholders*, David G. Yosifon, 21 Health Matrix 189 (2011).
- SYMPOSIUM: *Public Health Reform: Patient Protection and Affordable Care Act Implications for the Public's—Health*, guest edited by Elizabeth Weeks Leopard
  - *Introduction*, Elizabeth Weeks Leonard, 39 J.L. Med. & Ethics 312 (2011).
  - *From Health Care Reform to Public Health Reform*, Micah L. Berman, 39 J.L. Med. & Ethics 328 (2011).
  - *The Patient Protection and Affordable Care Act, Public Health, and the Elusive Target of Human Rights*, Lance Gable, 39 J.L. Med. & Ethics 340 (2011).
  - *PPACA and Public Health: Creating a Framework to Focus on Prevention and Wellness and Improve the Public's Health*, Gwendolyn Roberts Majette, 39 J.L. Med. & Ethics 366 (2011).
  - *Obesity and Health System Reform: Private vs. Public Responsibility*, Tony Yang & Len M. Nichols, 39 J.L. Med. & Ethics 380 (2011).
  - *Congress, Courts, and Commerce: Upholding the Individual Mandate to Protect the Public's Health*, James G. Hodge et al., 39 J.L. Med. & Ethics 394 (2011).
  - *The Individual Mandate: Implications for Public Health Law*, Wendy E. Parmet, 39 J.L. Med. & Ethics 401 (2011).
  - *Conscripted Physician Services and the Public's Health*, Marshall B. Kapp, 39 J.L. Med. & Ethics 414 (2011).
  - *The New Era of Comparative Effectiveness: Will Public Health End Up Left Behind?*, Richard S. Saver, 39 J.L. Med. & Ethics 437 (2011).
  - *When Public Health and Genetic Privacy Collide: Positive and Normative Theories Explaining How ACA's Expansion of Corporate Wellness Programs Conflicts with GINA's Privacy Rules*, Jennifer S. Bard, 39 J.L. Med. & Ethics 469 (2011).
- SYMPOSIUM: *Return of Research Results: How Should Research Results Be Handled?*, edited by Bartha Maria Knoppers & Emmanuelle Lévesque.
  - *Return of Results: Towards a Lexicon?*, Bartha Maria Knoppers and Amy Dam, 39 No. 4 J.L. Med. & Ethics 577 (Winter 2011).
  - *Return of Research Results: General Principles and International Perspectives*, Emmanuelle Lévesque, Yann Joly & Jacques Simard, 39 No. 4 J.L. Med. & Ethics 583 (Winter 2011).
  - *Pediatric Research and the Return of Individual Research Results*, Denise Avard, Karine Sénécal, Parvaz Madadi & Daniel Sinnett, 39 No. 4 J.L. Med. & Ethics 593 (Winter 2011).
  - *Familial Communication of Research Results: A Need to Know?*, Lee Black & Kelly A. McClellan, 39 No. 4 J.L. Med. & Ethics 605 (Winter 2011).
  - *Biobanks and the Return of Research Results: Out with the Old and In with the New?*, Ma'n H. Zawati & Amélie Rioux, 39 No. 4 J.L. Med. & Ethics 614 (Winter 2011).
  - *The Return of Results of Deceased Research Participants*, Anne Marie Tassé, 39 No. 4 J.L. Med. & Ethics 621 (Winter 2011).
  - *The Needle in the Haystack: International Consortia and the Return of Individual Research Results*, Susan E. Wallace, 39 No. 4 J.L. Med. & Ethics 631 (Winter 2011).
- SYMPOSIUM: *The Association of American Law Schools 2011 Annual Meeting: Section on Torts and Compensation Schemes*.

- *Vaccines and Drugs: A Brave New Tort World*, Catherine M. Sharkey, 8 No. 2 Ind. Health L. Rev. 259 (2011).
- *The Vaccine No-Fault Act: An Overview*, Robert L. Rabin, 8 No. 2 Ind. Health L. Rev. 267 (2011).
- *Administrative Compensation for Pharmaceutical - and Vaccine-Related Injuries*, James R. Copland, 8 No. 2 Ind. Health L. Rev. 275 (2011).
- *The Case Against Preemption: Vaccines & Uncertainty*, Mary J. Davis, 8 No. 2 Ind. Health L. Rev. 291(2011).
- *The Case For Preemption: Why the U.S. Supreme Court and the Administration are Wrong to Curtail Implied Conflict Preemption*, Malcolm E. Wheeler, 8 No. 2 Ind. Health L. Rev. 317 (2011).

- *The Abortion Informed Consent Debate: More Light, Less Heat*, Nadia N. Sawicki, 21 Cornell J.L. & Pub. Pol'y 1 (2011).
- *The Ban on "Off-Label" Pharmaceutical Promotion: Constitutionally Permissible Prophylaxis Against False or Misleading Commercial Speech?*, Kate Greenwood, 37 Nos. 2 & 3 Am. J.L. & Med. 278 (2011).
- *The Commercial Speech Doctrine in Health Regulation: The Clash Between the Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm*, David Orentlicher, 37 Nos. 2 & 3 Am. J.L. & Med. 299 (2011).
- *The Constitutional Protection of Trade Secrets and Patents under the Biologics Price Competition and Innovation Act of 2009,* Richard A. Epstein, 66 Food & Drug L.J. 285 (2011).
- *The Evolving Role of Physicians in a Reformed American Health Care System*, Gov. Howard Dean, 39 Hofstra L. Rev. 9 (2011).
- *The Food-Borne Ultimatum: Proposing Federal Legislation to Create Humane Living Conditions for Animals Raised for Food in Order to Improve Human Health*, Lynn M. Boris, 24 No. 2 J.L. & Health 287 (2011).
- *The Medicaid Platform: Can the Termites be Kept at Bay?*, Frank J. Thompson, 36 J. Health Pol. Pol'y & L. 549 (2011).
- *The Money Blind: How to Stop Industry Bias in Biomedical Science, Without Violating the First Amendment*, Christopher T. Robertson, 37 Nos. 2 & 3 Am. J.L. & Med. 358 (2011).
- *The Need for Public Deliberation: Giving the Public a Voice on Affordable Health Insurance*, Fay Lomax Cook, 36 J. Health Pol. Pol'y & L. 879 (2011).
- *The Push to Increase the Use of EHR Technology by Hospitals and Physicians in the United States Through the Hitech Act and Medicare Incentive Program*, Jessica Pipersburgh, 38 No 2. J. Health Care Fin. (Aspen) 54 (2011).
- *When Regulation Becomes Personal: Asserting Retaliatory Enforcement Claims Against Regulatory Agencies*, Mark Brian Skerry, 21 Health Matrix 279 (2011).
- *When Was the Last Time You Reviewed Your Corporate Compliance Plan?*, Catherine M. Boerner, 13 No. 6 J. Health Care Compliance 35 (2011).
- *Where are the Grounds for the Legality of Abortion? A 13th Amendment Argument*, Laura Sjoberg, 17 Cardozo J.L. & Gender 527 (2011).
- *Wrongful Denial of Medicaid Coverage Causes Death—and Lawsuit*, 25 No. 5 Health Care Collector 9 (2011).
- *You Can't Say That on Television: Constitutional Analysis of a Direct-to-Consumer Pharmaceutical Advertising Ban*, Lia Mulligan, 37 Nos. 2 & 3 Am. J.L. & Med. 444 (2011).

Melissa Ann Dizon recently graduated from Albany Law School. Nicholas Battaglia is a third-year student at Albany Law School. Melissa was, and Nicholas is, a member of the Law School's Health Law Society.

For Your Information

By Claudia O. Torrey

Happy New Year! I trust you will find the following items of interest:

- Effective January 2012, a new subpart G added to 42 CFR Part 401 implements section 1874(e) of the Social Security Act—making Medicare data available to qualified entities for the evaluation of the performance of providers and suppliers. Entitled "Availability of Medicare Data for Performance Measurement," the regulation outlines both how entities can become qualified to access the data, and the necessary steps that qualified entities must take to protect the privacy of Medicare beneficiaries. With a goal of increased provider transparency/supplier performance and increased beneficiary privacy, it is believed that this new Affordable Care Act[1] measurement tool will be an important driver in improved overall quality and reduced Medicare costs.
- The CMS[2] Center for Innovation was established by the ACA to "test" innovative payment and care models that have the potential to lower health care costs for Medicare, Medicaid, and the Children's Health Insurance Program ("CHIP"); the Innovation Center has a total of $10 billion in direct funding for fiscal years 2011 through 2019. If a test model proves successful the Secretary of Health and Human Services is allowed to expand, via rulemaking, the duration and scope of said model—including implementation for all CHIP, Medicaid, and Medicare populations on a nationwide basis.

  In December 2011, the Innovation Center's inaugural group of Innovation Advisors (selected from across the nation) is slated to start a six-month intensive orientation and applied research "journey."
- In a six to three opinion by United States Supreme Court Justice Anthony Kennedy, "commercial speech" trumped health privacy.[3] At issue, Vermont's Prescription Confidentiality Law enacted in 2007 which restricted the **nonconsensual** sale, disclosure, and use of pharmacy records that reveal the prescribing practices of identified physicians. The purpose of the law was to: safeguard the integrity of the doctor-patient relationship, protect medical privacy and confidentiality, reduce medical costs, and deter harassment by drug vendors.[4] Drug companies and data miners asserted that the Vermont statute was a constraint on the commercial free speech of businesses—impeding on their right to gather and distribute information.

  Justice Kennedy stated that "speech in aid of pharmaceutical marketing" is a form of expression protected by the Free Speech Clause of the First Amendment; this speech requires heightened judicial scrutiny.[5] Justice Kennedy also noted that Vermont was inconsistent with its application of the statute.
- A bit of humor: "I've never let my schooling interfere with my education."[6]

Endnotes

1. Pub.L.111-148 and Pub.L.111-152 (March 2010) ("ACA").
2. Center for Medicare and Medicaid Services.
3. *Sorrell v. IMS Health Inc.*, 564 US__, 131 S.Ct. 2653, 180 L.Ed. 2d 544 (2011).
4. 131 S.Ct. at 2661.
5. *Id.* at 2659.
6. Mark Twain.

Claudia O. Torrey, Esq. is a Charter Member of the Health Law Section and a Sustaining Member of the New York State Bar Association.

Active Parents in Passive Clothing? Has the Mission-and-Philosophy Exception Swallowed the Active-Parent Rule?

By Robert H. Iseman

Many general hospitals[1] in New York participate in multi-provider health care delivery systems. These networks are usually coordinated by parent entities[2] (often another not-for-profit corporation) or natural persons (often a representative or representatives of a religious group or a similar organization) who are designated as the "member" or "members" of the network providers.[3]

The role of a "member" of a not-for-profit corporation is described in detail in Article 6 of the Not-for-Profit Corporation Law (NPCL). Members are similar to shareholders in business corporations. Thus, the "sole member" of a not-for-profit corporation is in the position of someone who owns all the stock in a business corporation. Members, like shareholders, may be divided into classes, each with specific rights and obligations.

The NPCL provides members with an array of important governance authorities, including the following:

- Election of the board (NPCL § 613[a]);
- Removal of the board with or without cause (NPCL § 706[c]);
- Adoption, amendment or repeal of corporate bylaws (NPCL § 602[b]);
- Amendment of the certificate of incorporation (NPCL § 802[a][1]);
- Election and removal of corporate officers with or without cause (NPCL § 713[b] and § 714[a]);
- Approval of any encumbrance of personal property (NPCL § 506[d]);
- Approval of any plan of dissolution and distribution of assets (NPCL § 1002[a]);
- Approval of any disposition of all or substantially all corporate assets (NPCL § 510[a][1]);
- Approval of any plan of consolidation or merger (NPCL § 903[a][2]).

The concept of one not-for-profit corporation being designated as a "member" of another not-for-profit corporation, and exercising the governance authority given to members under the NPCL, has provided the foundational legal basis and the structural building blocks for virtually all health care systems in the state of New York for at least the last 30 years.

The exercise of such membership-derived governance authority has never required the licensure of a hospital member as an "established" operator under the laws of New York or any other state. This is because the governance rights of members involve areas of sponsor-level decision-making, not operational detail. Thus, unlicensed members have no authority over such key operational areas as formation of corporate policies, regulatory compliance, standards of care, or medical staff credentialing.

As discussed in detail below, the exercise of membership rights is often referred to as "passive" control exercised by a "passive parent" entity, as compared to the exercise of authority over a hospital that requires licensure, often referred to as "active" control exercised by an "active parent" entity.

The exercise of membership rights to protect fundamental sponsorship interests is especially important in the case of hospitals founded and sponsored as part of the healing ministry of the Roman Catholic Church. Those who use the name and property of the Church in support of a health care ministry are held canonically responsible for their stewardship.[4] Generally speaking, it is the obligation of the canonically responsible person to protect and preserve the property of the Church, to ensure that the property of the Church is not sold, leased or encumbered without the required approvals, and to make certain that such property is used only for purposes that are consonant with the religious beliefs of the Church.[5]

Canon 1284 requires the responsible Church representatives to "ensure that the ownership of ecclesiastical goods is safeguarded in ways which are valid in civil law." The effectuation of this canonical duty through civil law governance control is necessary, of course, because only New York civil law is cognizable in our courts. The membership rights of the hospital's religious sponsor are the manner by which the canonical responsibilities are safeguarded in civil law.

For many years this model of sponsorship has coexisted with the New York regulatory structure in what might be described as a constructive tension. From time to time the New York State Department of Health (DOH) and various special-interest advocacy groups have raised the question of whether the sponsoring members of hospitals hold and exercise operational control, thus requiring their establishment and licensure. This question was raised for the first time in 1986 (as discussed in detail below) and now seems to have once again reared its head.

As we begin the year 2012, the question of membership rights over hospitals is again on the mind of DOH as a result of certain perceived governance and quality-of-care problems that DOH links to the passive-parent model. Speaking to the Public Health and Health Planning Council on November 17, 2011, DOH Deputy Commissioner Richard Cook made the following observations, as reported in the November 18, 2011, issue of *Crain's Health Pulse*:

> "I am very troubled there are governance relationships in networks that do not come before this council," Mr. Cook said. Most troubling? Passive parent relationships, where the parent can name or replace board members of another institution, but have no power over such things as quality or budgets. As more facilities enter into partnerships, the issue will become more important. "I'm challenged to believe passive parents provide transparency," he said.

It is ironic that DOH's concern seems focused on secular passive parents (not religiously sponsored systems) that in some instances have not exercised enough control over a licensed provider, while leaving the board of the sponsored, licensed entity with the impression that all authority rests with the passive parent. It is this confusion over what authority rests where and the resultant inaction that seems to have attracted DOH's attention.

This article provides a historical account of the active/passive parent rules, examines the current issues raised by DOH, and offers for consideration and debate certain remedial recommendations.

The Regulatory Line Between Active and Passive Authority

Since January 1, 1989, the regulations of the Commissioner of Health, found at 10 NYCRR Section 405.1(c) and (d),[6] have defined the line between the "active" operational control of an acute care hospital, which requires Article 28 establishment and licensure, and the "passive" unlicensed but lawful exercise of sponsorship prerogatives as a "member" of a hospital corporation under the Not-for-Profit Corporation Law. The list of active parent powers found in Section 405.1(c) is as follows:

(1) Appointment or dismissal of hospital management-level employees and medical staff, except the election or removal of corporate officers by the members of a not-for-profit corporation;

(2) Approval of hospital operating and capital budgets;

(3) Adoption or approval of hospital operating policies and procedures;

(4) Approval of certificate of need applications filed by or on behalf of the hospital;

(5) Approval of hospital debt necessary to finance the cost of compliance with operational or physical plant standards required by law;

(6) Approval of hospital contracts for management or for clinical services; and

(7) Approval of settlements of administrative proceedings or litigation to which the hospital is party, except approval by the members of a not-for-profit corporation of settlements of litigation that exceed insurance coverage or any applicable self-insurance fund.

The exercise of any of these powers transcends passive parent status and requires establishment and licensure of the parent entity.[7]

While passive control is based generally on the statutory rights of "members" under the NPCL, it also includes important elements of governance under the "mission-and-philosophy exception" found in Section 405.1(d), which reads as follows:

> (d) Nothing in subdivision (c) of this section shall require the establishment of any member of a not-for-profit corporation, which operates a hospital, based upon such member's reservation and exercise of the power to require that the hospital operate in conformance with the mission and philosophy of the hospital corporation.

The exception permits passive parent entities to exercise the active parent powers enumerated in Section 405.1(c) without Article 28 establishment and licensure as long as the passive parent corporation's authority over an active power is limited to ensuring compliance with mission and philosophy. Through use of the mission-and-philosophy exception, passive parent entities generally reserve to themselves the right to approve capital and operating budgets and strategic plans of hospitals, but solely for the purpose of ensuring compliance with "mission and philosophy."

Note that it is the statement of mission and philosophy of the *subsidiary hospital organization* that is relevant here, although in most systems the mission and philosophy statements of the subsidiary organizations are approved by the parent to ensure congruence with the parent entities' own statement of mission and philosophy.

The Regulatory History of Section 405.1(c) and (d)—A Trip Down Memory Lane

An adequate understanding of the active/passive parent rules and the consequences of the rules being

changed requires a review of the history and purpose of Section 405.1(c) and (d). This review is both analytical and historical, based on the author's engagement by the New York State Catholic Health Care Council, in 1987, to respond to DOH's concerns that New York hospitals were being unlawfully "operated" by unlicensed representatives of the Roman Catholic Church.

The history begins[8] with the work in the 1970s of a Roman Catholic priest, Father Adam Maida (now Cardinal Maida), who at the time was serving as Vice Chancellor and General Counsel of the Diocese of Pittsburgh.[9] Both a civil lawyer and a canon lawyer, Father Maida wrote and lectured frequently on the canonical responsibilities of the sponsors of Roman Catholic health care facilities.[10] He emphasized the need for the canonically responsible representative of the Church to maintain adequate civil law control (through reserved civil law governance authority) to ensure that their sponsored ministry meets the requirements of the Church as expressed in Canon Law. Father Maida warned that a religious sponsor violates the Canon Law of the Church and is subject to Church sanction if it permits a hospital to conduct its affairs in a manner inconsistent with Church teaching or fails to reserve sufficient civil law authority to meet its canonical obligations.[11]

Religious sponsors all across the country, including those in New York, heeded Father Maida's admonitions. They reserved to themselves as "members" of their sponsored hospitals sufficient civil law authority to enable them to meet their canonical responsibilities. The membership designation and the reserved powers were included in the hospitals' certificates of incorporation and bylaws.

The reserved authority often went beyond the strict statutory rights of members and included approval of budgets and strategic plans. As a practical matter, however, the members did not conduct an in-depth, line-by-line review and exercised this authority at a conceptual level to ensure consistency with mission and philosophy.

By the mid-1980s DOH had become aware of this practice and raised the question of whether the reservation of civil law authority to the religious sponsors resulted in the unlicensed operation of the sponsored hospital. Some of DOH's concerns were reflected in proposed regulations, published in the spring of 1987, which were part of a broader attempt to strengthen code enforcement. Among other things, the regulations would have permitted DOH to review and approve a hospital's corporate bylaws. DOH also announced informally its intention to conduct a survey to determine the identity of any designated "members" of hospital corporations and the nature and extent of the reserved authority exercised by the members. As representatives of the Catholic Conference (Monsignor John Alesandro, Richard McDevitt, and the author) argued in testimony before the Codes Committee of the State Hospital Review and Planning Council on January 27, 1988, the proposed regulations, if adopted, would make it impossible for Catholic health care providers to fulfill their obligations under Canon Law.

For Catholic health care providers, the draft regulations presented the classic Hobson's choice: they could either relinquish or limit their membership rights, and thus fail to safeguard Church property as required under canon 1284, or subject themselves to the jurisdiction of DOH, thus resulting in an impractical and perhaps unconstitutional entanglement with the State. It was noted that some dispositions of Church property being used in the operation of hospitals required the approval of the Holy See. Although somewhat "tongue in cheek," some asked whether DOH believed that its regulatory control should or could extend to the Vatican!

The legal questions also arose in a very practical context. At the time, the Roman Catholic Church sponsored about 12% of the acute care capacity in the state of New York.[12] Looming over the dispute, therefore, was the possibility that the Church, if confronted with an untenable and hostile regulatory scheme inconsistent with its values, might elect to withdraw from health care sponsorship in New York. This would have produced calamitous results, especially for the poor and underserved.

The Grand Compromise

These factors resulted in everyone's recognizing the virtue of compromise. Attention turned to two questions: (1) What authority could be exercised by the religious sponsor without crossing the line into the operations? and (2) What was the minimal civil law authority required to meet the requirements of Canon Law? Face-to-face negotiations began in late 1987. DOH was represented by then-Deputy Commissioner Raymond Sweeney and then-General Counsel Peter Millock. The author and Monsignor John Alesandro, a civil and canon lawyer, met with DOH on behalf of the New York State Catholic Health Care Council.

We argued that DOH could not impair by regulation the statutory rights of members under the Not-for-Profit Corporation Law. The author referred to the exercise of these statutory rights as "passive" authority because none of them involved direct operational control. We agreed that passive authority would not include the powers which eventually were listed in Section 405.1(c) as being indicative of so-called "active parent" status.[13] This compromise was based on Monsignor Alesandro's opinion that they were not canonically required, and because there was no impingement on the authority of members.

Monsignor Alesandro was concerned, however, that the passive-parent authority based upon the statutory rights of members was not sufficient to fulfill a religious sponsor's canonical obligations because it did not permit the religious sponsor to have any control over the deploy-

ment of Church resources through operating and capital budgets and strategic plans. This concern resulted in the "mission-and-philosophy exception," now found in Section 405.1(d). The intent was to ensure that the budgets and strategic plans of the religiously sponsored hospital corporations reflected the allotment of adequate resources for care of the poor and underserved and that the budgets reflected a responsible and faithful stewardship of Church property.[14]

In drafting the mission-and-philosophy exception, there was recognition of the obvious—that the exception was broad and, if abused, could result in the passive parent's exercising active-parent control over budgets, strategic plans, and other powers limited to "active parents" under § 405.1(c). The intent of the exception was to permit the religious sponsors to exercise limited authority in areas otherwise requiring licensure, for the sole purpose of meeting their canonical obligations, and based on the assumption that the power could be justified in a specific situation by mission protection. We agreed that if any concerns arose in this area, the statements of mission and philosophy would be made available for review by DOH upon request and we would meet to discuss any problem that might arise.

Another compromise was struck over the need for the religious sponsor to approve certain large expenditures of money and the incurrence of debt. Here, it was agreed that the religious sponsor could approve the transfer or encumbrance of property and/or the incurrence of debt unless the expenditure was required to meet applicable legal requirements for licensed operation; or in the words of the regulation, the passive parent could not exercise the authority to approve expenditures required "to finance the cost of compliance with operational or physical plant standards required by law." Thus, the passive parent could not refuse to permit the expenditure of money needed to maintain regulatory compliance, but would be permitted to approve expenditures and debts not so required.

Finally, we discussed the authority to approve the settlement of claims and litigation. We agreed that this would be the sole province of the licensed operator unless the settlement was not covered by insurance or exceeded coverage. In such cases passive-parent approval would be permitted because the payment of the uninsured or excess claim would implicate Church property.

During the next several years there was an exchange of correspondence between the undersigned and DOH which resulted in an "agreed upon" list of reserved passive-parent authority. The articulation of the passive-parent powers was negotiated and expressed in meticulous detail. For example, following the principle that the passive-parent powers generally would be limited to those statutory authorities given to members under the Not-for-Profit Corporation Law, the passive parent had the right to "elect" the chief executive officer (the precise language used in the statute), but would not have the right to "select" or "appoint" the CEO.

The following is a list of the original passive-parent powers that was confirmed by the author in correspondence with DOH:

(a) approve the statement of mission and philosophy adopted by the hospital corporation;

(b) require that the corporation operate in conformance with its mission and philosophy;

(c) elect corporate officers through a vote of the membership of the corporation (*Note* that the reservation of the authority must be limited to the "election" of the officers and must not extend to "appointment");

(d) remove corporate officers, with or without cause;

(e) approve amendments to the corporation's certificate of incorporation;

(f) approve any plan of merger or consolidation;

(g) adopt corporate bylaws;

(h) approve amendments to corporate bylaws;

(i) elect directors;

(j) remove directors, with or without cause;

(k) approve mortgages or pledges of corporate personal property, except when such mortgages or pledges are necessary to finance compliance with operational or physical plant standards required by law;

(l) approve the disposition of all or substantially all of the assets of the corporation by two-thirds vote of the membership;

(m) approve any plan of dissolution and distribution of assets;

(n) approve any gift, sale, lease or encumbrance of the assets of the corporation in excess of a prescribed amount.

Incident to the exchange of correspondence defining the agreed-upon list, we also agreed, as a courtesy, to send copies of the organizational documents of newly created passive parent entities and their subsidiary organizations to DOH for informational review. Over the years, this resulted in some fine-tuning of the list of passive-parent authority.

Defining and Addressing the Problem—If There Is One

The wholesale review of the active/passive parent rules is unnecessary and imprudent. New York is the only state (with the possible exception of Maine) that regulates

strictly the governance relationship between hospital sponsors exercising membership rights and the licensed hospital entity itself. The simple but important question is, why is the exercise of member authority a problem in New York but not in other states?

There is no evidence to suggest that any of the perceived operational problems identified by DOH are in any way connected to, let alone caused by, the passive-parent structure. The law clearly requires the governing body and management of a hospital to be solely responsible for quality of care and regulatory compliance. DOH has many enforcement options to address situations in which hospital boards and management are not fulfilling their legal responsibilities.

The canonical rules applicable to Roman Catholic health care providers have not changed since the approval of Section 405.1(c) and (d). There is simply no reason for DOH to take any action that would result in reliving the public policy dispute of the 1980s that led to the active/passive parent rules. Generally speaking, Section 405.1(c) and (d) have worked well since 1989. There is no need to even consider any substantial change, especially when some fine-tuning would suffice.

Based upon recent discussions with DOH, it appears that the specific concern is with the implementation of the mission-and-philosophy exception and its relationship to the approval of capital and operating budgets and strategic plans. While the fundamental need for the mission-and-philosophy exception remains the same under Canon Law today as it did in 1989, some minor adjustments in DOH's own policies and procedures and clarifying amendments are all that is required.

The transparency in governance sought by DOH is easily achieved without any statutory or regulatory change. There is no mystery about the identity of the members who hold the passive authority. The member designation and delegation of governance authority are found in the hospital's certificate of incorporation (a public document) and bylaws (not a public document, but subject to DOH's inspection).

DOH's concerns about the breadth of the mission-and-philosophy exception can be addressed in the context of the existing language found in 405.1(d), together with some clarifications that reflect the intent of the parties in the negotiations leading up to Section 405.1(c) and (d). First, DOH has a number of remedies within the existing regulatory language. A point overlooked frequently is that the statement of mission and philosophy limiting the approval authority of the parent is the statement of mission and philosophy *of the licensed hospital*. This is a statement of the licensed entity available for review by DOH. As a clarification to the regulatory language, DOH could require that hospital statements of mission and philosophy be in writing and be made available for inspection by DOH. This is appropriate because the scope of the statement of mission and philosophy is directly related to the breadth of the parent's approval authority.

Second, a definition of the term "mission and philosophy" could be included in the regulations to be certain that such a statement is focused on sponsor-level prerogatives and not operational detail. Ensuring that the statements of mission and philosophy meet such definitions and are available for review by DOH would help limit and curb any unlawful intrusion into the budgetary or strategic planning process or other areas of operational control.

Third, the regulation could be amended to clarify that mission-and-philosophy approvals do not extend to portions of the budget or strategic plan that are required "to finance the cost of compliance with operational or physical plant standards required by law." This language, which presently defines the right of the sponsor with respect to the incurrence of debt (*see* § 405.1[c][5]) would thus be applied to the application of the mission-and-philosophy exception.

Taking these three changes into account, an amended version of Section 405.1(c) and (d) might read as follows:

> (d) Nothing in subdivision (c) of this section shall require the establishment of any member of a not-for-profit corporation, which operates a hospital, based upon such member's reservation and exercise of the power to require that the hospital operate in conformance with the <u>written statement of</u> mission and philosophy of the hospital corporation<u>, provided that acts necessary to finance the cost of compliance with operational or physical plant standards required by the Public Health Law for the delivery of patient care services may not be subject to such approval. For the purposes of this section, the written statement of mission and philosophy of a hospital corporation means a statement of the hospital's core purposes, key values and beliefs, and an explanation of how such purposes, values and beliefs will be achieved. Such statements shall be available for review by DOH upon request.</u>

Conclusion

The role of members is sponsoring but not operating hospitals and health care delivery systems in New York. The sponsorship role, which generally is unregulated in other states, can be accommodated without heavy-handed regulatory intrusion and in a manner that preserves both the prerogative of members and the nondelegable authority of the established, licensed operator.

Endnotes

1. Acute care facilities as defined in Public Health Law § 2801(10).
2. The parent entity fulfills a number of important functions. These include organizing the network providers into an efficient and accessible continuum of care responsive to community needs; collaborating in areas designed to conserve resources, such as joint purchasing; improving access to capital through obligated group financing (if required approvals are obtained); facilitating clinical integration and the use of best practices; sharing resources; reflecting common mission, philosophy, values and purpose; and, if there is sufficient integration to meet applicable antitrust standards (as either a single economic entity under the *Copperweld* doctrine or as a properly integrated joint venture), contracting jointly with payors and self-insured businesses. The principles underlying health care reform, which are based largely on paying global fees for demonstrated value rather than separate fees for service, and the advent of so-called Accountable Care Organizations (ACOs) make the functioning of such networks indispensible in today's health care environment.
3. It is also common for the parent entities to themselves have designated members. Such a member of the member becomes a "grandparent" of the network provider. Such members of the parent entity are generally the ultimate sponsor or the representatives of the ultimate sponsor of the network.
4. The accountable person is referred to in Canon Law as the responsible "Public Juridic Person." *See* canon 116. Sometimes the Public Juridic Person is an individual, such as a diocesan bishop, and sometimes a group or an entity, such as a congregation of Religious women.
5. These obligations are founded in canons 1276, 1284 and 1290-98, among others. The responsibilities of the diocesan bishop to safeguard all ecclesiastical property is far-reaching, governed not only by canon 1284 but by all the canons dealing with the administration of ecclesiastical property (cc. 1273-1289) and those setting forth special rules for the alienation of property (cc. 1290-1298). Canon 1276 provides:

   > §1. It is for the ordinary to exercise careful vigilance over the administration of all the goods which belong to public juridic persons subject to him, without prejudice to legitimate titles which attribute more significant rights to him.
   >
   > §2. With due regard for rights, legitimate customs and circumstances, ordinaries are to take care of the ordering of the entire matter of the administration of ecclesiastical goods by issuing special instructions within the limits of universal and particular law.

6. The rules found in Part 405, including the active/passive parent rules, apply only to acute care facilities but have been applied by analogy to nursing homes, other entities falling within the definition of the term "hospital," and other providers whose regulatory structure is silent on the subject. Other categories of providers, such as home health care, have not applied these rules by analogy because Public Health Law Article 36 has long followed its own concept of "controlling person." *See* 10 NYCRR § 760.1(c) for CHHAs and 10 NYCRR § 765-1.1(c) for LHCSAs.
7. Passive parent entities that avoid licensed active parent status under the list of powers found in § 405.1(c) must also concern themselves with the rules requiring DOH approval of management contracts. Section 600.9(d) of the Commissioner's regulations requires approval of any contract that delegates any of the following functions to a management contractor:

   > (d)(1) Except as provided in section 405.3 of this Title, the governing authority or operator may not contract for management services with a party which has not received establishment approval.
   >
   > (2) The criteria set forth in this paragraph shall be used in determining whether there has been an improper delegation to the management consultant by the governing authority or operator of its responsibilities:
   >
   > (i) authority to hire or fire the administrator or other key management employees;
   >
   > (ii) maintenance and control of the books and records;
   >
   > (iii) authority over the disposition of assets and the incurring of liabilities on behalf of the facility.…

8. Additional historical information may be found in "The Catholic Church and Health Care Public Policy in New York State 1924-2004" by Jack Balinsky, at pp. 99-101 (http://www.nyscatholic.org/admin/news/document/ issues_840 HealthCareComplete.pdf).
9. Father Maida subsequently became Bishop of the Diocese of Green Bay, Wisconsin, Archbishop of Detroit, and a Cardinal in the Church.
10. The writings of Father Maida include *Ownership, Control and Sponsorship of Catholic Institutions* (1975) and *Church Property, Church Finances and Church Related Corporations, a Canon Law Handbook*.
11. This includes the content of the Ethical and Religious Directives for Catholic Health Services ("ERDs"). While the ERDs often prompt highly charged discussion of proscribed medical procedures such as abortion and sterilization, they contain the teachings of the Church specifically applicable to health care providers in numerous other areas, such as care of the poor and the underserved, social justice for workers, and decision-making at the end of life.
12. And a much greater percentage if the overall delivery system, D&T center, long-term care, home care and hospice were taken into account.
13. Recognized by all but left as an open issue was the possibility that the passive-parent powers of the members could be used to indirectly operate the hospital. The obvious example is the member's exercising or threatening to exercise the right to remove trustees or directors who did not follow the member's direction in areas reserved for the licensed operator.
14. While the mission-and-philosophy exception was negotiated on behalf of the religious sponsors, we all recognized and agreed that the principles of fairness and constitutional law required that the exception be made available to all members of not-for-profit corporations, secular and sectarian alike.

Robert H. Iseman is the founding partner of Iseman, Cunningham, Riester & Hyde, LLP, and has represented institutional and individual health care providers and health care insurers for more than 35 years.

Health Plan Appeal Rights in New York After the Affordable Care Act

By Samuel C. Salganik

Introduction

Patients in New York have long had the right to appeal when they disagree with their health plans. The Patient Protection and Affordable Care Act (the "ACA" or "federal health reform") strenghthens and expands those protections. It requires plans to allow patients to appeal adverse plan decisions, and it roughly doubles the number of New Yorkers with the right to external review. The ACA also encourages states to strenghthen their own external review laws, which New York did this past summer. After these changes to federal and state law, nearly all of New York's commercially insured citizens, more than 10 million people,[1] now have new rights when they disagree with their health plans. Though procedural in nature, these rights are critical. Far less expensive and time-consuming than court proceedings, these protections allow patients access to life-saving treatments and prevent families from being forced into bankruptcy after their insurers deny expensive claims. While many aspects of the ACA become effective in 2014, these safeguards are already in place. This article is designed as a reference for advocates seeking to acquaint themselves with this new landscape of procedural protections.

A commercially insured patient's appeal rights vary depending on the answers to three questions: (1) Is the patient enrolled in a self-insured plan or a fully insured plan? (2) Is the patient's plan grandfathered? and (3) Is the patient's plan covered by ERISA? Part I of this article explains how to answer these three questions and provides some background as to why they are important. The first of these questions—self-insured vs. fully insured—is the most important. Part II of this article describes in detail the appeal rights of patients enrolled in self-insured plans, and Part III does the same for the fully insured context. The last sections of each of these two Parts discuss the significance of a plan's grandfathered and/or non-ERISA status. Part IV provides a full-page chart synthesizing the most important information from the article.

I. Identifying the Type of Plan, and Why It Matters

This article describes the appeal rights of the roughly 60% of New York's nonelderly population who are covered by employer- or union-sponsored insurance, as well as the roughly 4% who purchase commercial coverage directly as individuals or families.[2] Within this commercially insured group, though, there are many types of health plans. Sections I.A through I.C explain how to distinguish self-insured from fully insured plans, grandfathered from non-grandfathered plans, and ERISA from non-ERISA plans.

A. Self-Insured vs. Fully Insured

There are two main ways employers can structure their health plans, and the legal consequences of this choice are significant. In a "fully insured" plan, the employer pays regular premiums to a health insurance company, which in turn assumes the risk of paying the bills when enrollees utilize health services. In a "self-insured" plan, by contrast, the employer or union itself is responsible to pay the bills when enrollees get sick. Employers who opt for self-insured plans, though, usually hire insurance companies to administer the plan (e.g., creating coverage rules, reviewing claims, handling member services inquires, and negotiating prices with network providers). In New York, roughly 45% of those enrolled in work-based insurance are in self-insured plans and the remaining 55% are in fully insured plans.[3]

> *"[N]early all of New York's commercially insured citizens, more than 10 million people, now have new rights when they disagree with their health plans."*

Since patients are interacting with an insurance company in either type of plan, as well as carrying insurance cards with insurance company corporate brands (e.g., United, Aetna, etc.), employees rarely know whether they are enrolled in a self-insured or fully insured plan. A patient's summary plan description or certificate of coverage will disclose whether her plan is self-insured or fully insured, and employers must provide these documents to health plan enrollees free of charge.[4] As a general rule of thumb, fully insured plans are more common at smaller employers, while self-insured plans are more common at larger firms with employees in several states: In New York more than 80% of those covered through firms with fewer than 50 employees are in fully insured plans, while more than 70% at firms with more than 1,000 employees are in self-insured plans.[5] Ordinarily, the employer's human resources department will know whether the plan is fully or self-insured.

The distinction between self-insured and fully insured plans is important because of the effects of the Employee Retirement Income Security Act of 1974 ("ERISA"). ERISA applies to all employer- and union-sponsored plans (whether self- or fully insured) other than those provided through government or church employers. For plans

within ERISA's purview ("ERISA plans"), the self-insured variety is exempted from state law by ERISA's preemption provision.[6] ERISA's savings clause then explicitly preserves the right of states to regulate the insurance industry, and thus the insurance products purchased by fully insured ERISA plans.[7] This leaves a legal framework where self-insured ERISA plans are only subject to federal law, while fully insured plans are subject to both federal and state law.[8] In cases of conflict between federal and state law, the aspects of each law that are most protective of the patient usually apply.[9]

B. Grandfathered vs. Non-Grandfathered

A grandfathered plan is one that existed on March 23, 2010—the date of passage of the ACA—and has not changed substantially since then.[10] During President Obama's push for health reform, he often promised that Americans who liked their current health insurance could keep it; grandfathered plans are the result of that promise. When a plan makes substantial changes, for instance to co-pays or deductibles, it loses its grandfathered status. The federal government predicts that many large employer plans will maintain grandfathered status for some time, while the plans of small businesses are more likely to become non-grandfathered over the next few years.[11]

To keep patients informed, any grandfathered plan must disclose its grandfathered status in all materials describing benefits.[12] A plan's grandfathered status is important because grandfathered plans are exempt from many aspects of the ACA, including the ACA provisions regarding appeals of health plan benefit decisions.[13] New York State's appeal laws apply to grandfathered plans, making the grandfathered distinction particularly important with regard to self-insured plans, which are not subject to state law. The effects of a plan's grandfathered status on a patient's appeal rights are further discussed in Sections II.F and III.F.

C. ERISA vs. Non-ERISA

ERISA is a federal law that applies to all employer- and union-sponsored health plans other than those provided by government or church employers ("ERISA plans").[14] ERISA does not apply to plans purchased on the individual market, or to plans offered to New York State, county, or city employees, retirees and dependents. Non-ERISA plans are relatively common; at least two million New Yorkers are enrolled in New York's two biggest government employer plans—the New York State Health Insurance Program and the New York City Health Benefits Program—and another several hundred thousand purchase plans on the individual market.[15] Besides ERISA's preemption provision, ERISA is also important because of a set of regulations promulgated about a decade ago that require ERISA plans to follow their own written rules and to establish reasonable claims and internal appeals procedures (hereinafter "Old ERISA Appeals Regulations" or "ERISA Regulations").[16] These regulations apply to ERISA plans but not to non-ERISA plans.

The ACA appeal provisions and their implementing regulations build on the ERISA Regulations and make them applicable to all non-grandfathered health plans, whether covered by ERISA or not.[17] This means that a plan's non-ERISA status will only affect patients' appeal rights if that plan is *also* grandfathered and thus not subject to this aspect of the ACA. For that reason non-ERISA plans are discussed below together with grandfathered plans in Sections II.F and III.F.

II. Self-Insured Plans

Part II describes the procedural protections available to patients enrolled in self-insured plans when they disagree with their health plan, with a focus on non-grandfathered ERISA plans. Section II.A starts with identifying the laws applicable to self-insured plans. The next three sections outline the most fundamental protections now enjoyed by patients. Section II.B describes the system of internal appeals, Section II.C discusses external review, and Section II.D highlights a patient's rights to adequate notice and information throughout these processes. Section II.E briefly discusses judicial review. Section II.F then explores the availability of these procedures in grandfathered and/or non-ERISA plans.

A. What Laws Apply to Self-Insured Plans?

The ACA did not amend ERISA's preemption provisions, therefore self-insured ERISA plans are still exempt from state law. The ACA, though, provides far more substantive protections than federal law had previously contained. For example, most self-insured plans are now required to cover preventive services with no cost-sharing,[18] allow dependents under 26 years old to stay on a parent's coverage,[19] and provide at least partial coverage for out-of-network emergency care.[20] The ACA also precludes most plans from enforcing pre-existing condition exclusions against minors,[21] as well as from imposing lifetime caps or unreasonably low annual caps on essential benefits.[22] Plans are also still required to follow their own written rules, both substantive and procedural, and many appeals are won because plans fail to follow their own rules.

From a procedural perspective, the ACA requires self-insured plans to allow patients to appeal coverage determinations both internally to plan employees, and externally to neutral external reviewers.[23] The relevant regulatory bodies—the Department of Labor ("DOL"), the Department of Health and Human Services ("HHS"), and the Internal Revenue Service ("IRS")—jointly issued regulations on July 23, 2010, which they later amended on June 24, 2011, outlining these procedural protections in detail (the "New ACA Appeals Regulations" or "ACA Regulations").[24] The rest of Section II is dedicated to describing how the New ACA Appeals Regulations affect the rights of New Yorkers enrolled in self-insured ERISA plans.

B. Internal Appeals in Self-Insured ERISA Plans

1. Who Decides Internal Appeals? Based on What Factors?

Internal appeals are the first layer of procedural protection for patients who want to dispute health plans decisions. These appeals are decided by health plan employees, but federal law provides for a minimum level of independence. For example, the appeal decision-maker cannot be the same person or a subordinate of the person who handled the initial denial, and the decision-maker cannot afford deference to the initial denial.[25] Further, plans are barred from hiring, compensating, terminating, or promoting employees based on their propensity to uphold denials.[26] If the decision involves medical judgment, then the decision-maker must consult a medical professional with training or experience in the relevant field.[27]

Internal Appeals Self-Insured Plans
(non-grandfathered)

- Appeal decided by health plan employee.
- Available to dispute all adverse benefit determinations and rescissions.
- 180-day filing period after first notice of adverse benefit determination or rescission.
- Plans may offer 2nd-level internal appeal.

Internal appeals are decided based on the plan's internal rules and any applicable laws, so it will be difficult, for example, to argue in an internal appeal that a plan's medical guidelines are deficient. Internal appeals may not seem so appealing—contesting a plan's application of its own rules to its own employee—but nonetheless many internal appeals result in the plan overturning itself.[28]

2. Timelines and Scope

Self-insured ERISA plans must allow patients at least 180 days within which to file an internal appeal of any "adverse benefit determination."[29] This is not new; the Old ERISA Appeals Regulations long gave patients this right, and defined an adverse benefit determination as a "denial, reduction, termination, or failure to make payment (in whole or in part) for a benefit," whether on the basis of eligibility for membership in the plan, utilization review, or otherwise.[30] The New ACA Appeals Regulations build on this old system and add that plans must allow appeals of rescissions, whether or not they have any effect on a current benefit payment.[31] Patients thus do not have a right to appeal absolutely *any* plan decision, but many of the most important decisions, including any that affect benefit payments, will be subject to internal appeal.

Patients may appoint a representative to pursue an appeal on their behalf, and after the patient or advocate gathers all the information and lodges an internal appeal, the plan typically has 60 days to answer.[32] Some plans also allow second-level internal appeals, but they are not legally required to do so.

There are two special situations that give rise to unique rules: urgent care and concurrent care. In an urgent care situation—where, in the opinion of the attending provider, a delay could seriously jeopardize the life, health, or recovery of the patient or would subject the patient to severe pain—the plan must answer the appeal "as soon as possible" but not later than 72 hours after receiving the appeal.[33] In these situations the patient also has a right to file an appeal orally.[34] In a concurrent care situation—where the plan pre-approves a patient for a course of treatment for a specific period of time or a set number of treatments, but then later issues a denial before that course of treatment is completed—the patient has a right to continued care while the appeal is pending.[35] As described below, these two special situations also create special rights with regard to external review.

C. External Review in Self-Insured Plans

1. Who Decides on External Review? Based on What Factors?

With passage and implementation of the ACA, self-insured plans are now required for the first time to offer external review. Unlike internal appeals, external reviews are decided by accredited "independent review organizations" ("IROs"), companies that employ personnel with the requisite expertise to resolve these disputes. For self-insured ERISA plans, these IROs operate under contract with the plan itself,[36] but this is still considered a more neutral forum than an internal appeal, where a health plan employee serves as adjudicator.

External Review Self-Insured Plans
(non-grandfathered)

- Appeal decided by third-party IRO, under contract with health plan.
- Available to dispute decisions that involve medical judgment and rescissions.
- Four-month filing period after exhaustion of *all* internal appeals.
- For urgent or concurrent care, can file for external review immediately.

Importantly, IROs are required to consider current research on evidence-based practice guidelines, nationally accepted clinical standards, and peer-reviewed medical literature, in addition to the health plan's internal rules.[37] This openness on medical standards, the reviewer's medical expertise, and the fact that the decision-maker is not employed by the plan combine to make external review an attractive venue for adjudication from a patient's perspective.

2. Timelines and Scope

For claims within the scope of external review, plans must give patients a period of at least **four months** following the exhaustion of internal appeals within which to file for external review.[38] In the self-insured plan context, external review is available for two types of health plan decisions: (i) those "involving medical judgment" and (ii) rescissions.[39] This means that if a patient's claim is denied because the plan thinks it is not a covered benefit under the policy, for instance, it would arguably not be subject to external review because that determination may not involve medical judgment. The term "involves medical judgment" just appeared in the regulation this past summer, and the author is aware of no court decisions interpreting the term. The regulation itself provides two useful examples that suggest the term was meant to be interpreted broadly,[40] so advocates are encouraged to be open-minded; as this system becomes better established the meaning of key terms will crystallize.

For concurrent and urgent care situations, as defined in Section II.B above, patients may file for external review at the same time as their first-level internal appeal, an important right allowing them to reach a neutral arbiter before enduring months of internal appeals while awaiting medical treatment.[41] Standard external appeals are to be answered within 45 days; urgent external appeals are to be answered as "expeditiously" as possible, but always within 72 hours.[42]

D. Notice Rights in Self-Insured Plans

The New ACA Appeals Regulations give patients strong rights to the adequate notice and information necessary to prosecute both internal and external appeals. The new rules require for denial notices, whether issued initially or as the result of an internal appeal, to:[43]

- Sufficiently identify the claim in question (e.g., by date of service, provider, etc.);
- Describe the reasons for the denial;
- Describe the plan's internal and external review processes;
- Notify the patient that relevant diagnosis and treatment codes, and their meanings, are available upon request; and
- Include contact information for the state's designated consumer assistance or ombudsman program (which in New York is Community Health Advocates).

In addition to what must be included in adverse benefit determination notices, a great deal of other important information is available only upon request. It can take time for plans and employers to provide this documentation, so an advocate should place requests long before any deadlines are approaching. The information available upon request includes:

- All the plan documents constituting the patient's plan, including the summary plan description;[44] This is typically available from the employer, not from the insurer administering the plan. For some plans it is also available online.
- The diagnosis and treatment codes relevant to the denial, and their meanings;[45]
- Copies of all documents, records, and other information relevant to the claim, including the legal/medical standard used to deny a claim;[46] and
- Copies of all call logs, e.g., from a client's calls to member services.[47]

The ACA requires plans to furnish these notices in a "culturally and linguistically appropriate manner."[48] The regulations implementing this provision require plans to: (i) offer translated oral language services (e.g., member services hotline); (ii) provide, upon request, translated notices, and (iii) include a prominently displayed statement on all English notices informing patients of their right to translated notices and phone services.[49] But plans only need to do so with respect to a given language if *ten percent or more* of the population of the patient's home county is literate only in that language, a very high bar.[50] In New York State, for instance, self-insured plans must provide translations into Spanish in only Manhattan, Queens, and the Bronx.[51] Aside from Spanish-speaking residents of these three counties, New Yorkers in self-insured plans have essentially *no* right to linguistically appropriate notices or phone translation. Advocates have questioned whether this framework satisfies the ACA's mandate for culturally and linguistically appropriate notices, so far to no effect.[52]

E. Judicial Review

Patients enrolled in ERISA plans have a right to bring an action in federal or state court after exhausting all internal appeals offered by the plan.[53] Courts hearing these actions typically only review to determine that the plan properly applied its own written guidelines based on the information available during the internal appeals process.[54] For example, courts may reverse a plan's decision when a plan administrator ignores relevant factors,[55] inconsistently applies its own rules,[56] reverses a prior decision without new evidence,[57] or fails to properly consider the opinion of a treating physician.[58]

This limited scope of review has two important consequences. First, it is very difficult to introduce arguments that the plan's guidelines are defective—making external review a more attractive venue for many cases. Though patients may seek judicial review even after an unsuccessful external appeal, it is difficult to convince a court

Applicable Laws—Self-Insured Plans Effect of Grandfathered and/or Non-ERISA Status			
Type of Plan		Internal Appeal	External Review
ERISA	Non-Grandfathered	New ACA Appeals Regulation Old ERISA Appeals Regulation	New ACA Appeals Regulation
	Grandfathered	Old ERISA Appeals Regulation	NONE
Non-ERISA	Non-Grandfathered	New ACA Appeals Regulation	New ACA Appeals Regulation
	Grandfathered	NONE	NONE

that it should disturb a decision made by neutral medical experts.[59] Second, it is also very difficult to introduce evidence not contained in the internal appeal record. If a lawyer expects to end up in court, she should be very careful to prepare a strong record during the internal appeals process.

F. Grandfathered and/or Non-ERISA Plans

Grandfathered self-insured plans are exempt from the New ACA Appeals Regulations, but patients enrolled in grandfathered plans are not entirely unprotected. Those covered by grandfathered ERISA plans, at least, still have the right to internal appeals under the Old ERISA Appeals Regulations, which are nearly identical to the ACA-based internal appeal rights. These patients will not, though, have a legally protected right to external review.

Grandfathered self-insured plans that are also non-ERISA plans are not subject to the Old ERISA Appeals Regulations, thus patients enrolled in this type of plan may have no legally protected appeal rights at all. And if a grandfathered non-ERISA plan offers appeal rights in its plan documents, then this offer must be honored. Fortunately these plans are rare in New York. The relevance of grandfathered and/or non-ERISA status is demonstrated by the chart above.

III. Fully Insured and Individual Market Plans

Unlike self-insured plans, which are subject to federal law, fully insured plans are subject to state as well as federal law. This difference affects patients' rights in important ways. Part III is structured exactly as Part II, focusing first on non-grandfathered ERISA plans. Section III.A provides background on the sources of substantive and procedural law that apply to fully insured plans. Section III.B covers internal appeals in fully insured plans, which are very similar to those available in self-insured plans. New York's external review system, which differs in many respects from the federal system, is described in Section III.C. Section III.D outlines patients' notice rights, and Section III.E briefly describes judicial review. Section III.F analyzes the effects of a plan's grandfathered and/or non-ERISA status on this framework.

A. What Laws Apply to Fully Insured Plans?

In addition to the new ACA protections described in Section II.A above, fully insured plans and individual market plans are also subject to a variety of important patient protections under New York State law. For example, New York's guaranteed issue and community rating laws preclude plans in the individual and small group markets from charging higher premiums to sicker or older enrollees,[60] and New York's Managed Care Bill of Rights requires managed care plans to allow patients access to out-of-network care in certain situations.[61] New York law also includes specific benefit mandates, protecting patients' rights to coverage for treatments such as mammography screening, second surgical opinions, and second opinions for cancer diagnoses.[62] These New York laws exist on top of their federal counterparts, and the rules that are most protective of the patient apply.

With regard to internal appeals, fully insured plans are subject to both state and federal regulation. New York State law divides patients' challenges of plan decisions into two camps: "utilization review" is the process used when the dispute is based on medical necessity,[63] and the "grievance" process is used for all other disputes.[64] The federal internal appeal procedures from the ERISA and ACA Regulations also apply to fully insured plans, and Section III.B analyzes how these sets of rules interact with each other.

Since 1999, New York has required insurers to participate in an external review system where neutral third-party experts can overturn certain plan decisions.[65] The New ACA Appeals Regulations provide that plans participating in state external review systems that meet certain minimum federal standards are subject *only* to those state rules.[66] New York's system meets that test, thus fully insured plans are subject *only* to New York's external review laws, even if the federal standard may be more protective in some minor respects.[67] Section III.C below describes New York's external review system.

B. Internal Appeals in Fully Insured and Individual Market Plans

Both federal and state laws apply to internal appeals in fully insured plans, and the aspects of each law that are most protective of the patient are applied. Thus those enrolled in fully insured plans have some additional protections on internal appeal that are not available in the self-insured context.

Internal Appeals Fully Insured Plans

(non-grandfathered)

- Appeal decided by health plan employee.
- Available to dispute all adverse benefit determinations and rescissions.
- 180-day filing period after first notice of adverse benefit determination or rescission.
- Group plans may offer 2nd-level internal appeal.
- Grievance procedure also available for all other disputes.

1. Who Decides Internal Appeals? Based on What Factors?

Just as in self-insured plans, internal appeals in fully insured plans are decided by health plan employees based on the medical record and the plan's internal medical guidelines. All of the federal rules protecting the independence of these decisions-makers, as described in Section II.B.1, also apply in the fully insured context. In addition, New York State law requires that internal appeals be conducted by clinical peer reviewers, defined as either: (1) licensed or accredited non-physician medical professionals with expertise in the specialty relevant to the case, or (2) licensed physicians of whatever specialty.[68] The internal appeal framework in fully insured plans is extremely similar to that in self-insured plans, and roughly half of all internal appeals in fully insured plans result in the plan overturning itself.[69]

2. Scope and Timelines

The time frames in the New ACA Appeals Regulations are generally more protective of consumers than New York's utilization review and grievance procedures. Therefore, the federal timelines previously described in Section II.B.2 typically apply to all disputes of adverse benefit determinations or rescissions. One exception to this is that New York's urgent appeal response deadlines can be more stringent, requiring a plan's resolution within two business days after receiving all necessary information, which can sometimes be a shorter period than the maximum of 72 hours allowed under the federal rule.[70] But this difference is relatively minor; the thrust of the New ACA Appeals Regulations will apply to fully insured and individual market plans just as they apply to self-insured plans, at least with respect to internal appeals.

New York's grievance procedure allows patients in fully insured plans to appeal *any* decision made by their health plan, even those that are not subject to appeal under the New ACA Appeals Regulations.[71] Grievances can be initiated in writing or by phone (for certain issues) and plans must answer most grievances within 30 or 45 days, depending on the issue, or within 48 hours if urgent. Patients can appeal negative grievance determinations within 60 days. One could file a grievance if, for example, she wanted to challenge the plan's determination of when her coverage was set to start or end (and this did not yet have any effect on the payment of benefits), or if she wanted to complain that her plan never sent her information that she requested. Neither of these examples would be subject to appeal under the New ACA Regulations because they are not adverse benefit determinations.

C. External Review in Fully Insured and Individual Market Plans

1. Who Decides on External Review? Based on What Factors?

Since 1999, New York has operated a successful external review system. In 2011, the state external review law was amended to comply with minimum requirements under the ACA. External reviews in New York are, and will continue to be, heard by neutral third-party organizations under contract with the State Department of Financial Services (formerly known as the Department of Insurance). The state currently contracts with three different independent reviewers and assigns cases to them randomly.[72] This contrasts with the self-insured model where IROs contract directly with the health plans, and provides for an extra level of independence. In New York, about 40% to 50% of external reviews end with the plan's decision being overturned.[73]

External Review Fully Insured Plans

- Appeal decided by third-party IRO, under contract with state.
- Four-month filing period after final adverse determination, which is the *first* internal appeal decision.
- For urgent or concurrent care, can file for external review immediately.
- Available for denials due to:
  - medical necessity (incl. four subtypes),
  - experimental/investigational (special rules for rare diseases, clinical trials)
  - out-of-network *service* in HMO.

The factors applicable to a given external review vary in New York depending on the type of issue under dispute. Accordingly the discussions of the relevant evidence and standards of review are found in Section III.C.2, together with a description of each type of dispute eligible for external review.

2. Scope and Timelines

In New York, patients have four months to file for external review after receiving their final adverse determination ("FAD"), which is a bit of a misnomer.[74] The FAD is issued after the *first* unsuccessful internal appeal, even if the plan offers further internal appeals. By contrast, the federal system for self-insured ERISA plans allows external review only after exhausting *all* internal appeals, and applicable time periods only start after reaching that point. Many patients, and even advocates, have missed their opportunity for external review, a very important right, by filing a second-level internal appeal and waiting for a response as their external appeal deadline expires. As with self-insured plans, patients appealing in urgent or concurrent care situations have the right to seek external review at the same time as filing a first-level internal appeal.[75]

New York law does not provide for external review in as broad a selection of cases as does the federal system that applies to self-insured plans, which allows patients to apply for external review of any plan decision involving medical judgment as well as rescissions.[76] In contrast, New York only allows for external review for three specific types of denials: (1) denials because a treatment is not medically necessary, (2) denials because a treatment is experimental or investigational (including rare diseases and clinical trials), and (3) denials of access to an out-of-network service for patients enrolled in HMOs. The rules are a bit different for each category, addressed in turn below:

a. Disputes Regarding Medical Necessity

New Yorkers enrolled in fully insured plans have long had the right to seek external review for disputes as to medical necessity. As of January 1, 2012, this category was expanded to include: (1) disputes as the "appropriateness" of a treatment (e.g., chemotherapy vs. surgery to treat a certain cancer); (2) disputes as to "health care setting" (e.g., breast surgeon vs. general surgeon for a mastectomy); (3) disputes regarding "level of care" (e.g., inpatient vs. outpatient for substance abuse rehabilitation); (4) and disputes as to the "effectiveness of a covered benefit" (e.g., whether physical therapy is still improving patient's condition).[77] These four subcategories are new and the examples above are only one attempt at interpreting their scope; as time passes perhaps a new understanding will emerge.

For this category of dispute, the external reviewer is tasked to decide whether the plan acted "reasonably and with sound medical judgment *and in the best interest of the patient*."[78] The reviewer must consider the clinical standards of the health plan, the patient's medical records, and the attending physician's recommendation (as would be reviewed on internal appeal), but he also must consider any applicable and generally accepted practice guidelines developed by the federal government (e.g., for Medicare), or national or professional medical societies, boards, or associations. In cases where medical professional society guidelines are more flexible or patient-friendly than the guidelines of the insurance company, external review will be a better venue for patients than will internal appeal.

b. Disputes as to Whether a Treatment Is Experimental or Investigational

For this category of dispute, outside of the clinical trial and rare disease contexts, the reviewer is directed to decide if the recommended treatment is "likely to be more beneficial than any standard treatment."[79] The reviewer must consider all of the evidence described above for medical necessity cases, as well as specified "medical and scientific evidence," defined by statute to include things such as peer-reviewed medical literature and listed medical reference compendia and pharmacopeia.[80] In order for this type of case to be eligible for external review, the patient (or her advocate or doctor) must submit *two* such pieces of medical and scientific evidence.[81] As of January 1, 2012, applicants for this type of external review no longer need to show that they are suffering from a life-threatening or debilitating disease.

For patients suffering from rare diseases or seeking access to clinical trials, different rules apply. If the patient is suffering from a rare disease,[82] then the reviewer need only confirm that the treatment is likely to benefit the patient and that the benefit outweighs the risks. This can be supported by as little as a certification to that effect from a non-treating physician, rather than by two pieces of medical or scientific evidence.[83] Patients eligible for a qualifying clinical trial also need not submit two pieces of medical or scientific evidence, and the reviewer need only determine that the treatment is likely to benefit the patient in order to overturn the plan's denial.[84] Patients applying for rare disease or clinical trial external review are no longer required to show that they are suffering from a life-threatening or debilitating disease. The protections for these special situations are important, as it might otherwise be quite difficult to meet the required standard of evidence.

c. Disputes Over Access to Out-of-Network Service Where Plan Offers Alternative Service In-Network

HMO enrollees may also use the external review system when they are seeking access to an out-of-network *service* not available in-network, and the plan recommends the patient receive an *alternative service* in-network.[85] This category is far narrower than it first appears. It does *not* allow access to external review when a patient wants in-network benefits to see a more experienced out-of-network provider.[86] The dispute must be about a *service*—not provider—that is not available in the plan's

network. To win in this class of dispute, the patient must show that the recommended out-of-network treatment is materially different from any treatment available in-network, and that it is likely to be more clinically beneficial without substantially increased risk.[87]

The narrowness of this category may at first seem one way in which New York's system is less patient-friendly than the federal system that applies to self-insured plans. Under the federal system a dispute over access to an out-of-network provider would be eligible for external review since it involves medical judgment, at least if the patient can credibly argue that the in-network provider cannot "effectively" provide the needed service.[88] But it is also possible that the recent addition of language clearly including "health care setting" cases within the purview of external review in New York creates room for development with regard to this type of dispute. One advocate has argued that this language can encompass choice-of-provider disputes, citing discussions with federal regulators and noting that similar language in Virginia law is interpreted in that fashion.[89]

D. Notice Rights in Fully Insured and Individual Market Plans

A patient's right to adequate notice and information necessary to pursue an appeal are almost identical in fully insured plans as in self-insured plans, as described in Section II.D. The most notable exception to this parity is that New York's language access standards are a bit stronger than the federal rules.[90]

E. Judicial Review

For fully insured ERISA plans, the ERISA remedies described in Section II.E also apply. While state law that regulates *insurance* can still be effective against fully insured plans by virtue of ERISA's savings clause, most state law that does not fit into that category is rendered ineffective by ERISA's preemption provision.[91] Therefore, the procedural aspects of ERISA-based judicial review, including standards of review, form the exclusive framework for judicial review of internal appeals from fully insured ERISA plans. New York's external review law also clearly makes external review decisions admissible in court.[92] Since external reviewers are rightly viewed as neutral experts, it is very rare for patients to succeed in court after losing on external review.[93] For fully insured ERISA plans, judicial review looks much the same as it did for self-insured ERISA plans.

F. Grandfathered and/or Non-ERISA Plans

In the fully insured context, a patient's appeal rights are only substantially different if their plan is *both* grandfathered *and* non-ERISA, and this difference only shows up with regard to internal appeals.[94] For these grandfathered non-ERISA plans, none of the federal appeals rules from the ACA or ERISA apply. Consequently, with respect to internal appeals, patients in these plans must rely only on the utilization review[95] and grievance[96] systems available under New York State law. Critically, these patients may have as little as 45 days after an adverse determination to file an appeal, a far tighter period than the 180 days available for most other plans.[97] New York's external review laws, however, apply to all fully insured plans regardless of grandfathered or non-ERISA status. The chart below demonstrates the effect of grandfathered or non-ERISA status in the full insured context.

V. Conclusion and Summary Chart

Internal appeals and external review are important procedural tools that protect patients when their health plans make incorrect benefit decisions. The ACA and recent New York reforms strengthen these protections, for instance by extending deadlines and by making external review available to more patients and for a broader range of disputes. Hopefully this article provides a foundation

Applicable Laws—Fully Insured Plans
Effect of Grandfathered or Non-ERISA Status

Type of Plan		Internal Appeal	External Review
ERISA	Non-Grandfathered	ERISA and ACA Appeals Regulations NY State Utilization Review and Grievances	New York State External Review System
	Grandfathered	ERISA Appeals Regulations NY State Utilization Review and Grievances	
Non-ERISA	Non-Grandfathered	ERISA and ACA Appeals Regulations NY State Utilization Review and Grievances	
	Grandfathered	NY State U.R. and Grievances *only* as little as 45 days to file first appeal	

to allow advocates to navigate these new procedures successfully. In support of that goal, the table below summarizes the most important information from this article and provides citations to the principal sources of law applicable to each type of health plan.

Internal Appeal and External Review Rights in New York

Self-Insured Plans

Type of Plan	Internal Appeals	External Review
Self-Insured ERISA	• Appeal decided by health plan employee. • Available to dispute all adverse benefit determinations and rescissions. • 180-day filing period after first notice of adverse benefit determination or rescission. • Plans may allow 2nd-level internal appeal. • *Grandfathered plans*: Same rights, with only minor differences. Sources: A, C	• Appeal decided by third-party IRO, under contract with health plan. • Available to dispute decisions that involve medical judgment and rescissions. • Four-month filing period after exhaustion of *all* internal appeals. • For urgent or concurrent care, can file for external review immediately. • *Grandfathered plans*: Not legally required to offer external review. Sources: B, D
Self-Insured Non-ERISA	• Appeal decided by health plan employee. • Available to dispute all adverse benefit determinations and rescissions • 180-day filing period after first notice of adverse benefit determination or rescission. • Plans may allow 2nd-level internal appeal • *Grandfathered plans*: Not required to offer any appeal rights. Source: A	

Fully Insured Plans

Type of Plan	Internal Appeals	External Review
Fully Insured ERISA	• Appeal decided by health plan employee. • Available to dispute all adverse benefit determinations and rescissions. • 180-day filing period after first notice of adverse benefit determination or rescission. • Plans may allow 2nd-level internal appeal. • Grievances available for other disputes. • Grandfathered plans: Same rights, with only minor differences. Sources: A, C, E, G	• Appeal decided by third-party IRO, under contract with state. • Available for denials due to: – medical necessity (incl. four subtypes), – experimental/investigational (incl. special rules for rare diseases, clinical trials), – out-of-network *service* in HMO. • Four-month filing period after final adverse determination, which is the *first* internal appeal decision. • For urgent or concurrent care, can file for external review immediately. • *Grandfathered plans*: Same rights apply. Source: F
Fully Insured Non-ERISA (incl. individual market)	• Appeal decided by health plan employee. • Available to dispute all adverse benefit determinations and rescissions • 180-day filing period after first notice of adverse benefit determination or rescission. • Group plans may allow 2nd internal appeal. • Individual market plans allow one one internal appeal. • Grievances available for other disputes. • *Grandfathered plans*: May have as little as 45 days to file first internal appeal. Sources: A, E, G	

Sources

A - ACA Appeals Regulations, ¶ (b) (26 CFR 54.9815-2719T(b), 29 CFR 2590.715-2719(b), 45 CFR 147.136(b))*

B - ACA Appeals Regulations, ¶ (d) (26 CFR 54.9815-2719T(d), 29 CFR 2590.715-2719(d), 45 CFR 147.136(d))*

C - ERISA Appeals Regulations (29 CFR 2560.503-1)

D - DOL Technical Releases 2010-01 and 2011-02*

E - N.Y. Ins. Law and Pub. Health Law §§ 4900 et seq.

F - N.Y. Ins. Law and Pub. Health Law §§ 4910 et seq.

G - N.Y. Ins. Law § 4802; N.Y. Pub. Health Law § 4408-a.2

* - Does not apply to grandfathered plans.

Endnotes

1. United Hospital Fund, Health Coverage in New York, 2009 fig. 1 & tbl. 4 (2011), available at www.uhfnyc.org/assets/936.
2. Id. at fig. 1.
3. Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2010 Medical Expenditure Panel Survey-Insurance Component tbl. II.B.2.b.(1)(2010), available at www.meps.ahrq.gov/mepsweb/data_stats/summ_tables/insr/state/series_2/2010/tiib2b1.pdf.
4. Employers can be penalized up to $110 per day for failing to provide plan documentation within 30 days of request. 29 U.S.C. § 1132(c) (2006); 29 C.F.R. § 2575.502c-1 (2011); *see also* Kasireddy v. Bank of Am. Corp. Corporate Benefits Comm., 2010 U.S. Dist. LEXIS 109606 (N.D. Ill. 2010).
5. Agency for Healthcare Research and Quality, supra note 3, at tbl. II.B.2.b.(1)(2010).
6. 29 U.S.C. § 1144(a) (2006). For a small sample of seminal case law on ERISA preemption, *see, e.g.*, *Shaw v. Delta Airlines Inc.*, 463 U.S. 85 (1983) and *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995).
7. 29 U.S.C. § 1144(b)(2)(A) (2006). ERISA's deemer clause prevents states from "deeming" self-insured plans to be insurance and then regulating them. 29 U.S.C. § 1144(b)(2)(B) (2006).
8. *See* Metro. Life Ins. Co. v. Massachusetts, 471 U.S. 724, 747 (1985) (recognizing fully insured plans are subject to state law while self-insured plans are not).
9. Some state remedies arising out of claim administration (such as punitive damage claims) may be preempted by ERISA even if more patient protective than the federal standard. *See* Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41 (1987).
10. Patient Protection and Affordable Care Act (ACA) § 1251, 42 U.S.C.A § 18011 (2011). For detailed implementing regulations, see 26 C.F.R. § (2011), 29 C.F.R. § 2590.715-1251 (2011), 45 C.F.R. § 147.140 (2011). Information is also available at www.healthcare.gov.
11. Dep't of Health and Human Services, Keeping the Health Plan You Have: The Affordable Care Act and "Grandfathered" Health Plans, at www.healthcare.gov/news/factsheets/2010/06/keeping-the-health-plan-you-have-grandfathered.html (last visited Nov. 28, 2011).
12. 26 C.F.R. § 54.9815-1251T(a)(2) (2011); 29 C.F.R. § 2590.715-1251(a)(2) (2011); 45 C.F.R. § 147.140(a)(2) (2011).
13. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(a) (2011), 29 C.F.R. § 2590.715-2719(a) (2011), 45 C.F.R. § 147.136(a) (2011).
14. 29 U.S.C. § 1003 (2006).
15. United Hospital Fund, The Big Picture: Private and Public Health Insurance Markets in New York 34-42 (2009), available at www.uhfnyc.org/assets/753 (Empire Plan and New York City Health Benefits Program); United Hospital Fund, Health Coverage in New York, 2009 fig. 1 & tbl. 4 (2011), available at www.uhfnyc.org/assets/936 (estimating circa 600,000 insured on individual market). *But c.f.* Joel C. Cantor et al., *The Adequacy of Household Survey Data for Evaluating the Nongroup Health Insurance Market*, 42 Health Serv. Res. 1739 (2007) (arguing survey data greatly over-estimates size of individual market).
16. ERISA Claims Procedure Rule, 29 C.F.R. § 2560.503-1 (2011).
17. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(b)(2)(i) (2011), 29 C.F.R. § 2590.715-2719(b)(2)(i) (2011), 45 C.F.R. § 147.136(b)(2)(i) (2011).
18. ACA § 1001, 42 U.S.C.A. § 300gg-13 (2011) (may not apply to grandfathered plans). For parallel implementing regulations of the IRS, DOL, and HHS, see 26 C.F.R. § 54.9815-2713T (2011); 29 C.F.R. § 2590.715-2713 (2011); 45 C.F.R. § 147.130 (2011).
19. ACA § 1001, 42 U.S.C.A. § 300gg-14 (2011) (does not apply to grandfathered plans if the young adult has access to other group health coverage). For parallel implementing regulations of the IRS, DOL, and HHS, see 26 C.F.R. § 54.9815-2714T (2011); 29 C.F.R. § 2590.715-2714 (2011); 45 C.F.R. § 147.120 (2011).
20. ACA § 1001, 42 U.S.C.A. 300gg-19a (2011) (does not apply to grandfathered plans). For parallel implementing regulations of the IRS, DOL, and HHS, see 26 C.F.R. § 54.9815-2719AT(b) (2011); 29 C.F.R. § 2590.715-2719A(b) (2011); 45 C.F.R. § 147.138(b) (2011).
21. ACA § 1201, 42 U.S.C.A. 300gg (2011) (does not apply to grandfathered plans). For parallel implementing regulations of the IRS, DOL, and HHS, see 26 C.F.R. § 54.9815-2704T (2011); 29 C.F.R. § 2590.715-2704 (2011); 45 C.F.R. § 147.108 (2011).
22. ACA § 1001, 42 U.S.C.A. § 300gg-11 (2011) (applies to grandfathered plans). For parallel implementing regulations of the IRS, DOL, and HHS, see 26 C.F.R. § 54.9815-2711T (2011); 29 C.F.R. § 2590.715-2711 (2011); 45 C.F.R. § 147.126 (2011).
23. ACA § 1001, 42 U.S.C.A. § 300gg-19 (2011).
24. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T (2011), 29 C.F.R. § 2590.715-2719 (2011), 45 C.F.R. § 147.136 (2011).
25. ERISA Claims Procedure Rule, 29 C.F.R. § 2560.503-1(h)(3)(ii) (2011).
26. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(b)(2)(D) (2011), 29 C.F.R. § 2590.715-2719(b)(2)(D) (2011), 45 C.F.R. § 147.136(b)(2)(D) (2011).
27. ERISA Claims Procedure Rule, 29 C.F.R. § 2560.503-1(h)(3)(iii) (2011).
28. In the fully insured context, discussed in Part III below, about half of all internal appeals are successful for the patient. New York Dept. of Financial Services, New York Consumer Guide to Health Insurers 14-15 (2011), available at www.dfs.ny.gov/insurance/consumer/health/cg_health_2011.pdf.
29. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(b) (2011), 29 C.F.R. § 2590.715-2719(b) (2011), 45 C.F.R. § 147.136(b) (2011) (right to internal appeal); ERISA Claims Procedure Rule, 29 C.F.R. § 2560.503-1(h)(3)(i) (giving 180 days).
30. ERISA Claims Procedure Rule, 29 C.F.R. § 2560-503-1(m); *see also* IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(a)(2)(i) (2011), 29 C.F.R. § 2590.715-2719(a)(2)(i) (2011), 45 C.F.R. § 147.136(a)(2)(i) (2011) (defining term by reference back to older ERISA regulation).
31. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(b)(2)(ii)(A) (2011), 29 C.F.R. § 2590.715-2719(b)(2)(ii)(A) (2011), 45 C.F.R. § 147.136(b)(2)

(ii)(A) (2011). A "rescission" is a cancelation or discontinuance of coverage with retroactive effect. 26 C.F.R. § 54.9815-2712T(a)(12), 29 C.F.R. § 2590.715-2712(a)(12), 45 C.F.R. § 147.128 (2011).

32. ERISA Claims Procedure Rule, 29 C.F.R. § 2560.503-1(i) (2011) (60 days); 29 C.F.R. § 2560.503(1)(b)(4) (right to appoint representative).

33. ERISA Claims Procedure Rule 29 C.F.R. § 2560-503-1(m)(1) (defining urgent care); 29 C.F.R. § 2560.503-1(i)(2)(i) (giving time limit for plan to answer urgent appeal); *see also* IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(b)(2)(ii)(B) (2011), 29 C.F.R. § 2590.715-2719(b)(2)(ii)(B) (2011), 45 C.F.R. § 147.136(b)(2)(ii)(B) (2011) (discussing urgent cases in new ACA regulations by reference back to older ERISA regulations).

34. ERISA Claims Procedure Rule, 29 C.F.R. § 2560.503-1(h)(3)(vi)(A) (2011).

35. ERISA Claims Procedure Rule, 29 C.F.R. § 2560.503-1(f)(2)(ii)(A) (2011).

36. As of January 1, 2012 each plan has been required to contract with at least two IROs, and by July 1, 2012 they must contract with at least three. Plans are not *required* to assign cases randomly to IROs, but any other method of assignment will receive close scrutiny from DOL. *See* Dept. of Labor, Employee Benefit Security Administration, Technical Release 2010-01, at 4 (Aug. 23, 2010), available at www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-01.pdf; Dept. of Labor, Employee Benefit Security Administration, Technical Release 2011-02, at 8-9 (June 22, 2011), available at www.dol.gov/ebsa/pdf/tr11-02.pdf.

37. Dept. of Labor, Employee Benefit Security Administration, Technical Release 2010-01, at 5 (Aug. 23, 2010), available at www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-01.pdf; *see also* URAC, Issue Brief: Affordable Care Act (PPACA) External Review Regulations (Dec. 2010), available at www.urac.org/savedfiles/1URAC_IROIB_2010.pdf.

38. Dept. of Labor, Employee Benefit Security Administration, Technical Release 2010-01, at 3 (Aug. 23, 2010), available at www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-01.pdf.

39. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(d)(1)(ii) (2011), 29 C.F.R. § 2590.715-2719(d)(1)(ii) (2011), 45 C.F.R. § 147.136(d)(1)(ii) (2011).

40. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(d)(1)(iii) (2011), 29 C.F.R. § 2590.715-2719(d)(1)(iii) (2011), 45 C.F.R. § 147.136(d)(1)(iii) (2011).

41. Dept. of Labor, Employee Benefit Security Administration, Technical Release 2010-01, at 6-7 (Aug. 23, 2010), available at www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-01.pdf.

42. Id. at 5, 7 (deadlines for answers to standard and urgent appeals, respectively).

43. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(b)(2)(ii)(E) (2011), 29 C.F.R. § 2590.715-2719(b)(2)(ii)(E) (2011), 45 C.F.R. § 147.136(b)(2)(ii)(E) (2011).

44. See supra note 4 and accompanying text.

45. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(b)(2)(ii)(E) (2011), 29 C.F.R. § 2590.715-2719(b)(2)(ii)(E) (2011), 45 C.F.R. § 147.136(b)(2)(ii)(E) (2011).

46. ERISA Claims Procedure Rule, 29 C.F.R. § 2560.503-1(h)(2)(iii); *see also* IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(b)(2)(ii)(C) (2011), 29 C.F.R. § 2590.715-2719(b)(2)(ii)(C) (2011), 45 C.F.R. § 147.136(b)(2)(ii)(C) (2011).

47. Rather than stemming from regulations on appeals, this right is actually provided by HIPAA, which protects people's rights to access their own medical records. *See* 45 C.F.R. §§ 164.502(a)(2), 164.524 (2011).

48. ACA § 1001, 42 U.S.C.A. 300gg-19(a)(1)(B) (2011).

49. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(e)(2) (2011), 29 C.F.R. § 2590.715-2719(e)(2) (2011), 45 C.F.R. § 147.136(e)(2) (2011).

50. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(e)(3) (2011), 29 C.F.R. § 2590.715-2719(e)(3) (2011), 45 C.F.R. § 147.136(e)(3) (2011). This standard was stronger in the original July 2010 version of the regulation, but weakened in the June 2011 amendment.

51. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 76 Fed. Reg. 37221-24 (June 24, 2011) (listing applicable languages and counties in preamble to regulation).

52. For a detailed discussion of advocates' recommendations for improvements to these language access rules, see Letter from National Health Law Program, Commenting on Amendment to Internal Appeals and External Review Regulations (July 25, 2011), available at http://www.healthlaw.org/images/stories/healthreform/2011_07_25_Appeals_Comments.pdf.

53. ERISA § 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B) (2006).

54. *See, e.g.*, Met Life Ins. Co. v. Glenn, 554 U.S. 105 (2008); Miller v. United Welfare Fund, 72 F.3d 1066 (2d Cir. 1995).

55. *See, e.g.*, Zuckerbrod v. Phoenix Mutual Life Ins. Co., 78 F.3d 46 (2d Cir. 1996).

56. *See, e.g.*, DeAngelis v. Warner Lambert Co., 641 F. Supp. 467 (S.D.N.Y. 1986) (finding no reversible inconsistency).

57. *See, e.g.*, Regula v. Delta Family-Care Disability Survivorship Plan, 266 F.3d 1130 (9th Cir. 2001).

58. *See, e.g.*, Miller v. United Welfare Fund, 72 F.3d 1066 (2d Cir. 1995).

59. *See* IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(d)(2)(iv) (2011), 29 C.F.R. § 2590.715-2719(d)(2)(iv) (2011), 45 C.F.R. § 147.136(d)(2)(iv) (2011); *see also* infra note 93 and accompanying text.

60. N.Y. Ins. Law § 3231 (McKinney 2011).

61. N.Y. Pub. Health Law. § 4403(6)(a) (McKinney 2011).

62. *See, e.g.*, N.Y. Ins. Law §§ 3216, 3221, & 4303 (McKinney 2011) (describing benefit mandates for individual commercial, group commercial, and group HMO products); *see also* New York Dept. of Financial Services, Mandated and Make Available Benefits: Commercial, HMO & Article 43 Insurance Contracts, at www.dfs.ny.gov/insurance/health/lbenall.htm (last visited Nov. 21, 2011).

63. N.Y. Ins. Law § 4900(h) (McKinney 2011).

64. N.Y. Pub Health Law § 4408-a.2 (McKinney 2011); N.Y. Ins. Law § 4802 (McKinney 2011). Grievance procedure requirements apply to any plan with a network, including EPOs. N.Y. Ins. Law § 4306-c (McKinney 2011).

65. N.Y. Ins. Law § 4910 et seq. (McKinney 2011); *see also* Mark Scherzer, Implementing Health Care Reform: External Review of Health Plan Decisions 4-5 (2011), available at www.uhfnyc.org/assets/901.

66. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(c) (2011), 29 C.F.R. § 2590.715-2719(c) (2011), 45 C.F.R. § 147.136(c) (2011); *see also* Dept. of Labor, Employee Benefit Security Administration, Technical Release 2011-02 (June 22, 2011), available at www.dol.gov/ebsa/pdf/tr11-02.pdf; Scherzer, supra note 65. There was great dismay among advocates when the July 2011 amendments to the ACA appeals regulations weakened the minimum protections required of state external review schemes, but New York's system already

met the higher bar set in the June 2010 version of the regulation, so the weakening of the amended regulations did not affect New Yorkers.

67. See Dept. of Health and Human Services, Center for Consumer Information & Insurance Oversight, Affordable Care Act: Working with States to Protect Consumers, at http://cciio.cms.gov/resources/files/external_appeals.html (last visited Nov. 11, 2011) (listing New York as compliant with strictest federal standards).

68. N.Y. Ins. Law §§ 4904(d); 4900(b) (McKinney 2011); N.Y. Pub. Health Law §§ 4904(4); 4900(2) (McKinney 2011).

69. New York Dept. of Financial Services, New York Consumer Guide to Health Insurers 15 (2011), available at www.dfs.ny.gov/insurance/consumer/health/cg_health_2011.pdf.

70. N.Y. Ins. Law § 4904(b) (McKinney 2011); N.Y. Pub. Health Law § 4904(2) (McKinney 2011).

71. N.Y. Pub. Health Law § 4408-a.2 (McKinney 2011); N.Y. Ins. Law § 4802 (McKinney 2011).

72. 11 N.Y.C.R.R. § 410.8 (2011) (random assignment); New York Dept. of Financial Services, External Appeals—Frequently Asked Questions, Instructions, and Applications, at www.dfs.ny.gov/insurance/extapp/extappqa.htm (last visited Nov. 12, 2011) (listing IMEDICS, IPRO, and MCMC as the three selected external reviewers).

73. New York State Insurance Dept. and New York State Dept. of Health, New York State External Appeal Program Annual Report 29-35 (2005) (most recent report publicly available), available at http://www.dfs.ny.gov/insurance/extapp/extapp05.pdf.

74. N.Y. Ins. Law § 4910(b)(1) (McKinney 2011); N.Y. Pub. Health Law § 4910(2)(a) (McKinney 2011). Prior to the recent amendments, the patient had 45 days to seek external review. The amended version of the statute is effective for all final adverse determinations issued on or after January 1, 2012. Any reader interested in the rules *before* the recent amendment became effective should refer to Scherzer, supra note 65.

75. N.Y. Ins. Law § 4914(b) (McKinney 2011); N.Y. Pub. Health Law § 4914(2) (McKinney 2011).

76. *See* Part II.C infra.

77. N.Y. Ins. Law § 4910(b)(1) (McKinney 2011); N.Y. Pub. Health Law § 4910(2)(a) (McKinney 2011).

78. N.Y. Ins. Law § 4914(b)(4)(A) (McKinney 2011); N.Y. Pub. Health Law § 4914(2)(d)(A) (McKinney 2011) (emphasis added).

79. N.Y. Ins. Law § 4914(b)(4)(B) (McKinney 2011); N.Y. Pub. Health Law § 4914(2)(d)(B) (McKinney 2011).

80. N.Y. Ins. Law § 4900(g-5) (McKinney 2011); N.Y. Pub. Health Law § 4900(7-e) (McKinney 2011).

81. N.Y. Ins. Law § 4910(b)(2)(C) (McKinney 2011); N.Y. Pub. Health Law § 4910(2)(b)(iii) (McKinney 2011).

82. A "rare disease" is defined by statute to be a condition or disease which is subject to research of the NIH Rare Diseases Clinical Research Network or affects fewer than 200,000 U.S. residents per year, and for which there is no standard treatment covered by the health plan. N.Y. Ins. Law § 4900(g-7) (McKinney 2011); N.Y. Pub. Health Law § 4910(7-g) (McKinney 2011).

83. N.Y. Ins. Law § 4910(b)(2)(C) (McKinney 2011); N.Y. Pub. Health Law § 4910(2)(b)(iii) (McKinney 2011).

84. N.Y. Ins. Law § 4914(b)(4)(B) (McKinney 2011); N.Y. Pub. Health Law § 4914(2)(d)(ii) (McKinney 2011) (standard to overturn); N.Y. Ins. Law § 4910(b)(2)(C) (McKinney 2011); N.Y. Pub. Health Law § 4910(2)(b)(iii) (McKinney 2011) (delineating when two pieces of scientific evidence are required).

85. N.Y. Ins. Law § 4910(b)(3) (McKinney 2011); N.Y. Pub. Health Law § 4910(2)(c) (McKinney 2011).

86. New York Dept. of Financial Services, External Appeals—Frequently Asked Questions, Instructions, and Applications, at www.dfs.ny.gov/insurance/extapp/extappqa.htm (last visited Nov. 12, 2011) ("Am I eligible for an external appeal if my health plan denies coverage because I requested services from a non-participating provider?… No, if the out-of-network service is available in-network, even if an out-of-network provider has more experience in diagnosing or treating your condition.").

87. N.Y. Ins. Law § 4914(b)(4)(C) (McKinney 2011); N.Y. Pub. Health Law § 4914(2)(d)(iii) (McKinney 2011).

88. IRS, DOL, and HHS Rule on Internal Appeals and External Review Under the ACA, 26 C.F.R. § 54.9815-2719T(d)(1)(iii) (2011), 29 C.F.R. § 2590.715-2719(d)(1)(iii) (2011), 45 C.F.R. § 147.136(d)(1)(iii) (2011) (example 2).

89. Scherzer, supra note 65, at 8-10. *But c.f.* N.Y. Ins. Law § 4900(h) (McKinney 2011) (listing provider choice cases as excluded from definition of utilization review, though not necessarily from class of cases eligible for external review).

90. *See* N.Y. Pub. Health Law § 4408-a.2 (McKinney 2011) (requiring insurers to assure the grievance procedure is "reasonably accessible" to non-English speakers); N.Y. Ins. Law § 4802 (McKinney 2011) (same); N.Y. Pub. Health Law § 4408.1 (requiring insurers to disclose how they address needs of non-English speaking enrollees).

91. Determining whether a particular state law regulates insurance can be a murky process. *See, e.g.*, Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41 (1987) (finding state punitive damages law preempted by ERISA); UNUM Life Ins. Co. of America v. Ward, 526 U.S. 358 (1999) (saving California law from preemption without meeting all criteria outlined in *Pilot Life*).

92. N.Y. Ins. Law § 4914(b)(4) (McKinney 2011); N.Y. Pub. Health Law § 4914(2)(d) (McKinney 2011).

93. *See* Scherzer, supra note 65, at 4.

94. Some minor differences will show up with grandfathered ERISA plans because only the ERISA Regulations, and not the ACA Regulations, will apply. Also, non-ERISA plans offered on the individual market are precluded from offering more than one level of internal appeal. 45 C.F.R. § 147.136(b)(3)(G) (2011).

95. N.Y. Ins. Law §§ 4900 et seq. (McKinney 2011); N.Y. Pub. Health Law §§ 4900 et seq. (McKinney 2011).

96. N.Y. Pub. Health Law § 4408-a.2 (McKinney 2011); N.Y. Ins. Law § 4802 (McKinney 2011).

97. N.Y. Ins. Law § 4906(c) (McKinney 2011); N.Y. Pub. Health Law § 4906(3) (McKinney 2011).

Samuel C. Salganik is an Attorney and Skadden Fellow at Community Health Advocates (CHA), a division of the Community Service Society of New York.

The Medical-Legal Partnership: An Alliance Between Doctors and Lawyers in the Care of Patient-Clients with Advanced Life-Limiting Illness

Lynn Hallarman, M.D. and Denise Snow, J.D.

Introduction

Medical-Legal Partnership (MLP) is increasingly recognized as a tool to address unresolved medical-legal needs of vulnerable patients and their families. Medical-Legal Partnerships create an alliance between frontline medical providers and community legal advocates as a method for proactively addressing legal issues of patient-clients. For patients with life-threatening or advanced illness and their families, unresolved financial/legal-social issues can be a source of intense suffering and adversely impact their ability to cope with the extreme challenges of illness. Hospitalized patients in the midst of a health crisis are particularly at risk for "medical-legal suffering." The need for a rapid multi-dimensional intervention can be acute for patients with limited life expectancy and unresolved financial-legal issues. Hospital-based MLPs can assist clinicians in identifying and addressing major sources of financial-legal-social anxieties surrounding legacy planning, guardianships/planning for minor children and adult disabled children, future planning documents, access to care, next step in care, and shoring up resources. Palliative care consultation teams are increasingly partnering with legal advocates as a method to make early identification of complex health-related legal problems for patients with life-threatening or advanced illness whose needs are exigent.[1]

Anna's Story…Part 1

Anna is a twenty-one-year old single mother with malignant melanoma diagnosed in 2006 that has spread to the lungs. She does not have a curable disease. She is a full-time college student and lives with her parents and three-year-old daughter. Anna's parents have been helping with the care of their grandchild since her birth. She is estranged from the father of her child. Anna is depressed and overwhelmed with anxieties about her cancer, and caring for her small daughter while a full-time college student. She suffers from unrelenting fatigue and body aches. Anna is dependent on her status as a full-time student to maintain her health insurance and has had ongoing problems with her insurance carrier when she is forced to suspend her studies to undergo cancer treatments. Anna is under the care of a medical-oncologist who is hoping to prolong Anna's life as long as possible (maybe two years) with oral anti-cancer treatment.

History of the Medical-Legal Partnership

Recognizing problematic financial/legal circumstances as a treatment barrier led to the first formalized medical-legal partnership at Boston Medical Center in 1993 for pediatric patients and their families. It was observed that despite efforts to improve the health of pediatric patients with comprehensive preventive health services, these efforts were often undermined by multiple unmet social and legal needs such as lack of safe and stable housing or access to healthy food.[2] A paradigm emphasizing collaborative and proactive approaches between physicians and lawyers rather than "reactive and adversarial" interactions led to a network of medical-legal advocates working at the clinical site to resolve problems front end and as they relate to difficult medical illness. This model evolved from advocacy programs for vulnerable adult patients such as those with HIV/AIDS or those with mental health illnesses. Eventually the Boston program grew into the National Center Medical-Legal Partnership in 2009. The national network of MLPs includes about 80 MLPs partnering with 200+ institutions.[3] MLPs are also expanding to address the financial-legal needs in the care of patients with advanced or life-threatening illness including patient's admitted to hospice programs.

In January of 2011, New York State became the first in the nation to recognize the Medical-Legal Partnership.[4] The new law titled: "Health-Related Legal Services Program" defines the medical-legal partnership as:

> A collaboration between health care and legal service programs to provide on site legal services without charge to assist, on a voluntary basis, income eligible patients and their families to resolve legal matters created or aggravated by the patient's health.

The essential purpose of this legislation is to support the growth of statewide MLPs, reduce health care disparities for vulnerable persons by addressing social/legal determinants of health, and to promote cost effective strategies that also improve quality and patient outcomes.[5] Core components of an MLP should include: direct pro-bono patient services linked to a clinical setting, education of health care professionals and joining medical-legal advocacy to address structural-systems issues that worsen health care disparity and medical-legal distress.[6]

Recognizing Health-Related Legal Issues as a Core Care Component for the Seriously Ill Patient

Recognizing and responding to health-related legal problems in the clinical setting can be challenging for medical providers who often have no foundational skills in health law or social/legal advocacy. Unaddressed non-medical issues for cancer survivors remain under-recognized as complicating successful cancer care, especially for patients with limited resources, poor social support or comorbid medical illness.[7] Although cancer patients are surviving longer than ever, their survivorship is potentially complicated by ongoing burdensome symptoms, debility, work disruption, and financial instability. In a study on the effects of legal services on patient-client "well-being" patient/families who received legal services in the setting of cancer care describe reductions in stress, increased "peace of mind" and relief from dealing with bureaucracy in isolation.[8]

Physicians historically have been resistant to planning conversations, especially surrounding end of life. Critical conversations about prognosis are avoided, creating delays in next step planning and the shoring up of resources.[9] Appropriate referrals to social workers and legal advocates are not made proactively which is compounded by under-resourced clinical settings and overstretched care teams. For patients with advancing incurable disease, anticipatory planning is often left unaddressed until treatment failure is obvious and the ability to plan becomes emergent or impossible. When crisis hits and patients are hospitalized, problematic legal issues are set aside until urgent medical issues have been stabilized; however, for dying patients delays in resolution of exigent legal matters can result in poor coping, exacerbate social/legal issues, and ultimately add to illness-related suffering. Families can be left to make difficult decisions and deal with medical-financial hardships without the input of the patient who may now be too ill to participate. Legal issues that may have been resolved by the competent patient-client become the purview of hospitals and insurance companies leading to complicated probate, extended hospitalizations, and burdensome financial and legal legacies for families.

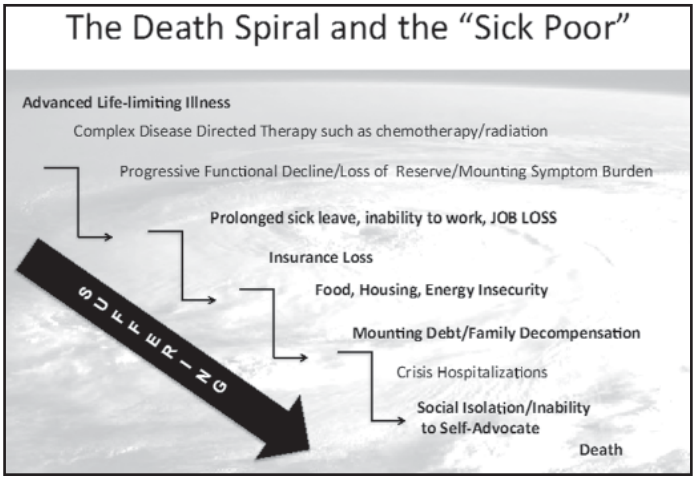
Anna's Story…Part 2

Anna was referred to the Medical Center's palliative care consultation team in December of 2007 to assist with her symptom management and help her to cope with the complex difficulties (and sorrows) of incurable fatal cancer. Anna does not want *to talk about her prognosis but is willing to meet with the palliative care team, including a social worker, to discuss a strategy for symptom management and dealing with her insurance issues and limited financial resources. The Palliative Care MD and Cancer Center Social Worker meet with the patient over a series of visits including one visit with her parents. A Health Care Proxy is done, her severe fatigue addressed, and immediate health insurance issues are resolved.*

Defining Medical-Legal Suffering

Eric Cassell in his article "The Nature of Suffering" broadly defines suffering as "the state of severe distress associated with events that threaten the intactness of the person."[10] Cassell speaks about the diminishment of self when serious illness takes from us our roles, for instance, as parent, spouse or wage earner. As illness advances and physical reserves diminish, dependence on others, especially those closest to us, for all aspects of living including physical safety, maintenance of housing, food supply, medical care and daily activities increase to levels that can challenge the most prepared and resource-rich families. Even intact financially stable families can be tipped into the ranks of the "sick poor" with one serious prolonged hospitalization. Problematic health-related legal issues can literally spiral out of control as the patient becomes less able and more dependent.[11] In keeping with Cassell's definition of suffering, a proposed definition of "medical-legal suffering" is:

> The stripping of personhood by the inability to resolve legal problems "created or aggravated" by advanced or disabling illness.



Identifying Patients/Families at Higher Risk for Financial-Legal-Medical Problems

Screening for health-related legal problems or potential problems should be part of all comprehensive patient care. Physicians are especially well positioned to identify legal issues that can directly impact patients/families. Family lawyers should also stay alert for potential health-related legal problems, especially for clients who are seeking advice in the setting of a new diagnosis of a life-threatening illness.

Clinicians/Lawyers should ask:

> Are there any particular financial or legal concerns you have in light of your [illness]?

Not only the underserved should be screened: *All* patients with advanced or terminal illness should be screened for "red flag" signs of potential distress including issues surrounding:

Finances: uninsured, sole wage earner, pursuing benefits/statuses, recent job loss or threat of job loss, discrimination.

Dependents: single parent, minor children, domestic partnership where survivor has no guardianship, patient with disabled children of any age.

Family: unmarried couples, food and energy insecurity, poor environmental or housing conditions, domestic violence, family leave.

Legal Status: immigrant status, history of tax evasion, in divorce proceedings, other legal problems.[12]

Other "red flags" include: patients who live alone (especially in the setting of terminal illness), patients with no visitors when hospitalized, low literacy, poor insight into their medical condition, patients with developmental delay or mental illness, repeated hospitalization, long length of stay in the hospital. Families of dying patients are also at risk for financial/legal problems including issues with: bills—pre- and post- death (who is responsible), credit card debt (who is responsible), funeral planning and associated costs, property ownership and distribution, long term care issues, stock ownership, property ownership, Veteran's benefits, pensions, probate, rights of family members, and access to unbiased legal advice.[13] *These issues can play out at the bedside of the very ill or dying patient compounding patient/family crisis, adding to confusion or lead to obstruction or delay of appropriate care.*

Anna's Story…Part 3

Three months later in March 2008, Anna is sent to the emergency room for headache, vomiting, inability to speak and right-sided weakness. She is found to have isolated brain metastases thought to be tumor-spread from her melanoma. She undergoes an urgent surgery for resection of the brain mass. The inpatient palliative care team evaluates her for symptom management and support. Her two month hospitalization is characterized by severe pain, nausea, lack of appetite, depression and highly anxious parents. Attempts at further anti-cancer treatment are made. Anna, however, remains weak and with diminished coping. Her doctors are concerned that she has entered into the final phase of terminal illness.

During the course of this hospitalization, Anna reveals her extreme worries to the Palliative Care Team about her daughter's future and her fears that the father of the child (or his parents) will attempt to take the child.

The palliative care team and social worker contact the MLP legal advocate with the permission of the patient. The advocate comes the same day to the bedside and counsels, pro-bono, Anna and her parents on the process of guardianship, and temporary papers are signed giving guardianship to Anna's parents.

Legal Advocates and Palliative Care Consult Teams

Palliative Care Teams deliver interdisciplinary care to patients with life-threatening or advanced life-limiting illness, and are particularly suited to partner with legal advocates. In the hospital setting palliative care teams assist patients and their families at the bedside or in structured family meetings in understanding and negotiating complex decision making, advance planning, prognosis, difficult decisions regarding life-sustaining treatments, emotional support as well as assisting with transitions to other care settings or home. Palliative care consultation can occur at *any time in serious illness*, even at time of initial diagnosis, and can assist patients upstream of crisis to help anticipate and proactively resolve health-related legal issues. It is during the palliative care family meetings that health-related legal issues are likely to emerge and immediate referrals for legal advocacy can be made.

Conclusion

Health-related legal issues can obstruct patients' and families' ability to adhere to complicated treatment plans and cope with the complexities of advancing or life-threatening illness. Unresolved health-related issues can throw patients and families into financial ruin, precipitate protracted legal conflict and exacerbate or cause illness related suffering. MLPs are a response to the growing need for integrative legal services as a therapeutic model to address legal issues in anticipation of progressive decline related to advancing illness, and can occur in the clinic or at the bedside of the very ill or dying patient. Clinicians/lawyers should screen all patients at any age or any income level for signs of health-related legal distress. MLPs offer a new paradigm of doctor-lawyer collaboration in the care of vulnerable persons, especially those who are reaching the end of their life.

Anna's Story…

In May 2008, Anna continues to deteriorate. She expresses to her care team the "deep relief" she feels knowing that her daughter will be safe with her parents. Anna dies a week later. The MLP advocate continues to work with Anna's parents to obtain permanent guardianship. In 2011, Anna's daughter at age 7 lives with her grandparents.

Endnotes

1. Rodabaugh K, Hammond M, Myszka D, Sandel A. A Medical-Legal Partnership as a component of a palliative care model. (2010) Journal of Palliative Medicine; 13(1): 15-19.
2. Zuckerman B, Sandel M, Lawton E, Morton S, Medical-legal Partnerships: transforming health care. (2008) Lancet: 372; 1615-7.
3. National Center for Medical-Legal Partnership. At www.medical-legalpartnership.org.
4. Public Health Law A3304-A Section 22: Health Related Legal Services Program, January 24th, 2011.

5. Proposed Bill of 111th Congress of the United States, 2d session: S.3668, July 29, 2010: Medical-Legal Partnership for Health Care (pending passage).
6. Paul E, Fullerton DF, Cohen E, Lawton, Ryan A, Sandel M, Medical-Legal Partnerships: Addressing Competency Needs Through Lawyers. Journal of Graduate Medical Education, (2009) Dec., pp. 304-308.
7. Fleishman, SB., Retkin R., Brandfield J., Braun V. (2006) The Attorney as the Newest Member of the Cancer Treatment Team, *Journal of Clinical Oncology*, Vol. 24. No 13, May, pp. 2123-2126.
8. Retkin R, Brandfield J, Bacich C., (2007) Impact of legal Interventions on Cancer Survivors. LegalHealth at www.legalhealth.org.
9. Mack J, Weeks JC, Wright AA, Block SD, Prigerson HG, End-of-Life Discussions, Goal Attainment, and Distress at the End of Life: Predictors and Outcomes of Receipt of Care Consistent With Preferences (2010) *Journal of Clinical Oncology,* Vol. 28. No. 7, March, pp. 1203-1208.
10. Cassell, EJ. The Nature of Suffering. (1982) *New England Journal of Medicine,* March 18; 306(11): pp. 639-45.
11. Hallarman L, Snow D, The Medical-Legal Partnership: "Medical Legal Suffering for Patients with Advanced Illness, (2012) *J. of Palliative Medicine*," Vol. 15, No. 1, Jan., pp. 123-124.
12. Klimmek R, Snow D, Wenzel J, Insurance-related and financial challenges reported by managed care enrollees with breast cancer. (2010) *Clinical Journal Oncology Nurses*, 14 (5): pp. 598-606.
13. Zevon M, Schwabish S, Donnelly JP, Rodabaugh KJ, Medically Related Legal Needs and Quality of Life in Care. (2007) *Cancer*, Vol. 109 (12) pp. 2600-2606.

Lynn Hallarman, M.D. is an Assistant Professor of Medicine at Stony Brook University Medical Center, in the Division of Hematology/Oncology in the Department of Medicine and jointly with the Department of Preventative Medicine. She is Senior Fellow at the Stony Brook University Center of Medical Humanities, Compassionate Care and Bioethics. She currently directs the Survivorship and Supportive Care Service at Stony Brook Hospital.

Denise Snow is Assistant Clinical Professor in the School of Nursing at Stony Brook University. She is also a public interest attorney working with cancer patients on Long Island.

At the Brink of Transformation: Restructuring the Healthcare Delivery System in Brooklyn (Excerpts)*

The Brooklyn Health Systems Redesign Work Group

Executive Summary

Brooklyn's healthcare delivery system is at the brink of dramatic change—change that will be characterized either by a reconfiguration of services and organizations to improve health and healthcare , or by a major disruption in services as a result of financial crises at three hospitals. Today, Brooklyn is grappling with high rates of chronic disease and a healthcare delivery system that is, in many areas, ill-equipped to address them. High rates of preventable hospital admissions and avoidable emergency department visits indicate deficiencies in primary care and inefficient use of high-cost resources. Further, while there are several fine hospitals in Brooklyn that are well-managed and financially stable, Interfaith Medical Center, Wyckoff Heights Medical Center and Brookdale Hospital Medical Center are experiencing financial crises. At the same time, a great opportunity presents itself in new models of patient-centered care, focused on prevention, and supported by technology and appropriate reimbursement incentives. We must choose the affirmative path of opportunity and transformation.

Six months ago, Commissioner Nirav Shah of the New York State Department of Health appointed the Brooklyn Health System Redesign Work Group ("the Work Group") to assess the strengths and weaknesses of Brooklyn's hospitals and healthcare system and evaluate the longer term viability of the hospitals as providers of care to the borough's 2.5 million residents. The Work Group was convened in the context of growing financial distress at the three hospitals and concerns about the long-term stability of other providers given changes in Medicaid and Medicare funding and an evolving healthcare marketplace. With Brooklyn's high rates of obesity, high blood pressure and diabetes, and 1 million Medicaid beneficiaries among its residents, the state has a strong interest in the quality, accessibility, efficiency and viability of healthcare in the borough.

Over the past six months, the Work Group has convened three public meetings, visited all 15 hospitals in Brooklyn and a federally qualified health center, met with hospital executives, board members, medical staffs and healthcare experts, and reviewed reams of data. We have also considered the healthcare environment in New York and around the nation. The Medicaid and Medicare programs are undergoing ambitious and forward-looking reforms unprecedented in at least 30 years. These reforms include new models of care and payment that emphasize care coordination, prevention, and performance. They demand integration and collaboration among providers along the continuum of care, in order to improve the quality of care for individuals, improve the health of communities, and reduce costs through improvement. With or without federal reforms, clinical integration, clinical outcomes, expansion of primary care and contraction of inpatient beds must be priorities in order to improve health and healthcare, while reducing unnecessary costs.

In this context, the Work Group has developed a set of findings, principles and tools to guide the reconfiguration of Brooklyn's healthcare delivery system. We believe these principles and tools are applicable to delivery systems around the state. This report also sets forth recommendations pertinent to certain at-risk hospitals in Brooklyn, but does not direct the elimination of a specified number of beds or the relocation of specified services in Brooklyn. Instead, it creates a process through which restructuring plans can be developed, evaluated and implemented with community involvement and state oversight.

The findings, principles, and process set forth here are intended to transition healthcare in Brooklyn into integrated and comprehensive systems aligned with community needs. All of the following recommendations are based on the determination that the state has an interest that goes beyond saving any single institution and extends to ensuring the well-being of its citizens.

Work Group Findings: Brooklyn Healthcare

Based on its review of data, interviews of healthcare facility executives, board members, and medical staffs, public hearing testimony, discussions with experts, and site visits, the Work Group has made the following findings:

- Brooklyn faces daunting population health challenges. High rates of chronic disease are exacting a human and economic toll.
- Community health needs and healthcare resources vary widely by neighborhood. Disparities in health status are also associated with poverty, race and ethnicity.
- Brooklyn hospitals compete for market share amongst themselves and with academic medical centers in Manhattan. Brooklyn patients, particularly those with commercial insurance and those seeking high-end surgical services, are increasingly seeking care in Manhattan.

- More than 15 percent of adult, medical-surgical hospital admissions and 46 percent of all emergency department visits that do not result in a hospital admission in Brooklyn could be averted through high quality, accessible care in the community. High rates of primary care treatable and preventable emergency department use and preventable (PQI) hospitalizations suggest that many Brooklyn patients are not using appropriate, effective, and less costly primary care necessary to keep them healthy and out of the hospital.
- While nearly one-third of the residents of several Brooklyn neighborhoods report that they lack a primary care provider, there is also evidence that many Brooklyn patients seek care in the ED, not because they lack a primary care provider, nor because they believe their condition is emergent, but rather based on convenience or the nature of their primary care provider's practice.
- High rates of preventable hospitalizations and above-average lengths of stay suggest that a significant portion of inpatient care in Brooklyn hospitals would not be necessary if primary and other outpatient care were improved and inpatient care were managed more efficiently.
- Almost 30 percent of Brooklyn's hospital beds are vacant on an average day. Given low occupancy levels, modest reductions in preventable hospitalizations and lengths of stay would permit the elimination of 1,235 beds, even after taking into account projected population growth.
- Heavy use of hospital services among people with mental illness and substance use disorders suggests that these conditions, and associated co-morbidities, could be managed better in the community.
- Six Brooklyn hospitals—Brookdale Hospital Medical Center (Brookdale), Brooklyn Hospital Center (Brooklyn Hospital), Interfaith Medical Center (Interfaith), Kingsbrook Jewish Medical Center (Kingsbrook Jewish), Long Island College Hospital (LICH), and Wyckoff Heights Medical Center (Wyckoff), collectively referred to as the "focus hospitals"—do not have a business model and sufficient margins to remain viable and provide high quality care to their communities as currently structured. Three of these hospitals, Interfaith, Brookdale, and Wyckoff, are experiencing financial crises and require aggressive action. The financial position of Long Island College Hospital (LICH) has also been grim, but it has recently been placed under the umbrella of SUNY Downstate Medical Center and can be turned around with its support. Brooklyn Hospital and Kingsbrook Jewish have effected restructurings that have stabilized their positions, but will not remain viable in the long run, as stand-alone facilities under their current business models, given changes in Medicare, Medicaid and the healthcare market. These two institutions can play a leadership role in creating integrated systems to strengthen healthcare delivery in the communities served by all six hospitals.
- The boards of some of these hospitals have failed to satisfy fully their responsibilities to the organizations and their communities. They have not evaluated financial and clinical performance, set strategic goals to address them, and held management accountable for achieving them. Instead, they have adopted a strategy that seeks merely to be the last man standing in their communities. It is clear that this strategy is a failed one.
- Healthcare reforms at the federal and state levels demand a fundamental change in the clinical, organizational and financial paradigm for these institutions to permit them to participate effectively in new models of integrated care that emphasize prevention, care coordination, and performance and produce real value for individual patients and the community.
- In order to realize the promise of these reforms, it is necessary to engage patients, and other community stakeholders, at the local level, in data-driven planning processes to develop patient-centered systems of care that address community health needs, while reducing excess utilization and costs.

Recommended Restructuring Principles

The Work Group recommends that the following principles drive the restructuring of the delivery system:

- In order to improve the health status of Brooklyn residents and to succeed under emerging payment methodologies, healthcare providers must create integrated systems of care and service delivery models, comprised of physicians, federally qualified health centers, hospitals, nursing homes, home care agencies, behavioral health providers, and hospice programs.
- New models of payment and delivery will require a rethinking of the hospital-based bricks and mortar pattern of healthcare.
- Patient-centered primary care services, strategically located and linked to acute and long-term care providers, must be developed.
- Restructuring must reduce waste and improve the quality of care, the settings for care, the engagement of patients in care, the way clinicians deliver care, and ultimately community health.

- Strong institutional governance and experienced leadership are needed to stabilize Brooklyn's most troubled hospitals and to steer them into new integrated healthcare systems.
- Academic medical centers and other providers from outside Brooklyn that seek to establish affiliations or ambulatory care facilities in the borough must partner with local hospitals and other providers and strive to serve Brooklyn residents in Brooklyn.
- Restructuring support, whether in the form of debt relief, grants, loans or reimbursement adjustments, must be conditioned on the creation of a sound governance and management structure; the development of viable strategic, financial, and operational plans consistent with the principles outlined here, and the achievement of quality benchmarks and savings. Any support must be revenue neutral.
- The Brooklyn crisis and the state's response highlight the need for more structured, collaborative health planning and oversight of troubled facilities.
- Innovative options for capital formation, including private investment, are needed to support capital and operational improvements in Brooklyn hospitals; but private investment must not be allowed to undermine a facility's commitment to the community or its accountability for the quality of care.
- The cost structure of healthcare facilities in Brooklyn, including labor and medical education cost centers, must be rationalized.
- The state should support the participation of nursing homes in emerging systems of care.

Recommended Tools for Change

The Work Group recommends that the following tools be developed and deployed, where applicable, to support change not just in Brooklyn and not just for troubled hospitals, but across the state and along the continuum of care, among strong and fragile providers alike:

Expand the State Health Commissioner's Powers over Healthcare Facility Operators

Effective governance of healthcare facilities and systems will be essential to the future of healthcare in Brooklyn. To ensure that the he or she has the necessary power to protect the public health, the Commissioner of the New York State Department of Health (henceforth "the Commissioner") should be granted expanded authority over healthcare facility operators as follows:

- Legislation should be enacted to give the Commissioner authority, at his or her discretion, to appoint a temporary operator for healthcare facilities that present a danger to the health or safety of their patients; or have operators that have failed in their obligations; or are jeopardizing the viability of essential healthcare capacity, absent intervention by the state.
- Legislation should be enacted to give the Commissioner authority to replace healthcare facility board members who are not fulfilling their duties to the organizations they are charged with governing.

Appoint a Brooklyn Healthcare Improvement Board

The Commissioner should appoint a Brooklyn Healthcare Improvement Board (BHIB) to advise the Commissioner and, at his or her direction, oversee, initiate where necessary, manage and ensure the implementation of this report's recommendations.

Provide Financial Support for Restructuring Through an Application Process

This application process, as envisioned by the MRT Payment Reform Work Group, will provide a vehicle for supporting and overseeing implementation of the recommendations in this report as they apply to particular facilities. The application will require feasible and actionable plans for restructuring, as well as strong governance, long-term oversight, and cost savings.

To support this process, legislation should be enacted to provide these focus hospitals, and others that qualify, under the principles outlined in this report, with access to capital and/or the means of reducing debt burdens that substantially impair the hospitals' ability to restructure. In addition, the subsidiary legislation for the Dormitory Authority of the State of New York (DASNY) should be extended.

Rationalize the Distribution of DSH/Indigent Care Pool Funds

Brooklyn's hospitals serve significant numbers of uninsured and Medicaid patients and will be affected by pending changes in the distribution of federal disproportionate care (DSH) funds. The MRT Payment Reform Work Group has articulated the following principles for reform of the allocation of these funds, which should be adopted:

- Develop a new allocation methodology consistent with CMS guidelines to ensure that New York State does not take more than its share of the nationwide reduction;
- Adopt a fair and equitable approach to allocate funds across hospitals, with a greater proportion of funds allocated to those hospitals that provide services to uninsured and underinsured patients;
- Simplify the allocation methodology and consolidate the Indigent Care pools.

Provide Funding for a Multi-Stakeholder Planning Collaborative in Brooklyn

To assure that the new healthcare systems under development address community health needs, a data-driven, multi-stakeholder health planning collaborative, like the Brooklyn Health Improvement Project, should be created or expanded with state and other support. It should include representatives of consumers, health plans, providers, business, labor, and New York City Department of Health and Mental Hygiene. This collaborative would provide input into the development of health systems and the deliberations of the Brooklyn Healthcare Improvement Board, and support interventions to improve healthcare utilization and health status in Brooklyn. It could also engage in activities to curb unnecessary health spending, such as such as the creation of a community advisory board for major investments in medical technology like the CTAAB in the Finger Lakes region.

Support Involvement of Private Physician Practices in Integrated Health Systems

The Work Group encourages the state to support the development of large physician practices in underserved areas and the involvement of physician practices in integrated systems of care. The state should consider working with Medicaid managed care plans, commercial payers and foundations to fund embedded care managers or social workers in physician practices, who can help to prevent hospitalizations and readmissions and assist in addressing health-related needs such as transportation to appointments and housing. Tax credits for physicians who provide significant charity care should also be considered. To the extent that physician practices receive enhanced support from the state, however, the funding should be tied to the satisfaction of quality standards, like patient-centered medical home accreditation, and to services to Medicaid beneficiaries and uninsured patients.

Develop new alternatives for capital support for primary care providers. Primary care providers are often undercapitalized and have difficulty securing affordable capital financing necessary to expand and build facilities. To expand primary care in the communities most in need, the state should explore new programs that use public support to leverage outside investment in high quality primary care projects.

Brooklyn Hospitals: Specific Recommendations

The Work Group focused its attention on the three most troubled hospitals in Brooklyn that require immediate intervention to avert financial collapse: **Brookdale Hospital Medical Center, Interfaith Medical Center, and Wyckoff Heights Medical Center.** The Work Group notes that Long Island College Hospital (LICH) also would also fall into this category, but for its recent affiliation with SUNY Downstate Medical Center which has created the potential for a turnaround. In addition, the Work Group considered the position of two other key hospitals, **Brooklyn Hospital Center and Kingsbrook Jewish Medical Center**, that do not exhibit the same level of financial distress as the others. However, they need to put in place plans for long term for sustainability and can play a leadership role in creating integrated systems to strengthen healthcare delivery in the communities served by all six hospitals. Specific recommendations are made for these six hospitals:

Brookdale Hospital Medical Center and Kingsbrook Jewish Medical Center: The Work Group recommends that Kingsbrook Jewish take the lead in establishing an integrated system with Brookdale, either under a common active parent or other accountable governance structure. The Work Group recommends new executive leadership at Brookdale and a separation from MediSys. A viable plan would require the creation of a new governance structure and a new board of directors for the integrated system.

The restructuring of Brookdale's debt and other obligations is essential to the success of this proposal. Any reconfiguration would also require the implementation of a plan to strengthen primary care in the communities served by the two institutions and clinical integration among participating providers. The Kingsbrook/Brookdale system should also consider reducing its bed complement and investing in additional ambulatory care services. Development and implementation of this plan recommendation should take place under the guidance of the Brooklyn Healthcare Improvement Board, with input from the communities served.

Brooklyn Hospital Center, Interfaith Medical Center, and Wyckoff Heights Hospital: The Work Group recommends the integration of these three institutions into a single system under an active parent, or other accountable governance structure, led by Brooklyn Hospital Center. In light of the precarious financial positions of Interfaith and Wyckoff, the Work Group would like to ensure that Brooklyn Hospital, which has recently emerged from bankruptcy and is demonstrating sound financial practices, is not brought down by this plan. Indeed, we recommend that Brooklyn Hospital be given the support to lead the transformation and restructure the operations at Interfaith and Wyckoff.

This system should streamline inpatient and tertiary care in a manner that is sustainable and aligned with community needs. A critical element of the restructuring plan must be enhanced access to high quality primary care and outpatient services. Development and implementation of the plan should proceed under the guidance of the Brooklyn Healthcare Improvement Board, with input from the communities served.

SUNY Downstate Medical Center and Long Island College Hospital (LICH): In light of the recent acquisition of LICH, SUNY Downstate should consider consolidating inpatient services at the LICH campus, thereby eliminating excess capacity and permitting the medical center to focus its inpatient resources and expertise on one location. With the new campus and the expansion of services at the neighboring Kings County Hospital, SUNY Downstate should reconsider any planned expansion of beds at the former Victory Hospital site and any development of an ambulatory facility in the vicinity of University Hospital or at the former Victory Hospital site. Any request by SUNY Downstate to open additional inpatient beds at the Victory Hospital site should be denied.

Kingsboro Psychiatric Center: The Office of Mental Health (OMH) should close the inpatient service of Kingsboro Psychiatric Center (KPC) and, working with the Department of Health, redirect resources to community-based behavioral health services that would function in collaboration with Brooklyn hospitals. Intermediate psychiatric hospital care for Brooklyn residents and court referrals should be provided primarily by South Beach Psychiatric Center, which currently serves a large section of Brooklyn. KPC's existing array of community-based services should remain within the community.

Conversion of a majority of the high cost KPC inpatient beds into intensive community treatment and support services would be well-timed with the implementation of the Medicaid Health Home initiative in the borough. Improved coordination, coupled with expanded service availability, will significantly reduce the burden on Brooklyn's emergency rooms and inpatient services.

Woodhull Hospital, Kings County Hospital and Coney Island Hospital: These hospitals are operated by the New York City Health and Hospitals Corporation (HHC). Although they have been linked principally with the other institutions in the HHC system, rather than with local facilities, it is now essential that they become more active partners in the Brooklyn delivery system.

**In November 2011, a Medicaid Redesign Team Work Group convened by Governor Cuomo issued a report and recommendations on restructuring the healthcare delivery system in Brooklyn. This is the Executive Summary and Findings from that Report. The full report is available at http://www.health.ny.gov/health_care/medicaid/redesign/brooklyn.htm.*

Summary of Medicare Shared Savings Program Final Rule on Accountable Care Organizations

Health Industry Practice Group at Manatt, Phelps & Phillips

On November 2, 2011, the Centers for Medicare and Medicaid Services ("CMS") published a Final Rule implementing the Medicare Shared Savings Program ("MSSP") established under Section 3022 of the Patient Protection and Affordable Care Act (the "Final Rule"). The Final Rule signals CMS's strong desire to encourage widespread formation of accountable care organizations ("ACOs"). By addressing many of the most significant objections raised by industry stakeholders in response to the proposed rule that was released last spring (the "Proposed Rule"), the Final Rule is likely to stimulate the formation of ACOs during 2012 and 2013. The regulatory analysis supporting the release of the Final Rule indicates that CMS assumes 1 to 5 million Medicare beneficiaries will align with between 50 and 270 ACOs during the first four years of the program.

> ***Broadening the list of entities eligible to form an ACO to include FQHCs increases the likelihood that dual eligibles and less affluent Medicare beneficiaries will participate in Medicare ACOs.***

A summary of the Final Rule is provided below.

Who Is Eligible to Be a Participant in an ACO?

The following entities are eligible to form an ACO:

- ACO professionals[1] in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals[2] employing ACO professionals
- Critical Access Hospitals ("CAHs") that bill under Method II[3]
- Federally Qualified Health Centers ("FQHCs")
- Rural Health Clinics ("RHCs")

Other entities may provide services through an ACO but may not form their own. ACOs may not participate in the MSSP if they include a participant involved in other shared savings initiatives.

What Is the Time Frame for Participation in the MSSP?

CMS will begin accepting applications "shortly after January 1, 2012." Information on the application process will be included in a Notice of Intent CMS will post at https://www.cms.gov/sharedsavingsprogram.com. If accepted, an ACO must enter into a participation agreement with CMS for at least three years.

For 2012, applicants may choose to have either April 1, 2012 or July 1, 2012 as the start date of their participation agreements. For applicants approved to participate in 2013 and all subsequent years, the start date will be January 1. Beginning with participation agreements effective in 2013, the term of the agreement will be three years. ACOs may add or remove participants and providers or suppliers during the agreement period but must notify CMS of the change within 30 days.

What Type of Legal Structure Must an ACO Establish?

An ACO must be a legal entity, formed under applicable state, federal, or tribal law, that is authorized to conduct business in each state in which it operates for purposes of (i) receiving and distributing shared savings; (ii) repaying shared losses or other monies determined to be owed to CMS; (iii) establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards; and (iv) fulfilling other ACO functions. An ACO formed by two or more otherwise independent participants must be a legal entity separate from any of its participants.

What Type of Governance Structure Must an ACO Maintain?

An ACO must maintain an identifiable governing body with authority to execute the functions of the ACO, including, but not limited to, the definition of processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care. An ACO must provide for meaningful participation in the governing body by the ACO's participants or their designated representatives. Subject to certain exceptions, participants must control at least 75% of the ACO's governing body. Each ACO must also appoint a beneficiary representative to the governing body. If the ACO's governing body does not meet the 75% control threshold or include a beneficiary representative, the ACO may request a waiver and describe to CMS why

> ***Key Changes in Final Rule***
>
> - ***ACOs have flexibility to propose governance structures that do not meet the 75% participant control test or include a beneficiary representative.***
> - ***It is no longer required that each ACO participant have proportionate control of the governing body.***

it does not meet these requirements and how the ACO will involve participants and beneficiaries in governance.

What Type of Leadership and Management Structure Must an ACO Employ?

An ACO's operations must be managed by an executive, officer, manager, or general partner whose appointment and removal are under the control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency, processes, and outcomes. Clinical management and oversight must be managed by a senior-level medical director who is one of the ACO's physicians, is physically present on a regular basis in an established ACO location, and is a board-certified physician and licensed in one of the states in which the ACO operates.

How Will Beneficiaries Be Assigned to an ACO?

CMS will employ a "preliminary prospective assignment methodology with final retrospective reconciliation." This means that CMS will provide to the ACO a list of beneficiaries likely to receive care from the ACO's participants based on primary care utilization during the most recent periods for which adequate data are available. During the performance year, CMS will update the list quarterly based on the most recent 12 months of data. At the end of each performance year, CMS will reconcile the list to reflect beneficiaries who actually met the criteria for assignment.

> ***Early identification of participating beneficiaries through a preliminary prospective assignment methodology—combined with the ability to receive claims data for participating beneficiaries—should drive the creation of care management programs necessary for success under the MSSP.***

After identifying all patients that received a primary care service (defined as the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, and 99341 through 99350, G0402, G0438 and G0439) from a physician who is a provider/supplier in the ACO, CMS will engage in a two-step process. Under the first step, a beneficiary is assigned to an ACO if the beneficiary received the plurality of his or her primary care services from PCPs within the ACO. The second step considers only beneficiaries who have not had a primary care service furnished by any PCP. In this step, a beneficiary is assigned to an ACO if the beneficiary received a plurality of his or her primary care services from physicians (including specialist physicians) and certain non-physician practitioners (nurse practitioners, clinical nurse specialists, and physician assistants) within the ACO.

To operationalize this process, CMS will identify an ACO as a collection of Medicare-enrolled taxpayer identification numbers ("TINs"). An ACO will have to report to CMS the TINs of the ACO and its participants, as well as a list of participating Medicare providers' and suppliers' national provider identifiers ("NPIs"). Each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one ACO for purposes of Medicare beneficiary assignment. ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive. CMS clarified that individual provider NPIs are not exclusive to one ACO. When providers whose services are the basis of assignment bill under multiple TINs, each TIN would be exclusive to only one ACO but the provider would not be required to be exclusive to one ACO. CMS will deem an ACO to have a sufficient number of primary care professionals if the number of beneficiaries historically assigned to the ACO's participants in each of the three years before the start of the agreement period is 5,000 or more.

What Type of Care Management and Health IT Initiatives Must an ACO Undertake?

As in the Proposed Rule, CMS does not identify specific care management criteria that ACOs must satisfy. Rather, CMS simply requires an ACO to document in its application its plans to define, establish, implement and periodically update its processes.

CMS eliminated the requirement that at least 50% of the ACO's PCPs engage in meaningful use. Instead, the Final Rule includes the following quality measure: "Percent of PCPs who successfully qualify for an EHR Incentive Program Payment," which will be weighted twice that of any other measure for scoring purposes. CMS left largely intact its requirements for an ACO to document in its application its plans to (i) promote evidence-based medicine; (ii) promote beneficiary engagement; (iii) report internally on quality and cost metrics; and (iv) coordinate care. However, CMS removed some of the specific requirements it included in the Proposed Rule, including those related to health information technology. CMS also removed a proposed regulatory provision requiring that ACOs "have a process in place (or clear path to develop such a process) to exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO. For providers participating in the electronic exchange of information, this process must be consistent with meaningful use requirements under the Medicare electronic health record Incentive Program."

How Will CMS Share Data with ACOs?

At the start of its agreement period and every quarter thereafter, CMS will provide an ACO with deidentified, aggregated reports on beneficiary use of health care services. At the beginning of the agreement period, during each quarter, in conjunction with the annual reconciliation, and at the beginning of each performance year, CMS will provide an ACO, upon request, with information regarding the preliminarily prospectively assigned beneficiaries

whose data was used to generate the aggregate reports. The information will be limited to beneficiary name, date of birth, sex and beneficiary health insurance claim number. CMS will also, upon request, provide an ACO with a standardized data set consisting of patient identifiable claims data generated under Medicare Parts A, B and D. CMS will provide the data set on a monthly basis. The data set will not include information protected under federal alcohol and drug abuse confidentiality regulations at 42 CFR Part 2.

Before requesting claims data about a particular beneficiary, the ACO must inform the beneficiary of the request and give the beneficiary a 30-day period to opt out. An ACO must also provide beneficiaries with a form explaining their right to opt out of data sharing as part of the beneficiary's first primary care service visit with an ACO participant upon whom assignment is based.

How Will Beneficiaries Be Notified of Their Assignment to an ACO?

ACO participants must notify beneficiaries at the point of care of their participation in an ACO by posting signs in their facilities and making available to beneficiaries standardized written notices developed by CMS. All beneficiary notification and signage are included in the definition of "marketing materials and activities."

The Final Rule establishes a "file and use" approach under which an ACO may use marketing materials or commence marketing activities 5 business days following submission of such materials to CMS if the ACO certifies compliance with all MSSP marketing requirements and CMS does not disapprove the materials or activities within the 5-day period. CMS may issue written notice of disapproval of marketing materials or activities at any time, including after the expiration of the initial 5-day review period, at which time the use of such marketing materials or the marketing activities must be discontinued. Marketing materials and activities must: i) use template language developed by CMS, if available; ii) not be used in a discriminatory manner or for discriminatory purposes; iii) comply with requirements related to beneficiary inducements; and, iv) not be materially inaccurate or misleading. CMS also modified its definition of permissible marketing materials to specifically include social media such as Twitter and Facebook.

On What Grounds May an ACO's Participation in the MSSP Be Terminated?

CMS may terminate a participation agreement with an ACO when an ACO, ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities fail to comply with any of the requirements of the MSSP. If CMS concludes that termination of an ACO is warranted, it may but is not required to provide a warning notice to the ACO regarding noncompliance with one or more program requirements; request a corrective action plan from the ACO; or place the ACO on a special monitoring plan. CMS must notify an ACO in writing of its decision to terminate the participation agreement. An ACO may terminate its participation agreement by providing at least 60 days' advance written notice to CMS and its ACO participants of its decision to terminate. An ACO will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement.

How Will ACOs Participate in Shared Savings?

Two Tracks. The Final Rule offers two models of risk sharing. First, there is the one-sided model, where the ACO shares only in savings if the ACO spends less compared to what Medicare would have spent without the ACO. Second, there is the two-sided model, in which the ACO also shares in losses if the ACO spends more compared to what Medicare would have spent without the ACO. In Track One, ACOs will participate in the savings-only model for all three years of their initial participation agreement with CMS. Under Track Two, the two-sided model applies for all three years of the ACO's participation agreement.

Determining the Benchmark. To determine whether an ACO saved the Medicare program money, CMS must estimate what Medicare would have paid for the care of the beneficiaries attributed to the providers in the ACO (the "benchmark"). The benchmark spending data includes all Part A and Part B expenditures. Catastrophic claims (above the 99th percentile and approximately $100,000 per patient per year) are capped at the 99th percentile. The expected claims costs will be risk-adjusted based on health status (under the same method as utilized by Medicare Advantage). CMS will then apply trend factors to adjust for growth in health care expenditures for each of the beneficiary categories during the three years of the participation agreement. The Final Rule eliminates certain payments, including indirect medical education ("IME") and disproportionate share hospital ("DSH") payments from the benchmark. CMS will also calculate the benchmark using population-specific expenditures for each of the following categories of beneficiaries: (1) End Stage Renal Disease ("ESRD"), (2) disabled, (3) aged, dually eligible individuals, and (4) aged, non-dually eligible individuals (collectively, "beneficiary categories").

The ACO's Share of Savings. CMS will compare actual expenditures to the benchmark after applying a "minimum savings

> ***Key Changes in Final Rule***
>
> - ***ACOs have the option to avoid all downside risk throughout the entire three-year term of their participation agreement.***
> - ***ACOs will also share in first dollar savings if the minimum savings threshold is satisfied.***

rate," which reflects fluctuations so small that they likely are not due to the ACO's efforts. Under the one-sided model, the minimum savings rate ranges from 2% for large ACOs to 3.9% for small ACOs. Under the two-sided model, the minimum savings rate is 2% for all ACOs. All ACOs are entitled to receive 50% of the savings under the one-sided model. Payments of savings are contingent upon meeting the quality scores set forth in the ACO's participation agreement. For example, if the ACO attains an 80% quality score, the ACO then is entitled to 80% of the 50% shared savings that are available. An ACO's sharing rate in all participation agreements with downside risk will be 60%. Under both models, all ACOs, regardless of size, will be eligible to share in the first dollar of savings. Under the one-sided model, there is a maximum shared savings payment to the ACO of 10% of the benchmark. Under the two-sided model, the cap is 15%.

The ACO's Share of Losses. There is a similar 2% corridor from the benchmark where the ACO will not be responsible for losses. The shared loss rate for an ACO is 1 minus the ACO's shared savings rate, up to a maximum shared loss rate of 60%. For example, an ACO with a shared savings rate of 60% is responsible for 40% of the losses. An ACO's shared losses may not exceed 5% of the benchmark in its first year in the two-sided model, 7.5% of the benchmark in its second year, and 10% of the benchmark in its third year.

Financial Security. All applicants participating in Track Two and some applicants participating in Track One will be required to demonstrate financial resources to absorb possible losses. ACOs may demonstrate their ability to repay losses in many ways, including by demonstrating sufficient cash reserves, arrangements with insurers, or assurances from providers within the ACO. The Final Rule eliminates the 25% withhold by CMS of any shared savings payments, which would be applied to future shared losses.

What Type of Quality Standards Will Be Applied to ACOs?

The Final Rule focuses on measures that directly assess the overall quality of care furnished to beneficiaries with a preference for National Quality Forum-endorsed measures. The Final Rule substantially reduces the number of quality measures—from 65 to 33— on which ACOs are scored. CMS also sought to align the measures with those used in other programs and initiatives. The Final Rule does not include hospital patient safety measures; however, claims-based hospital measures will be monitored by CMS.

ACO participants choosing the one-sided model will not need to retain reserves to cover unanticipated ACO program financial losses. States that regulate risk-bearing organizations may need to consider whether these one-sided ACOs require risk-bearing regulatory oversight.

ACOs that do not align their IT requirements and workflows with quality measure goals will be significantly challenged to hit their targets and pull down their full shared saving allotments.

As in the Proposed Rule, each measure is pay-for-reporting in an ACO's first performance year. In year two, 25 of the 33 measures are pay-for-performance. In year 3, all measures are pay-for-performance, with the exception of Measure Seven (health status/functional status). Twenty-two measures will be collected using the Group Practice Reporting Option ("GPRO") tool, prepopulated for a sample of assigned beneficiaries. Seven measures will be collected via the Consumer Assessment of Healthcare Providers and Systems ("CAHPS") patient survey that CMS will pay to administer in the first two years in order to ensure standardized administration. Three measures will be collected

What Are the Differences Between the One-Sided and Two-Sided Models?

Design Element	One-Sided Model	Two-Sided Model
Threshold Savings to Trigger Shared Savings	Between 2% and 3.9% based on number of assigned beneficiaries	2% regardless of ACO size
Savings Eligible for Sharing	First dollar of savings	First dollar of savings
Maximum Share of Savings	50%	60%
Maximum Sharing Cap	10% of benchmark	15% of benchmark
Threshold Losses to Trigger Shared Losses	N/A	2%, regardless of ACO size
Losses Eligible for Sharing	N/A	First dollar of losses
Share of Losses	N/A	40%-60% depending on quality score
Maximum Loss Cap	N/A	Year 1: 5%; Year 2: 7.5%; Year 3: 10%

ACO Performance Level (Percentile FFS / MA Rate or %)	Quality Points (Except EHR)	EHR Measure Points
90+	2 point 1	4 points
80+	1.85	3.7
70+	1.7	3.4
60+	1.55	3.1
50+	1.4	2.8
40+	1.25	2.5
30+	1.1	2.2
<30	No points	No points

via claims data and one measure will be collected through the EHR incentive program.

CMS will require ACOs to achieve the quality performance standard on 70% of the measures within each domain. To calculate the standard, the points earned for each domain's measures will be added up and divided by the total available points. This will result in a domain score, which will then be added up and divided by four (the total number of domains) to reach the final shared savings rate.

Calculating the quality performance standard will indicate whether an ACO has sufficiently met goals that would qualify it for shared savings. ACOs will be able to earn a maximum of two points per measure (except for the EHR meaningful use measure, which is worth four points) under both the one-sided and two-sided models.

CMS finalized its proposal to establish the minimum attainment level for a measure at a national flat 30% or, where applicable, the national 30th percentile level of performance of FFS or Medicare Advantage ("MA") quality rates. CMS also finalized its proposal to establish national, as opposed to regional, benchmarks for quality measures. The benchmarks will use a national sample of Medicare FFS claims data, MA quality data, or a flat percentage of FFS claims if MA quality data are not available.

What Protection from Antitrust Laws Will Be Granted to ACOs?

The Final Statement of Antitrust Enforcement Policy on ACOs issued by the federal antitrust enforcement agencies—the Department of Justice ("DOJ") and Federal Trade Commission ("FTC")—is both broader and simpler than the agencies' original proposal. The Final Statement now applies to collaborations among otherwise independent providers and provider groups that are eligible and intend to participate in the MSSP, even if they were formed prior to March 23, 2010.

Clinical Integration: Applicability to Commercial Markets. The agencies note that an ACO that meets the CMS eligibility criteria will also meet the criteria to conduct joint negotiations with private sector payers in the commercial market. To serve those patients in the commercial market, however, the ACO must use the same governance and leadership structures as well as the same clinical and administrative processes it uses in the MSSP.

Regulatory Review Process: The "Safety Zone." The Final Statement eliminates the formerly proposed mandatory antitrust review for certain collaborations as a condition of entry into the MSSP, but still maintains an antitrust "safety zone" as well as offering additional guidance for antitrust compliance for ACOs. The "safety zone" closely tracks the "safety zone" of the same name in the 1996 Enforcement Statements issued by the FTC and DOJ, which is frequently referenced in the Final Statement. The new "safety zone" applies to ACOs with market shares of 30% or less in each "common service." A "service" for these purposes is based upon each primary specialty for physicians, each MDC for inpatient facilities, and each outpatient category for outpatient facilities. The Final Statement continues to use a 75% PSA as a relevant geographic area for these calculations. As before, additional requirements govern the use of exclusivity provisions. Exceptions are made to allow rural facilities to have at least one relevant provider in each category without breaching the safety zone and to allow dominant providers to participate on a nonexclusive basis. An Appendix to the Statement explains how to calculate the PSA shares of "common services." In contrast to the Proposed Rule, there is no mandatory antitrust review of ACOs that have PSA shares above 50%.

Guidance for ACOs Outside the "Safety Zone." The Statement offers additional guidance to help assure antitrust compliance in ACO operations by identifying various types of conduct and contracting practices most likely to lead to antitrust violations. The conduct and practices to avoid generally include anything that might prevent payers from reducing costs, such as anti-steering provisions, most favored nations clauses and restrictions on the dissemination of useful information with enrollees, as well as unnecessary exclusivity or tying of services.

Voluntary Expedited Review for New ACOs. Any "newly formed ACO" (i.e., one which has not signed or jointly negotiated any contracts with private payers or participated in the MSSP as of March 23, 2010) can seek expedited 90-day review from the antitrust agencies. Request for such a review should be made on a form available on the agencies' websites, with the specified supplemental information potentially including: i) business plans and documents discussing the level and nature of competition among participants in the ACO; ii) information on the "current competitive significance of the ACO" or its participants, including the participants' PSAs; iii) information on the largest commercial health plans or other private payers for the ACO's services; and iv) any "substantial precompetitive justification" for the ACO.

How Will ACOs Be Protected from the Fraud and Abuse Laws?

Concurrent with the Final Rule, CMS and OIG issued an Interim Final Rule with comment period (the "Interim Final Rule") that establishes waivers of the Federal Physician Self- Referral Law (the "Stark Law") and the Federal Anti-Kickback Statute (the "AKS") as well as the provisions of the Federal Civil Monetary Penalties Law prohibiting inducements to physicians to limit services to beneficiaries and prohibiting inducements to beneficiaries (the "Gainsharing CMP" and the "Beneficiary Inducements CMP").

In a joint notice issued earlier this year, the agencies had proposed waivers that were fairly limited in scope—a waiver for distribution of shared savings and a waiver for arrangements complying with a Stark Law exception. The Interim Final Rule includes the proposed waivers as well as three new waivers developed in response to industry concern that the proposed waivers were too narrow:

- An "ACO pre-participation" waiver of the Stark Law, the AKS, and the Gainsharing CMP for ACO-related start-up arrangements in anticipation of participation in the MSSP. The waiver is subject to certain restrictions, including limits on the duration of the waiver and the types of parties covered, and compliance with certain governing body approval, documentation, and public disclosure requirements.

> ***The broadened fraud and abuse waivers extend exemptions to commercial ACOs. However, some ACOs may face more restrictions on how they profit and incent patients than outlined in these waivers due to state anti-kick-back or gainsharing laws.***

- An "ACO participation" waiver of the Stark Law, the AKS, and the Gainsharing CMP for ACO-related arrangements during the term of the ACO's participation agreement and for a specified time thereafter, subject to certain conditions similar to those established for pre-participation waivers.
- A "shared savings distributions" waiver of the Stark Law, AKS, and Gainsharing CMP for distributions and uses of shared savings payments earned under the Shared Savings Program (even if the actual distribution or use occurs after the expiration of the participation agreement), provided certain conditions are met.
- A "compliance with the Stark Law" waiver of the Gainsharing CMP and the AKS for ACO arrangements that implicate the Stark Law and meet an existing Stark exception, that would apply during the term of the ACO's participation agreement.
- A "patient incentive" waiver of the Beneficiary Inducements CMP and the AKS for medically related in-kind incentives offered by ACOs in the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimes, subject to certain conditions. The waiver would apply during the term of the ACO's participation agreement, although a beneficiary could receive the remainder of any service initiated and keep items received before the expiration or termination of the agreement.

CMS and OIG note that the waivers apply uniformly to each ACO, ACO participant, and ACO provider/supplier in the MSSP, and are self-implementing—no special action is required in order to be covered by a waiver. The agencies also caution that they will closely monitor ACOs entering the MSSP in 2012 through June 2013, and plan to narrow the waivers accordingly in response to abusive or fraudulent conduct.

How Will ACOs Be Protected from the Tax Exemption Laws?

In Notice 2011-20 dated March 31, 2011, the Internal Revenue Service ("IRS") set forth the IRS's "expectation" of the principal elements of guidance that it ultimately would provide on the subject of the participation by Section 501(c)(3) organizations in the MSSP through ACOs. Following the release of the Final Rule, the IRS issued a fact sheet dated October 20, 2011, that brings the "expectations" of Notice 2011-20 up to date (the "Fact Sheet"). Neither the notice nor the Fact Sheet constitutes final, binding guidance, but as a general rule, final guidance tends to materially conform to issuances such as the notice and the fact sheet.

The Fact Sheet confirms the IRS's three key conclusions of importance for Section 501(c)(3) organizations: (i) participation in the MSSP through an ACO generally furthers charitable purposes, (ii) Section 501(c)(3) organizations need not have control of an ACO that is a partnership for tax purposes, and (iii) a Section 501(c)(3) organi-

zation's share of payments from an ACO generally is not taxable as "unrelated business taxable income" ("UBTI").

Regarding the first conclusion, the IRS was careful to note that any particular ACO may be structured so that it has terms or features that cause the ACO to result in "private inurement" or "private benefit" in favor of non-Section 501(c)(3) participants. Therefore, each ACO agreement must be examined independently to confirm that the charitable purpose is unaffected by those possibilities.

> ***This guidance ostensibly enables non-profits to participate in ACOs without threatening their non-profit status, even when they lack significant control over the ACO venture.***

The second conclusion is possibly the most interesting. Historically, the IRS has been skeptical of ventures between Section 501(c)(3) organizations and other organizations, and has tended to require that Section 501(c)(3) organizations have total or significant control over the venture to ensure furtherance of tax-exempt purposes. In the case of the MSSP, the IRS has helpfully determined that the CMS regulations and oversight of the program inherently ensure furtherance of charitable purposes without the control requirement.

The third conclusion essentially follows from the first: If an ACO has a charitable purpose and avoids "private inurement" and "private benefit," payments from the ACO necessarily escape the tax on UBTI.

Both the notice and the Fact Sheet acknowledge that ACOs may engage in activities that are not part of the MSSP, and the conclusions of the notice and Fact Sheet do not necessarily apply in such cases. Therefore, any ACO that engages in broader activities is advised to consult its own tax counsel to consider the implications of such other activities.

Endnotes

1. ACO professional means a physician (defined as a doctor of medicine or osteopathy), or a practitioner (defined as a physician assistant, nurse practitioner, or clinical nurse specialist).
2. Hospital means an acute care hospital paid under Medicare's hospital inpatient prospective payment system.
3. Under Method II, a CAH bills for both facility and professional services. CAH eligibility is limited to those billing under Method II because it is the only billing method that provides CMS with the data it needs to perform various programmatic functions (e.g., assign beneficiaries to each ACO).

Manatt works broadly across the healthcare industry, representing state policymakers and agencies, payers and healthcare providers, foundations, associations, and product and service vendors. This article first appeared as an informational notice to clients of Manatt Phelps.

Billing and Reimbursement Issues for the Physician Office

By Laurie T. Cohen and James Shannon

Overview

In today's environment, a medical office's billing operation is critical to the office's financial stability and overall success. This operation can also be the source of significant risk, especially given the myriad policies and procedures of the numerous payers with which most physicians' offices deal. In this regard, physicians need to understand that they are ultimately responsible for the accuracy and validity of any claims submitted to payers on their behalf, regardless of whether they have delegated such function to their employees or to outside billing or management companies.

Payers with which a medical practice may deal include governmental entities (e.g., Medicare and Medicaid), workers' compensation and no-fault carriers, as well as health maintenance organizations (HMOs) and commercial health insurers. Also, some large employers may self-insure their employees' health benefits, in which case the medical practice may deal directly with the employer or with a third-party administrator the employer designates to process and pay claims and carry out other administrative functions.

Regardless of the type or number of payers with which a medical practice may deal, the billing staff must make a tremendous effort to stay abreast of changing payment policies and procedures. Although the communication of such changes may be formalized in correspondence or newsletters sent by particular payers to the medical practice or learned through attendance at billing and coding conferences, one or more members of the medical office staff should assume responsibility for (1) tracking payment policy and procedural changes, (2) communicating such changes to other members of the staff and (3) making billing system updates to recognize such changes.

State and federal regulations as well as participating provider agreements also contain numerous provisions relevant to a medical practice's billing function. For example, the time limits within which a medical practice must submit claims for payment, the minimum time period governing the retention of financial records and the time frames within which a payer must remit payment to a provider after a claim has been submitted are often addressed in state or federal regulations or provider agreements, depending upon the payer.[1]

New York has adopted comprehensive utilization review legislation, which provides a specific process for physicians and others to appeal claim denials directly to an HMO or commercial health insurer when a claim is denied because the payer determines that the service for which the claim was submitted was medically unnecessary. An external review process using an independent review agent is also available to physicians who remain dissatisfied with the outcome of the internal appeal process in such cases.[2]

As mentioned above, a medical practice's billing operations can be a significant source of risk, specifically in the form of government or private payer investigations and audits. In issuing its voluntary *Compliance Program Guidance for Individual and Small Group Physician Practices*[3] in October 2000, the Office of Inspector General (OIG) of the federal Department of Health and Human Services (HHS) stated that "a major part of any physician practice's compliance program is the identification of risk areas associated with coding and billing."[4]

In addition to the voluntary compliance guidance for physicians issued by the OIG, New York State mandates that certain providers develop, adopt and implement compliance plans to detect and prevent fraud, abuse and waste in the State Medicaid program. This mandate applies to any provider who orders, provides, bills or claims $500,000 or more from Medicaid in a 12-month period.[5]

These risks are discussed briefly in § 15.1 and explored in more depth in § 15.8 below, as is the importance of documentation to verify the accuracy of claims submitted. The following topics also are addressed in § 15.8: professional courtesy, billing company arrangements, consultations, "incident to" billing rules, reassignment-of-payment rules and the use of advance beneficiary notices. Finally, some physicians have sought to minimize the interference presented by the imposition of various payer policies and procedures by declining to participate with insurers and HMOs or by opting out of participation in the Medicare program. This section also summarizes how a physician opts out of Medicare and the implications of doing so.

Billing, Coding and Documentation Guidance

What type of billing practices create a risk for a physician practice?

The most frequent targets of investigations and audits include: (1) billing for items or services not rendered or provided as claimed; (2) submitting claims for equipment, medical supplies and services that are not reasonable and necessary; (3) double billing, which results in duplicate payment; (4) billing for noncovered services as if covered; (5) knowing misuse of a provider identification number; (6) billing for unbundled services; (7) failing to properly use coding modifiers; (8) clustering; and (9) upcoding the level of service provided.[6]

Why is documentation of a provider's services so important?

Documentation in the medical record serves many purposes.[7] In the context of billing, documentation can be used to verify what and where services were provided and by whom and to support the appropriateness of services to demonstrate the accuracy of the billing. Such documentation can be critical in response to an audit or investigation. Unfortunately, a physician's assertion that a service was provided or that it was medically appropriate is not enough; both governmental and private payers are demanding more evidence to establish such a case.

What documentation should a medical record include for each patient encounter?

The medical record should include, at a minimum, the following: (1) the reason for the encounter; (2) relevant history; (3) physical exam findings; (4) prior diagnostic test results; (5) assessment; (6) clinical impression or diagnosis; (7) plan of care; and (8) date and legible identity of the provider/observer.[8]

Claims Submission, Prompt Payment Rules, Financial Records Retention and Overpayment Recoveries

Claims Submission Time Frames

Claims generally must be submitted to payers within prescribed time periods to ensure the payment of such claims. Failure to submit claims on a timely basis could result in the forfeiture of payment from certain payers. Governmental payers have different time periods for submission of claims, which are prescribed by statute or regulation. The time frames for the submission of claims to private payers generally are governed by contract or individual payer policies, however, a statutory amendment effective January 1, 2010, requires commercial health insurers and HMOs to give providers at least 120 days to submit a claim.[9] Exceptions are provided for claims related to Medicaid Managed Care, Family Health Plus or Child Health Plus, in which case the parties can agree to a shorter period of time, but not less than 90 days.[10] Physicians should review existing provider contracts to ascertain applicable time frames or request copies of payment policies to determine if the payer has a policy addressing the time frame for claim submission.

What is the time frame for submission of Medicare claims?

The Patient Protection and Affordable Care Act of 2010 (PPACA) greatly simplified the Medicare requirements for timely submission of claims, but also significantly reduced the time period for doing so.[11] Claims for services rendered after January 1, 2010 must be submitted within one calendar year after the date of service.[12]

PPACA gave the Secretary of HHS the authority to specify exceptions to the one-calendar-year time limit for filing claims. At present CMS recognizes four exceptions: (1) administrative error of an employee, Medicare contractor or agent of the HHS performing Medicare functions and acting within the scope of its authority; (2) retroactive entitlement to Medicare benefits; (3) retroactive entitlement of dual eligible beneficiary resulting from a State Medicaid Agency recoupment six months or more after the service was furnished; and (4) retroactive disenrollment from a Medicare Advantage Plan or Program of All-inclusive Care of the Elderly provider organization 6 months or more after the service was furnished.[13]

What is the time frame for submission of Medicaid claims?

Claims must be submitted under the Medicaid system within 90 days from the date service is rendered.[14] The regulation does provide for extensions of this time period if the claim is delayed due to circumstances beyond the control of the provider, for example, "attempts to recover from a third-party insurer, legal proceedings against a responsible third-party or the recipient of the medical care, services or supplies or delays in the determination of client eligibility by the social services district."[15]

What is the time frame for submission of no-fault insurance claims?

No-fault insurance claims must be submitted no later than 45 days after service is rendered.[16] The time period may be extended if the eligible injured person or his or her representative submits written proof setting forth the reasons for failing to comply with the time period.[17]

What is the time frame for submission of workers' compensation claims?

Bills for medical services rendered in workers' compensation cases should be submitted to a self-insured employer or carrier within 90 days from the last day of the month in which the services were provided.[18] A provider must comply with this requirement if it wishes to pursue an administrative award should the employer or carrier refuse to pay the bill.[19] Delayed submissions may be excused if a provider establishes good cause for the untimely submission.[20]

Prompt Payment Rules

Generally, a governmental payer must reimburse a provider within a certain amount of time following the submission of a claim. If it fails to do so, the governmental payer may have to pay interest in addition to the full amount of the claim. Under New York law, health plans also must pay claims promptly or face paying interest on the claims. The applicable time frames all assume that the claim is complete and accurate and that the payer has received all the information necessary to process the claim.

What rules apply to commercial health insurers and HMOs?

A health plan must remit payment to a provider within 45 days of receiving a paper claim and 30 days for an electronic claim.[21] If the health plan's liability for the claim is in dispute, the health plan must notify the provider of such dispute in writing within 30 days of receiving the claim.[22] Failure to provide such notice will oblige the health plan to pay the claim within the 45/30-day period or face penalties, including the payment of any interest that accrues from the date the payment was required to be made.[23]

What rules apply to Medicare claims?

Claims under Medicare can be submitted either electronically or on paper. Electronic submissions will appear in the Medicare system almost 24 hours after the claim is submitted. Payment will be made between 14 and 30 days after submission of the claim.[24]

Paper claims, on the other hand, can take as long as three weeks to appear in the Medicare system, and payment will not be made until 29 to 30 days after submission of the claim. The time can be even longer if the claim is returned because of errors. Although filing a paper claim does not require the payment of any fee, paper claim forms must be purchased.[25]

What rules apply to Medicaid?

State Medicaid agencies must pay 90 percent of all clean claims it receives within 30 days of receipt[26] and 99 percent of all clean claims within 90 days of the claim's receipt.[27] The remaining 1 percent of clean claims must be paid, with limited exceptions, within 12 months.[28]

What rules apply to no-fault insurance?

A no-fault insurer, organization or corporation must remit payment to a health care provider within 30 days of receiving the claim or face paying not only the full amount of the claim but interest as well.[29]

What rules apply to workers' compensation?

For workers' compensation claims, an employer must pay a health care provider within 45 days after a bill for treatment is submitted to an employer.[30] If an employer will not pay the bill, the employer must give written notice to the provider stating the reasons for nonpayment.[31] In the absence of payment within 45 days or notice of the reasons therefor, a provider may notify the chair of the Workers' Compensation Board of nonpayment and request that an administrative award be made as payment for the bill.[32]

Financial Records Retention

For various reasons, health care providers should retain their financial records related to billing and reimbursement under both governmental and private payer programs. Many governmental programs audit providers to ensure that fraud is not occurring. Additionally, audits are conducted to prevent incorrect billing and overpayment. By not retaining financial records related to billing and reimbursement for the requisite time period, providers run the risk of legal or professional culpability for any errors that may occur. Therefore, providers should retain records for at least six years after payment of a claim. Some governmental payers require a longer period for records retention. Private payers may also require longer retention of financial records, which a physician can determine by consulting his or her contract with the private payer.

How long should a provider retain financial records related to Medicare claims?

Providers should retain financial records related to Medicare claims for at least 10 years, as the Centers for Medicare and Medicaid Services (CMS) may pursue providers under the federal False Claims Act and the federal Claims Collection Act for up to 10 years following payment of a claim.[33]

How long should a provider retain financial records related to Medicaid claims?

With the enactment of the New York False Claims Act in 2007, all records pertaining to services or supplies provided under Medicaid should also be retained for at least ten years from the date the care, services or supplies were furnished or billed, whichever is later.[34]

How long should a provider retain financial records related to no-fault claims?

Providers are not required by law to retain financial records pertaining to no-fault insurance billings. However, insofar as an insurer may perform routine or targeted audits, providers should retain such records for at least six years should any questions arise regarding billing and reimbursement.

How long should a provider retain financial records related to workers' compensation claims?

Although employers must retain records pertaining to an employee's on-the-job injury for 18 years,[35] no such requirement exists for a provider's records related to treatment and billing for workers' compensation claims. Even so, the Workers' Compensation Board recommends that providers also retain their records for 18 years.

Overpayment Recoveries

There are many efforts underway by private health plans and government health programs to audit retrospectively the claims submitted by physicians and other providers. These audits are conducted to validate the services provided as well as to review the accuracy and adequacy of coding and physician documentation. New

York has enacted legislation which addresses in part the activities of private health plans.

What are the state law rules regarding alleged overpayments to physicians?

Under New York State law, health plans are required to provide 30 days written notice to physicians before engaging in overpayment recovery efforts unless the overpayment is the result of a duplicate payment for the same service. When seeking an overpayment, the notice shall state the patient name, service date, payment amount, proposed adjustment and an explanation of the proposed adjustment.[36]

Does the physician have a right to challenge the overpayment recovery?

The law provides that a health plan must provide a physician with the opportunity to challenge an overpayment recovery. Such challenge is required to include the specific grounds on which the physician is challenging the recovery.[37]

Is there a time limit that applies?

In general, a health plan cannot initiate overpayment recovery efforts more than 24 months after the original payment was received by a physician unless the health plan's efforts are based on a reasonable belief of fraud or other intentional misconduct, or abusive billing, or the overpayment recovery is required by, or initiated at the request of, a self-insured plan, or the recovery is required or authorized by a state or federal government program or coverage that is provided by this state or a municipality thereof to its respective employees, retirees or members.[38]

How is "abusive billing" defined?

Abusive billing is defined in the law as a billing practice that results in the submission of claims that are not consistent with sound fiscal, business, or medical practices and at such frequency and for such a period of time as to reflect a consistent course of conduct.[39]

May a health plan extrapolate from a sample of claims to determine the amount of the overpayment?

While the insurance department issued a 2004 opinion[40] upholding the use of extrapolation, except for disputes regarding medical necessity, the opinion predates the 2006 law requiring health plans to include certain information in the written notice of overpayment, as previously detailed, so the issue remains unsettled.

Internal Utilization Review and External Appeal Rules

Pursuant to the Managed Care Reform Act passed in New York in 1996, health plans must have a formal utilization review process to make decisions regarding the medical necessity of a medical service or treatment.

What is utilization review?

Utilization review is defined as the process a health plan uses to determine whether health care services that have been provided, are being provided or are proposed are medically necessary.[41]

What are the time frames within which a health plan must complete the utilization review process?

A health plan must make and communicate a decision regarding services or treatment according to the following guidelines: (1) for proposed services or treatment (prospective), within three business days of receiving the necessary information;[42] (2) for current services or treatment for which a continuation or extension is sought (concurrent), within one business day of receiving the necessary information;[43] and (3) for services or treatment already provided (retrospective), within 30 days of receiving the necessary information.[44]

What information is a provider or patient entitled to receive if the health plan determines a service is not medically necessary?

Any notice of an adverse determination must be in writing and must include the clinical rationale for the determination, along with instructions about how to appeal such decision to the health plan.[45]

Who can appeal an adverse determination?

A patient, a patient's designee or the patient's health care provider may appeal an adverse medical necessity determination to the health plan.[46] Whether the appeal is standard or expedited depends on the nature of the adverse determination.

Can an adverse determination upheld by the health plan be appealed to any other body?

Patients or their designees and providers can obtain an independent review of a health plan denial based upon a lack of medical necessity or because the services are considered experimental or investigative.[47] To be eligible for independent review, the denial must first be appealed through the health plan's internal appeal process, or the health plan and the patient must agree to waive the internal process.

Within 45 days of receiving notice of a final adverse determination from a health plan's internal appeal process or a notice of waiver of such process, the patient or the provider must request an external appeal through the New York State Insurance Department.[48] The insurance department reviews the request and, if it determines the request is eligible for external appeal, randomly assigns an external appeal agent. The external appeal agent has 30 days to conduct the appeal unless the patient's physician determines that a delay would pose an "imminent or serious threat" to the patient's health, in which case the appeal must be completed within 3 days.[49]

Must the patient pay a fee for an external appeal?

A health plan can impose up to a $50 fee on a patient who requests an external appeal.[50] All other costs associated with the external appeal are borne by the health plan. If the patient prevails, the fee must be returned. In addition, a fee cannot be imposed if the patient has coverage under Medicaid or Child Health Plus or if the fee would pose a hardship for the patient, as determined by the health plan.

Must the provider pay a fee for an external appeal?

A health plan can impose up to a $50 fee on a provider who requests an external appeal of an adverse retrospective determination, which will be refunded if the adverse determination is overturned.[51] As of January 1, 2010, a provider who requests an external appeal of an adverse concurrent determination will be charged the full cost of the appeal if the adverse determination is completely upheld or one-half the cost of the appeal if the adverse determination is upheld in part.[52] However, the health plan may only impose up to a $50 fee on the patient if the provider requests an external appeal of an adverse concurrent determination as the patient's duly appointed designee.[53]

Is the external appeal agent's decision binding?

The decision of the external appeal agent is binding, but does not preclude a patient from seeking judicial review of such decision. Furthermore, a patient need not use the external review process prior to initiating a court action.

Potential Billing-Related Risks for Physician Practices

Billing Companies

Do Medicare rules prohibit physicians from paying billing companies based on a percentage of receipts?

Although the OIG frowns upon percentage billing arrangements, federal law does not prohibit such arrangements. Specific rules do apply, however, when physicians pay billing companies on a percentage basis. Furthermore, the OIG has issued fraud alerts and has otherwise communicated its long-standing concern that such arrangements are ripe for upcoding, unbundling and other manipulation.[54] The OIG has also reminded physicians that they remain responsible for the billing errors and fraud of the billing companies with whom they contract.

Does New York law prohibit physicians from paying billing companies based on a percentage of gross or net practice receipts?

Yes. A physician may be at risk for professional misconduct in New York if he or she permits "any person to share in the fees for professional services, other than: a partner, employee, associate in a professional firm or corporation, professional subcontractor or consultant authorized to practice medicine, or a legally authorized trainee practicing under the supervision of a licensee."[55] The New York State Department of Health (DOH), as the agency responsible for disciplining physicians, has indicated that any compensation arrangement [with a billing company] which is based upon a percentage of physicians' gross revenues or profits, or net revenues or profits, of their practice or a discrete portion thereof, constitutes illegal fee splitting.

Is there any exception to the New York law prohibiting percentage payment arrangements?

The Department of Health has previously indicated that the only permissible percentage compensation arrangements are those entered into between physicians and collection agencies attempting to collect past-due bills which would otherwise be uncollectible.

Professional Courtesy

What practices constitute professional courtesy?

Professional courtesy is defined as a physician's practice of waiving all or part of the fee for services provided to the physician's office staff, other physicians or their families, including the waiver of a coinsurance or deductible payment.[56]

Is a physician prohibited from extending professional courtesy in all cases?

No. Professional courtesy can, however, violate fraud and abuse rules depending upon how recipients of professional courtesy are selected and how such courtesy is extended.

Under what circumstances can the extension of professional courtesy put a physician at risk?

If a physician selects individuals to receive professional courtesy based upon their past or future referrals, the anti-kickback statute may be implicated.[57] A physician who regularly waives deductibles or copayments may also violate the prohibition on providing inducements to Medicare beneficiaries and be subject to civil monetary penalties for such conduct.[58] Lastly, a physician may be in breach of a health plan contract obligation if he or she routinely fails to collect copayment and deductible amounts, thereby subjecting such contract to termination.

Under what circumstances can a physician extend professional courtesy to non-Medicare patients?

To the extent that a physician extends professional courtesy equally, either through the waiver of copayments or waiver of the entire fee, to colleagues and their family members, so as not to distinguish between colleagues who refer patients to the physician and those who do not, such practice is not likely to implicate the anti-kickback statute. The physician must still be cognizant

of any other contractual obligations that specific health plans may impose regarding the collection of copayments and deductibles to avoid breaching such contracts.

Under what circumstances can a physician extend professional courtesy to Medicare patients?

Medicare policy considers the use of copayments and deductibles as an important utilization control. To the extent that a physician routinely waives copayments and deductibles, Medicare believes such practice could encourage the overutilization of services. Furthermore, a physician who regularly accepts 80 percent of the physician fee schedule as payment in full after waiving the patient's copayment could be accused of submitting false claims to Medicare. Medicare will pay 80 percent of the physician fee schedule amount or 80 percent of the actual charge, whichever is lower. By routinely waiving copayments, the physician's actual charge would be 80 percent of the fee schedule amount, and Medicare should pay only 80 percent of this lower amount.

Nonetheless, Medicare does recognize a general exception to the rule against waiving copayments and deductibles for financially needy Medicare patients.[59] In such cases, physicians should thoroughly document the criteria used to determine a patient's financial need. Such criteria should not result in the routine waiving of such payments for all Medicare patients but should rationally define financial need or hardship.

"Incident to" Billing

What are "incident to" services?

To be considered *incident to*, the services must be

- An integral, although incidental, part of the physician's professional service;
- Commonly rendered without charge or included in the physician's bill;
- Of a type that are commonly furnished in physician's offices or clinics;
- Furnished by the physician or by auxiliary personnel under the physician's direct supervision.[60]

Medicare will pay for "incident to" services at 100 percent of the physician fee schedule amount. Not all payers will pay for "incident to" services provided by an individual other than the physician if the physician has not provided any other billable service during the same office visit. Physicians should check with the payer prior to billing for "incident to" services.

What conditions must be satisfied to bill "incident to"?

Under Medicare, services delivered by a physician assistant (PA) or nurse practitioner (NP) or other nonphysician employee could be billed "incident to" when the primary physician performs the initial service and the patient is later seen by the PA, NP or other nonphysician employee, as long as the physician provides subsequent services of a frequency that reflects his or her active participation in the management of the course of treatment. The physician must satisfy the direct supervision requirement with respect to every nonphysician service. Direct personal supervision does not mean the physician must be present in the same room with the PA or NP or other employee providing the service. The physician must, however, be present in the office suite and immediately available to provide assistance and direction throughout the time the service is being delivered. To bill for the nonphysician's services under the physician fee schedule, the physician need not actually see the patient during the particular office visit.

Reassignment of Claims Under Medicare or Medicaid

Providers who have agreed to accept Medicare's or Medicaid's assignment method of payment will receive Medicare's or Medicaid's approved amount of reimbursement for a claim. Following the submission of a claim to Medicare or Medicaid, payment will be forwarded to the provider. Only providers of assigned services can receive payment for a claim.[61] As such, providers are generally prohibited from reassigning payment to a third party, with some exceptions. The use of a power of attorney to assign payment is generally precluded.[62] Providers who reassign payment due under an assigned Medicare or Medicaid claim will subject themselves to various consequences, with the most severe being revocation of the right to receive assigned Medicare or Medicaid payments.[63] In addition, many health plans have policies prohibiting the reassignment of claims to third parties. Physicians need to review their participating provider agreements for the existence of specific rules and any exceptions related to the reassignment of claims.

What is the rationale for the prohibition against reassigning a claim?

Reassigning claims payments in the past has proved a source of erroneous or exaggerated claims or fraudulent practices.[64] Consequently, reassignment of claims is allowed only under narrow exceptions provided by law, thus eliminating a third party's motivation to engage in abusive billing practices or to submit claims for services that were not provided.

What are the Medicare exceptions under which a claim may be reassigned?

Medicare provides the following exceptions to the general rule regarding reassignment of claims:[65]

- *Payment to employer*: A provider's employer may receive a provider's assigned payment if the provider is required by contract to turn over all fees to the employer.

- *Payment to an enrolled Medicare entity*: An entity enrolled in the Medicare program may receive a provider's assigned payment if the provider and the entity have a contractual arrangement whereby the entity bills for the provider's services. However, the provider and the entity remain jointly and severally responsible for any overpayments. The services may be furnished on or off the premises of the entity submitting the claim.
- *Payment for diagnostic tests*: A provider may pay another physician, medical group or supplier for the technical and/or professional component of diagnostic tests, however such charges are limited, effective January 1, 2010, by the anti-markup rule.[66]
- *Payment under reciprocal billing arrangements*: Providers may pay a beneficiary's regular physician for services provided by another physician on an occasional reciprocal basis.
- *Payment under locum tenens arrangements*: A patient's regular physician may be paid for a locum tenens physician's services during the regular physician's absence if certain requirements are met.
- *Payment to a governmental agency*: The Medicare program may pay benefits due a provider to a governmental agency or entity.
- *Payment pursuant to a court order*: The Medicare program may pay benefits due a provider pursuant to the order of a court of competent jurisdiction.
- *Payment to an agent*: The Medicare program may make payment in the name of a provider to an agent who provides collection or billing services.

What are the Medicaid exceptions under which a claim may be reassigned?

The Medicaid program in New York State provides the following exceptions to the general rule regarding reassignment of claims:

- A provider's employer may be paid, if the provider is required as a condition of employment to turn over its fees to said employer.[67]
- A facility where the service was provided may be paid, as long as the facility has a contractual arrangement with affiliated providers to submit their claims in its claim for reimbursement.[68]
- A foundation, plan or similar organization, including HMOs furnishing health care through an organized health care delivery system, may be paid. A contractual arrangement must exist between the provider and the organization, under which the organization submits the claims.[69]
- Payment may be made pursuant to a court order.[70]
- Payment may be made to a governmental agency pursuant to a reassignment from a provider.[71]
- Payment may be made to a business agent, such as a billing service, which prepares statements and receives payments in the name of the provider, as long as the agent's compensation is not based on a percentage or the amount billed, and is not dependent on collection of the payment.[72]

What are the consequences of reassigning payment of a claim in violation of the Medicare rule?

Under Medicare, a provider who is found to be engaging in the reassignment of payment of claims will be notified in writing that his or her conduct violates the Medicare laws and regulations.[73] A copy of the writing will be forwarded to the regional Medicare office.[74] From there, the regional office will determine whether further steps are necessary.[75] The regional office may either revoke assignment privileges or prosecute for breach of an assignment contract.[76]

Before revocation of assignment privileges occurs, the regional office must give the provider 15 days within which to submit a statement explaining why his or her right to payment should not be revoked.[77] If the regional office decides to revoke a provider's assignment privileges, payment will be made directly to the beneficiary who received the services.[78] The revocation will remain in effect until the regional office determines that the unauthorized reassignment has stopped and there is reasonable assurance that unauthorized reassignment will not recur.[79]

Advance Beneficiary Notice (ABN)

Physicians must provide advance written notice to patients before they provide a service that Medicare covers in some circumstances but which Medicare might not cover in a particular case.[80] This advance notice gives the Medicare patient an opportunity to make an informed decision prior to receiving the service. Patients who are not notified before they receive such services are not responsible for payment.

What must an ABN include?

An ABN must be in writing, cite the particular service for which payment is likely to be denied and include the physician's reason for believing Medicare payment will be denied.[81] An ABN is not acceptable if the physician routinely gives this notice to all beneficiaries to whom he or she furnishes services or if the notice is no more than a statement that Medicare may not pay for the service.

The physician should have the patient sign the ABN before the service is rendered. If the patient decides not to receive the service after being informed that such service

may not be covered, the patient should sign the ABN, acknowledging his or her refusal to receive the service. An ABN is not required for services that are never covered by Medicare, such as routine physical examinations or cosmetic surgery.

Do other payers require ABNs?

According to the DOH's provider contracting guidelines,[82] a physician's contract with an independent practice association or HMO must contain certain provisions that bar the provider from seeking payment for covered services directly from a patient enrolled in such HMO. A provider may bill a patient directly for uncovered services as long as the provider advises the patient in advance that the service is not covered and tells the patient how much he or she would have to pay for the service. Although not as specific as the Medicare rules, this provision similarly obliges the provider to advise a patient in advance if the patient will be expected to pay for an otherwise uncovered service.

Opting Out of Medicare

Physicians may contract privately with Medicare beneficiaries when certain conditions are met.[83] Physicians entering into private contracts must opt out of the Medicare program for two years for all covered items and services they furnish to Medicare beneficiaries. A physician must opt out for all Medicare beneficiaries, not just those willing to enter into private contracts.

How does a physician opt out of Medicare?

The physician must file an affidavit notifying the Medicare Administrative Contractor that has jurisdiction over the claims that would otherwise be submitted that he or she has opted out of the Medicare program. For two years from the date of the affidavit, the physician is out of the Medicare program and Medicare will not pay for claims submitted by such physician, except for claims submitted for emergency or urgent care services where the beneficiary has not entered into a private contract.[84] After two years the physician will reenter the Medicare program, unless the physician files another affidavit with the Medicare Administrative Contractor.[85] A valid affidavit must be in writing and signed by the physician. The affidavit must include, among other things, the physician's full name, address, telephone number, billing number, NPI or, if the physician does not have an NPI, a tax identification number.[86]

What is a private contract?

A private contract is a voluntary agreement between a physician and a Medicare beneficiary who agrees to pay fully out-of-pocket for a Medicare-covered service. Under such agreements, the physician is not bound by the charge limits imposed under Medicare, and the beneficiary agrees not to submit a claim to Medicare for the service provided.

What guidelines govern private contracts?

The private contract must

- be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract.
- clearly state whether the physician/practitioner is excluded from Medicare.
- state that the beneficiary or his or her legal representative accepts full responsibility for payment of the physician/practitioner's charges for all services furnished by the physician/practitioner.
- state that the beneficiary or his or her legal representative understands that Medicare limits do not apply to what the physician/practitioner may charge for items or services furnished by the physician/practitioner.
- state that the beneficiary or his or her legal representative agrees not to submit a claim to Medicare or to ask the physician/practitioner to submit a claim to Medicare.
- state that the beneficiary or his or her legal representative understands that Medicare payment will not be made for any items or services furnished by the physician/practitioner that would have otherwise been covered by Medicare if no private contract existed and a proper Medicare claim had been submitted.
- state that the beneficiary or his or her legal representative enters into the contract with the knowledge that he or she has the right to obtain Medicare-covered items and services from other physicians and practitioners who have not opted out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians/practitioners who have not opted out.
- state the expected or known effective date and expected or known expiration date of the opt-out period.
- state that the beneficiary or his or her legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare.
- be signed by the beneficiary or his or her legal representative and by the physician/practitioner.[87]

When can a beneficiary enter into a private contract?

Generally, a beneficiary can enter a private contract at any time. However, a contract that a beneficiary or his or her legal representative enters into when the beneficiary requires emergency care services or urgent care services is not valid.[88]

What are the record-keeping requirements for private contracts?

The physician must give a copy of the contract (a photocopy is permissible) to the beneficiary or his or her legal representative before furnishing items or services to the beneficiary under the terms of the contract. The physician should also retain the private contract with the original signatures of both parties for the duration of the opt-out period. The contract must be made available to the CMS upon request.[89]

How long is a private contract valid?

The contract is valid for the two-year opt-out period. The patient must renew or update the contract for each opt-out period.[90]

Administrative Contractors

The federal government increasingly relies upon private contractors to carry out a wide range of vital program functions for Medicare, from processing claims and provider reimbursement to identifying and pursuing cases of fraud and abuse. Such contractors include:

- Medicare Administrative Contractors (MACs).[91] The MACs replaced the fiscal intermediaries and carriers, the primary difference being that an A/B MAC handles both Parts A and B for a given jurisdiction. The 48 fiscal intermediary and carrier jurisdictions were consolidated into just 15 A/B MAC jurisdictions. In addition, 4 of the 15 A/B MACs are also tasked with handling home health and hospice claims and there are 4 specialty MACs which process durable medical equipment claims. The MAC contracts are subject to competitive bidding at least every five years.

  The MACs for New York are: A/B MAC: National Government Services, Home Health & Hospice MAC: Noridian Administrative Services, and DME MAC: National Heritage Insurance Corp.

- Recovery Audit Contractors (RACs).[92] The RACs are tasked with: (1) identifying underpayments and overpayments; and (2) recouping overpayments under Medicare Parts A and B. As with many of the administrative contractors, RACs increasingly use sophisticated data analysis to identify areas of concern and to select providers to be audited. RACs are reimbursed a percentage of the overpayments collected. The RAC for New York is currently DCS Healthcare Services.

- Program Safeguard Contractors (PSCs).[93] The primary task of PSCs is to identify and develop cases of suspected fraud, take immediate action to prevent inappropriate payments and refer cases of potential fraud to the OIG or law enforcement. CMS is currently in the process of transitioning from PSCs to Zone Program Integrity Contractors (ZPICs). While ZPICs will have the same duties, the main purpose of the transition is to promote coordination by better aligning the seven ZPIC jurisdictions with those of the MACs. At present, no ZPIC has been designated for Zone 6, which includes New York, so Safeguard Services, LLC remains the PSC for the State.

While Medicare has been at the forefront of using administrative contractors, the Deficit Reduction Act of 2005 required CMS to begin implementing a Medicaid Integrity Program to combat fraud, waste and abuse in the Medicaid program.[94] The four parts of the program, to be accomplished through private contractors, are: (1) review provider actions; (2) audit claims; (3) identify overpayments; and (4) provide education with respect to payment integrity and quality of care. In addition, the CMS will provide assistance to state efforts regarding fraud and abuse.

On the state level, the New York State Office of the Medicaid Inspector General makes extensive use of private contractors to support its fraud and abuse efforts. In addition, as of December 31, 2010, states were required to contract with RACs for the purpose of identifying Medicaid underpayments and overpayments and recouping overpayments.[95] Medicaid RACs are paid a contingency fee based on recovered overpayments.

Resources

The following list contains additional selected resources that offer helpful information on billing and reimbursement for Medicare, Medicaid, no-fault insurance and workers' compensation. Although most private payers have websites with information for providers regarding billing and reimbursement, the sheer number of private payers in New York State precludes listing them here.

Medicare

Official Governmental Medicare Information: www.medicare.gov (although this site is geared toward consumers, providers can find information on Medicare basics, Medicare publications and contact information for questions regarding Medicare. The site also offers a search tool for more specific requests about Medicare.)

For questions regarding Part A bills and services, hospital care, skilled nursing care and fraud and abuse, contact National Government Services at: 1-888-855-4356.

For questions regarding Part B bills, services and fraud and abuse, contact National Government Services at: 1-866-837-0241.

Medicare Learning Network: www.cms.gov/MLNGenInfo/ (designed for health care providers as a learning resource about Medicare policies and payment rules)

National Government Services: www.ngsmedicare.com (As the Medicare Administrative Contractor for New York State, National Government Services offers consumers and providers information relating to all aspects of Medicare. Empire publishes a provider newsletter offering the most up-to-date information on Medicare and related issues, available for free on the website or via hard copy with a subscription fee.)

Medicaid

New York State Department of Health (DOH): www.health.state.ny.us (provides information regarding the Medicaid program in New York State, featuring a Medicaid reference guide, a monthly publication on Medicaid and recent news on Medicaid)

e-mail: nyhealth@health.state.ny.us

The electronic Medicaid system of New York (eMedNY): http://www.emedny.org/ (in addition to processing Medicaid claims, eMedNY provides extensive information on Medicaid, including Provider Manuals). Inquiries regarding practitioner services, institutional services and professional services should be directed to 1-800-343-9000.

Medicare/Medicaid

Centers for Medicare & Medicaid Services (CMS): www.cms.gov (offers providers information on, among other things, budget and performance requirements, Medicare coding and payment systems, provider billing and CMS forms, and Medicare and Medicaid publications geared toward providers)

Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850
410-786-3000

New York State No-Fault Insurance

New York State Insurance Department: www.ins.state.ny.us (provides information regarding all insurance in New York State, including no-fault insurance. Providers can contact the department to receive more information regarding no-fault laws and regulations in New York State. The department can offer a provider guidance regarding billing and reimbursement of claims. Contact information will vary based on the physician's location and specific information requested. See website for further contact information.)

Workers' Compensation

New York State Workers' Compensation Board: www.wcb.state.ny.us (offers information for health care providers on a variety of topics related to workers' compensation, including medical fee schedules, filing claims and what to do when a bill for treatment is not paid. Contact information will vary based on the physician's location and specific information requested. See website for further contact information.)

New York State Insurance Fund: www.nysif.com (offers medical providers a checklist regarding submission of bills. It also allows providers to make inquiries regarding billing and payment and provides workers' compensation claim forms. A contact page allows providers to contact the New York State Insurance Fund through email with specific questions regarding billing and reimbursement of workers' compensation claims.)

Endnotes

1. These rules are discussed in § 15.2 below.
2. These processes are detailed in § 15.7 below.
3. See chapter 48 for a description of the Office of Inspector General and more detail on physician office compliance.
4. Office of Inspector General, *Compliance Guidance for Individual and Small Group Physician Practices*, 65 Fed. Reg. 59,434, *available at* http://oig.hhs.gov/authorities/docs/physician.pdf (OIG *Compliance Guidance*). This publication contains examples of each type of billing risk and sets forth recommendations on the written standards and procedures relative to billing and coding.
5. See www.omig.state.ny.us/data for additional information.
6. OIG *Compliance Guidance*, *supra* note 4.
7. See chapter 12 on the importance of medical records documentation in the context of a medical malpractice suit.
8. OIG *Compliance Guidance*, *supra* note 4.
9. N.Y. Insurance Law § 3224-a(g) (Ins. Law).
10. *Id.*
11. PPACA § 6404(a).
12. 42 U.S.C. § 1395(f)(a)(1).
13. 42 C.F.R. § 424.44(b); Centers for Medicare & Medicaid Services, *Transmittal No. 2140* (January 21, 2011*), available at* http://www.cms.gov/transmittals/downloads/R2140CP.pdf.
14. N.Y. Comp. Codes R. & Regs. tit. 18, § 540.6(a)(1) (N.Y.C.R.R.).
15. 11 N.Y.C.R.R. § 65-1.1(d); New York State Medicaid Program Manual, *Information for All Providers—General Billing*, *available at* http://www.emedny.org/ProviderManuals/AllProviders/index.html.
16. 11 N.Y.C.R.R. § 65-1.1(d) (conditions). *See Medical Soc'y v. Serio*, 100 N.Y.2d 854 (2003).
17. 11 N.Y.C.R.R. § 65-1.1(d) (conditions).
18. 12 N.Y.C.R.R. § 325-1.24.
19. *Id*.
20. *Id*.
21. Ins. Law § 3224-a(a).
22. Ins. Law § 3224-a(b).
23. Ins. Law § 3224-a(c).
24. Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual*, Pub. 100-4, ch. 1, § 80, www.cms.gov/Manuals/IOM/itemdetail.asp?itemID=CMS018912.
25. www.cms.gov/ElectronicBillingEDITrans/16_1500.asp.
26. 42 C.F.R. § 447.45(d)(2). A *clean claim* is a claim that can be processed without obtaining additional information from the provider.
27. 42 C.F.R. § 447.45(d)(3).

28. 42 C.F.R. § 447.45.
29. 11 N.Y.C.R.R. §§ 65-3.8 & 65-3.9.
30. N.Y. Workers' Compensation Law § 13-g(1) (WCL).
31. *Id*.
32. *Id*.
33. 31 U.S.C. § 3731(b)(2); 49 C.F.R. § 89.37.
34. N.Y. State Finance Law § 192.
35. WCL § 110(1).
36. Ins. Law § 3224-b(b)(1).
37. Ins. Law § 3224-b(b)(2).
38. Ins. Law § 3224-b(b)(3).
39. *Id*.
40. N.Y. Insurance Department Office of General Counsel Opinion 04-12-32, http://www.dfs.ny.gov/insurance/ogco2004/rg041232.htm.
41. N.Y. Public Health Law § 4900(8) (PHL).
42. PHL § 4903(2).
43. PHL § 4903(3).
44. PHL § 4903(4).
45. PHL § 4903(5).
46. PHL § 4910(2).
47. PHL § 4910(2)(a), (b).
48. PHL § 4914(2)(a); Ins. Law § 4914.
49. PHL § 4914(2)(b)–(c).
50. PHL § 4910(3).
51. 10 N.Y.C.R.R. § 98-2.9(h)(4); 11 N.Y.C.R.R. § 410.9(h)(4).
52. PHL § 4914(4)(b)&(c).
53. PHL § 4914(4)(d).
54. OIG Advisory Op. No. 98-4 (1998), http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_4.pdf.
55. N.Y. Education Law § 6530(19).
56. 66 Fed. Reg. 922 (Jan. 4, 2001).
57. See chapter 37 for a more in-depth discussion of the anti-kickback statute.
58. 42 U.S.C. § 1320a-7a.
59. 59 Fed. Reg. 65372 (Dec. 19, 1994).
60. Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual*, Pub. 100-2, ch. 15, § 60, http://www.cms.gov/manuals/downloads/bp102c15.pdf.
61. 42 U.S.C. § 1395u(b)(6); 42 C.F.R. § 424.80; 18 N.Y.C.R.R. § 504.9(a)(1).
62. 42 U.S.C. § 1395u(b)(6); 42 C.F.R. § 424.80(a).
63. 42 C.F.R. § 424.82.
64. Medicare Claims Processing Manual, § 30.2.2, *supra* note 24.
65. 42 U.S.C. § 1395u(b)(6); 42 C.F.R. § 424.80; Medicare Claims Processing Manual, § 30.2.15, *supra* note 24.
66. 42 U.S.C. § 1395u(n); Medicare Claims Processing Manual, § 30.2.1, *supra* note 24.
67. 18 N.Y.C.R.R. § 504.9(a)(1); 42 C.F.R. § 447.10(d)–(g).
68. *Id*.
69. *Id*.
70. *Id*.
71. 18 N.Y.C.R.R. § 504.9(a).
72. 18 N.Y.C.R.R. § 504.9(a)(1).
73. Medicare Claims Processing Manual, § 30.2.15, *supra* note 24.
74. *Id*.
75. *Id*.
76. *Id*.
77. *Id*.
78. *Id*.
79. *Id*.
80. Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual*, Pub.100-4, ch. 30, § 40.2-40.3, http://www.cms.gov/manuals/downloads/clm104c30.pdf.
81. Form No. CMS-R-131 is a standardized and simplified ABN form. A copy of this form appears in the Forms section of this manual. Copies of the form are available online at http://www.cms.gov/BNI/02_ABN.asp.
82. *HMO and IPA Provider Contract Guidelines*, *available at* www.health.state.ny.us/health_care/managed_care/hmoipa/guidelines.htm.
83. Medicare Benefit Policy Manual, § 40, *supra* note 60.
84. *Id.* at §§ 40.5 & 40.28.
85. *Id.* at § 40.34.
86. *Id.* at § 40.9.
87. *Id.* at § 40.8; 42 C.F.R. § 405.415.
88. *Id.*
89. *Id.*
90. *Id*.
91. 42 U.S.C. § 1395kk-1.
92. 42 U.S.C. § 1395ddd(h).
93. 42 U.S.C. § 1395ddd(a); 70 Fed. Reg. 35204 (June 17, 2005).
94. 42 U.S.C. § 1396u-6.
95. PPACA § 6411.

Laurie T. Cohen is a partner at Wilson Elser Moscowitz Edelman & Dicker LLP. Her practice focuses on corporate and regulatory health law and includes the representation of individual physicians, medical groups, hospital, and other health care providers.

James Shannon is Of Counsel to Wilson Elser Moscowitz Edelman & Dicker LLP and is a member of the firm's health care practice.

This article is a reproduction of Chapter Fifteen of *Legal Manual for New York Physicians, Third Edition* (NYS Bar Assn / Medical Society of the State of NY 2011). The content of this chapter was last updated in April of 2011.

NEWS flash

What's Happening in the Section

New Section Officers

On January 25, 2012, the Section elected a new slate of officers who will begin serving their one-year terms on June 1, 2012. The officers are as follows:

Section Chair:	Ellen V. Weissman, Hodgson Russ (Buffalo and NYC)
Chair-Elect:	Kathleen M. Burke, V.P., Board Relations, Secretary & Counsel, NY-Presbyterian Hospital (NYC)
Vice-Chair	Margaret Davino, Kaufman, Borgeest & Ryan (NYC)
Secretary	Kenneth R. Larywon, Martin, Clearwater & Bell LLP (NYC)
Treasurer	Raul A. Tabora, Jr., Ruffo, Tabora, Mainello & McKay, P.C. (Albany)

Meet Incoming Section Chair Ellen V. Weissman

Ellen V. Weissman heads the Health Law Practice Group of Hodgson Russ, and works out of the firm's offices in Buffalo and New York City. Ms. Weissman devotes her practice to serving health care clients in reimbursement, regulatory, and compliance matters. She advises health care clients on structuring transactions, including forming integrated delivery systems and ambulatory care alternatives in light of licensure, certificate of need, and reimbursement issues. Ms. Weissman counsels academic medical centers on graduate medical education reimbursement and compliance issues. She represents health care clients in Medicare and Medicaid appeals, including appeals before the Provider Reimbursement Review Board. She also represents providers in Medicare and Medicaid audits and investigations conducted by fiscal intermediaries, the Office of the Inspector General of HHS, the U.S. Department of Justice, Medicaid Fraud Control Units, and the New York Office of the Medicaid Inspector General.

Prior to joining Hodgson Russ, Ms. Weissman practiced with the New York City office of a national health care law firm, Wood, Lucksinger and Epstein. She also served as counsel to a New York City deputy mayor who chaired the New York City Health and Hospitals Corporation and as law clerk to U.S. District Judge Whitman Knapp in the Southern District of New York.

Ms. Weissman has lectured extensively in health law, and previously chaired the Section's Committee on Payment and Reimbursement.

Recent Events

- **Legal, Ethical and Mental Health Issues on Today's Higher Education Campus**. On February 21, 2012, the Section co-sponsored this all-day program. The program was co-sponsored with Fordham University School of Law, several other Bar Association Committees and the Women's Bar Association. It was held at Fordham Law School's Lincoln Center Campus. Co-chairs of the program were Health Law Section Members Mary Beth Morrissey, Lawrence Faulkner, and Carolyn Wolf.
- **Accountable Care Organizations.** The Section's Fall Meeting, which focused on accountable care organizations, was well attended, and well-received. The program was co-Chaired by Margie Davino of Kaufman, Borgeest and Ryan, LLP and Julia Goings-Perrot of Tarshis, Catania, Liberth, Mahon & Milligram, PLLC.
- **Annual Meeting.** The Annual Meeting was held on January 25, 2012 at the Hilton New York in NYC. Co-Chaired by Robert A. Hussar of Manatt Phelps and Melissa M. Zambri of Hiscock & Barclay, LLP, the program covered due diligence in health care transactions, CMS program integrity activities, OMIG and MFCU initiatives, corporate integrity agreements and program exclusion initiatives.
- **Presentation by Stephen Berger.** The luncheon address at the Section's Annual Meeting was given by Stephen Berger, the Chairman, Commission on Health Care Facilities in the 21st Century Chair, Brooklyn Health System Redesign Work Group.

Recent Supraspinatus Topics

- Study of Medicare Patients Finds Most Hospital Errors Unreported—NYTimes.com
- State Health Department Awards $500,000 in Doctors Across New York Funds
- St. John's Episcopal Hospital Laboratory Permit Suspended for 30 Days
- St. Luke's-Roosevelt and Mount Sinai Settle Respective Nursing Disputes
- Montefiore Nurses Dispute Heats Up
- Mail Order Pharmacy Approval Message
- Cuomo approves mail order pharmacy bills
- Wal-Mart: "We are not building a national, integrated, low-cost primary care health care platform"
- State Health Department Awards 4.5 Million to Combat Childhood Obesity
- 12 Are Charged in Medicare Fraud Schemes Said to Cost $95 Million—NYTimes.com
- Governor signs bill mandating insurance for autism care—Times Union
- Congress Asks I.R.S. About Oversight of Nonprofit Hospitals—NYTimes.com
- New York Settles Medicaid Fraud Suit for $70 Million—NYTimes.com

Section Committees

Unchanged	Chair/Co-Chair
Executive Committee	Section Chair
Membership	Karen Gallinari
Fraud Abuse and Compliance	Melissa Zambri Robert Hussar
Ethical Issues in the Provision of HealthCare	Lawrence Faulkner
In-House Counsel	Reginald Bullock
Public Health and Health Policy	Julia Goings-Perrot

Other Committee Changes

- The Special Committee on E-Health Information Systems has been made a Standing Committee. It will be chaired by Raul Tabora.
- The Special Committee on Legislative Issues has been made a Standing Committee, and will continue to be chaired by James Lytle.
- The Committee on Hospitals and Health Systems and the Long Term Care Providers Committee have been merged into a new Committee on Institutional Providers.
- The Physicians and Licensed Health Care Professionals Committee and the Professional Discipline Committee, have been merged into a new Committee on Health Professionals chaired by Barbara Ryan.
- The Committee on Payment and Reimbursement, and the Committee on Managed Care, Insurance and Consumer/Patient Rights have been merged into a new Committee on Reimbursement Issues to be co-chaired by Harold Iselin and Ross Lanzafame.
- The Mental Health Issues Committee and the Special Committee on Mental Retardation and Developmental Disabilities have been merged into a new Committee on Mental Health and Developmental Disabilities. It will be co-chaired by Carolyn Wolf and Hermes Fernandez.

The *Health Law Journal* will continue under the editorship of Robert Swidler, and Supraspinatus will continue to be managed by Paul Gillan.

Diversity

The Diversity Challenge of the Health Law Section has developed an Action Plan with three major components:

- outreach to the health law sections of minority bar associations.
- membership marketing materials appealing to a more diverse membership.
- a Summer internship program with 3 slots to encourage minorities to consider health law careers.

The Diversity Task Force, chaired by Lisa Hayes, working in conjunction with Membership Committee Chair Karen Gallinari, are planning programs and collaborations.

The Section was represented at the Association's "Celebrating Diversity" Reception on Monday, January 23, 2012 from 6-8 p.m. This event was part of the Annual Meeting at the Hilton New York. A free 1-year membership in the Health Law Section was offered to potential new members expressing an interest in health care law. Also during the Annual Meeting, the Section was a Gold Sponsor of the Edith I. Spivak Symposium of the NYSBA's Committee on Women in the Law, held on Tuesday, January 24, 2012.

Further information about upcoming programs is always available at www.nysba.org/health. Just click on "Events."

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 (listed on the back page) or Committee Chairs for further information about these Committees.

E-Health Information Systems
Raul A. Tabora Jr.
Ruffo Tabora Mainello & McKay PC
300 Great Oaks Boulevard, Suite 311
Albany, NY 12203
rtabora@ruffotabora.com

Ethical Issues in the Provision of Health Care
Lawrence R. Faulkner
General Counsel and Director of Quality Assurance
Arc Of Westchester
265 Saw Mill River Road, 3rd Floor
Hawthorne, NY 10532
lfaulkner@westchesterarc.org

Fraud, Abuse 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

Health Professionals
Barbara A. Ryan
Aaronson Rappaport Feinstein & Deutsch, LLP
600 3rd Avenue, 6th Floor
New York, NY 10016
baryan@arfdlaw.com

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

Institutional Providers
vacant

Legislative Issues
James W. Lytle
9 Fernbank Ave.
Delmar, NY 12054

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

Mental Health 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

Publications and Web Page
Robert N. Swidler
Northeast Health
2212 Burdett Avenue
Troy, NY 12180
swidlerr@nehealth.com

Public Health and Health Policy
Julia C. Goings-Perrot
Tarshis Catania Liberth Mahon & Milligram PLLC
1 Corwin Court
Newburgh. NY 12550
jgoings-perrot@tclmm.com

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

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

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
Northeast Health
2212 Burdett Avenue
Troy, NY 12180
(518) 271-5027
swidlerr@nehealth.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 2012 is $150.00. Send your request and check to Newsletter Dept., New York State Bar Association, One Elk Street, Albany, NY 12207.

HEALTH LAW JOURNAL

Editor
Robert N. Swidler
Northeast Health
2212 Burdett Avenue
Troy, NY 12180
(518) 271-5027
swidlerr@nehealth.com

Section Officers

Chair
Francis J. Serbaroli
Greenberg Traurig, LLP
200 Park Avenue, 14th Floor
New York, NY 10166
serbarolif@gtlaw.com

Chair-Elect
Ellen V. Weissman
Hodgson Russ LLP
140 Pearl Street, Suite 100
Buffalo, NY 14202-4040
eweissman@hodgsonruss.com

Secretary
Kathleen M. Burke
New York Presbyterian Hospital
525 East 68th Street, Room W-109
New York, NY 10021-4873
kburke@nyp.org

Treasurer
Margaret J. Davino
Kaufman Borgeest & Ryan LLP
120 Broadway, 14th Floor
New York, NY 10271-1699
mdavino@kbrlaw.com

ISSN 1530-3926 ISSN 1933-8406 (online)

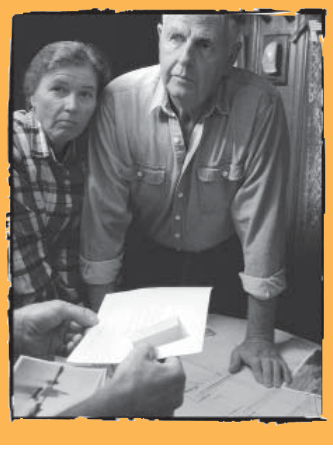
NEW YORK STATE BAR ASSOCIATION
HEALTH LAW SECTION
NYSBA One Elk Street, Albany, New York 12207-1002

ADDRESS SERVICE REQUESTED

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

There are millions of reasons to do Pro Bono.

(Here are some.)



Each year in communities across New York State, indigent people face literally millions of civil legal matters without assistance. Women seek protection from an abusive spouse. Children are denied public benefits. Families lose their homes. All without benefit of legal counsel.
They need your help.

If every attorney volunteered at least 20 hours a year and made a financial contribution to a legal aid or pro bono program, we could make a difference. Please give your time and share your talent.

DO THE PUBLIC GOOD
VOLUNTEER FOR PRO BONO

Call the New York State Bar Association today at **518-487-5640** or go to **www.nysba.org/probono** to learn about pro bono opportunities.