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Health Law Journal

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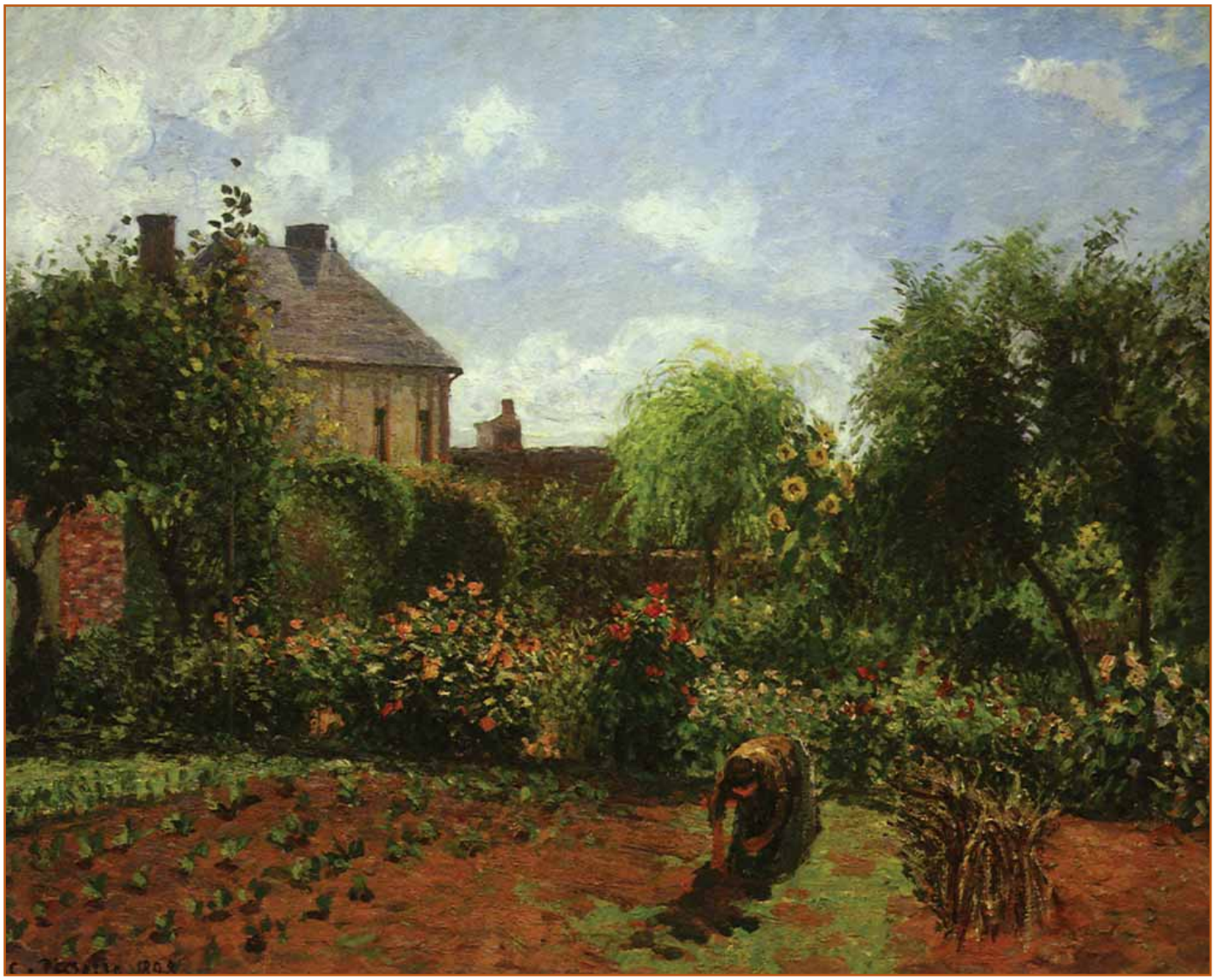

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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Cover artwork:
The Artist's Garden at Eragny **by Camille Pissarro (1898)**

A Message from the Section Chair

Many past chairs of the Health Law Section have taken the opportunity to use this column to talk about recent developments in health law or recent events and activities of the section. I thought I would veer from that path a bit and focus on how involvement in the Health Law Section can be professionally rewarding for all of our members and greatly advance our specialty.

At a time when we face far-reaching changes to the health law landscape, as well as to the practice of law in general, ensuring a rewarding professional practice servicing our clients to the best of our abilities as health care lawyers can be achieved with the assistance of section membership and participation. I believe this and would like to tell you why.

I am very proud to be the current Chair of the Health Law Section because I genuinely believe that I am a product of it in so many ways. I joined the section in law school and have maintained my membership since. I have worked with, worked on the other side of, or worked for most of our former chairs. I have written for this *Journal* on several occasions and either chaired, co-chaired or spoken at many of our CLE events over the years. I have attended nearly all of our CLE programs. I have also chaired one of our substantive committees and had the opportunity to participate in our executive committee and rise through the ranks of our section officers. I have likely called on over 50 members of the section at different points in time to pick their individuals brains on a substantive health law issue, some more than others. The section provided me with most of these opportunities and, as a result I have had, and continue to have, a rewarding career with wonderful professional opportunities.

Participation in the section pushes our legal specialty forward and provides our members with educational, networking and professional opportunities that are incredibly valuable. Every one of our 1100+ members can benefit from section membership. Active involvement in the section will provide you with opportunities to learn and understand all of the current developments in health law as well as practical issues in the practice of health law. Active involvement provides our members with the opportunity to meet and establish relationships with an incredible collection of health care lawyers unmatched in size and depth of experience. Active involvement advances our specialty through the scholarship in the *Health Law Journal*, the myriad reports and issues we take up and the collegial discussions that occur between our members on many of the pressing issues of the day.

I have shared my "story" about how the section has been valuable to me and I believe it can be valuable to all of you too. So, let me challenge you to take hold of your professional career trajectory, advance your chosen legal specialty and get involved in Health Law Section activities. I don't think you will be disappointed. You can—

- Join your colleagues at a Membership Reception. Our last such Receeption was on December 2, 2010 in NYC. We expect to have another in the early Spring.
- Take the opportunity to listen and participate in one or more of our upcoming Webinar Series, entitled "Doing the Deal With Health Care Providers." The first in the series was on November 16, 2010 and the second on January 11, 2011.
- Save the date and make sure you attend our Annual Meeting on January 26, 2011. We have a great meeting planned on significant health law issues that have arisen in the last year.
- Participate in one of our substantive committees. The executive committee has been working on a plan to get our committees to do more for our members—and with your help we can.
- Write something for the *Health Law Journal*. Share your professional skills with your peers; we can all gain from it.
- Ask your colleagues a question on our listserv. We have a great group of colleagues always willing to get involved in a lively discussion or point someone in the right direction.
- Reach out to our executive officers and committee chairs. Let us know why the section is valuable to you or why it hasn't been and what you would like to see the Health Law Section do or not do for its members.

Finally, I want to end with thanking Ed Kornreich for his immediate past Chairmanship of the section. Ed has been, and continues to be, a valuable participant in our section and we have all benefited from his dedication to our activities.

Ari J. Markenson

In the New York State Courts

By Leonard M. Rosenberg

Southern District of New York Holds That a Voluntary, Nonsalaried Member of a Hospital's Faculty Practice Is Not an Employee Under New York Labor Law §§ 740 and 741, and That Supervisory Individuals Cannot Be Held Liable for Retaliatory Personnel Actions Under Labor Law § 741

Geldzahler v. New York Medical College, __ F. Supp. 2d __, 2010 WL 3853245 (S.D.N.Y. Sept. 30, 2010). Plaintiff, a former faculty member and director of a medical residency program of Defendant New York Medical College ("NYMC"), brought a pro se action against NYMC, his former supervisor, Dr. Joseph Morales ("Dr. Morales"), and the replacement director of the residency program, Dr. Jay P. Goldsmith ("Dr. Goldsmith"), alleging that he was terminated from his position as director and then, two years later, removed from the NYMC faculty practice, in retaliation for complaints he made about the structure of the residency program and dangers to patient safety and welfare. Plaintiff sought relief for breach of contract, wrongful discharge, and for alleged violations of New York Labor Law §§ 740 and 741, also known as New York's Whistleblower Laws. Plaintiff's claims of breach of contract and wrongful discharge were dismissed in an earlier decision.

The District Court granted Defendants' motion for summary judgment and dismissed Plaintiff's §§ 740 and 741 claims in their entirety. Plaintiff's allegations of retaliation rested on two separate incidents. First, he was terminated from his position as director of the medical residency program by Dr. Morales in April 2007. However, he remained a member of the NYMC faculty practice, as a voluntary, unsalaried private dentist until 2009, when he was denied reappointment during NYMC's two-year reappointment cycle, based upon a

recommendation by Dr. Goldsmith in late 2008.

The Court first addressed Plaintiff's claims under § 740. As an initial matter, because Plaintiff did not bring his lawsuit until February 25, 2009, the Court dismissed his claim for retaliatory discharge in 2007 as time-barred under Labor Law § 740's one-year statute of limitations.

The Court further held that Plaintiff's claim for wrongful removal from the faculty practice in 2009 under § 740 was not cognizable because Plaintiff was not an "employee" of NYMC in 2009 as required under the statute. Section 740 applies only to "employees," which it defines as individuals who work "under the control and direction of an employer for wages or other remuneration." N.Y. LAB. § 740(1)(a). Once Plaintiff was terminated from his program director position in 2007, he no longer received a salary from NYMC, and earned income only through billings in his private practice. Therefore, he was not an "employee" protected by the anti-retaliation provisions of § 740, and could not recover under that statute.

The Court also dismissed Plaintiff's claim under § 741, which is the whistleblower statute specifically applicable to healthcare employees. First, because § 741 applies only to individuals who perform services "for wages or other remuneration," (N.Y. LAB. § 741(1)(a)), and Plaintiff stopped receiving a salary in 2007, the Court dismissed the portion of Plaintiff's § 741 claim that relied on Dr. Goldsmith's 2008 recommendation to terminate Plaintiff from the faculty practice, since Plaintiff was not an employee under § 741 at that time.

The Court also held that Plaintiff could not maintain a § 741 claim for his 2007 termination against Dr. Morales in his individual capacity because Dr. Morales was not Plaintiff's "employer" as that term is defined in § 741. Section 741 prohibits retaliatory actions taken by "employers," defined as a "partnership, association, corporation, the state, or any political subdivision of the state" who perform health services. *See* N.Y. LAB. § 740(1)(b). Unlike its sister statute, § 740, the definition of "employer" in § 741 does not include individual persons. The Court disagreed with the prior holding in *Sulieman v. Roswell Park Cancer Institute*, 2008 WL 2690278 (W.D.N.Y. June 30, 2008), in which the court held that § 741 could apply to individual supervisors as well as corporate employers. Instead, the *Geldzahler* Court found that, because individuals were explicitly *included* in the definition of employer in § 740, the conspicuous exclusion of individuals from the definition in § 741 must be considered deliberate.

Finally, the Court dismissed Plaintiff's § 741 claim against NYMC because it found that NYMC had reasons to discharge Plaintiff other than Plaintiff's complaints about the residency program. Specifically, there was extensive and undisputed evidence in the record of a long-contentious relationship between Plaintiff and Dr. Morales, who often differed on their views of how the residency program should be run and had a demonstrated inability to work together. Moreover, the Court found that the fact that Plaintiff had complained about the dangers posed by the residency program for years prior to his termination without adverse consequences clearly indicated that his complaints did not lead to his termination.

Court of Appeals Enforces Contract Provision Allowing Surgery Center to Share in Fees From Employee's Off-Site Anesthesiology Service

Glassman v. Prohealth Ambulatory Surgery Center, Inc., et al., 14 N.Y.3d 898 (N.Y. 2010). Plaintiff, an anesthesiologist, brought this action to recover damages for his former employer's breach of their employment agreement. Plaintiff alleged that Defendants, an ambulatory surgery center ("ASC") and its principals, failed to pay him the compensation and severance pay promised by the agreement should Plaintiff be terminated without "just cause" from his position as Director of Anesthesiology and Medical Director.

Defendants moved for summary judgment dismissal of the complaint on the ground that the entire agreement is unenforceable, as a similar type of fee sharing provision was deemed illegal under recent case law. The provision at issue provided that the ASC would share in fees earned for anesthesia services performed by Plaintiff outside of its location. Defendants argued that the provision contravened the ASC's operating certificate, which limits its authority to provide medical services to the ASC. Accordingly, the provision at issue constituted improper fee splitting. The motion court agreed that the fee sharing provision was unenforceable, but rather than setting aside the entire agreement, it severed the fee sharing provision and permitted Plaintiff to proceed to trial on his claim for severance pay.

After a bench trial, the trial court entered judgment for Plaintiff and awarded monetary damages. The Appellate Division affirmed. The Court of Appeals reversed, and remitted the matter to the trial court to address damages as they relate to the contractual provision at issue.

The Court of Appeals noted that while the practice outlined by the disputed contractual provision is inconsistent with 10 NYCRR 401.2(b), which states that "[a]n operating certificate shall be used only by the established operator for the designated site of operation," the fee sharing provision is still enforceable, as it is merely *malum prohibitum* (*i.e.*, an act forbidden by law, but not inherently immoral). The Court concluded that it would be inappropriate to allow the parties to escape their contractual obligations, freely entered into, "where there are regulatory sanctions and statutory penalties in place to redress violations of the law."

The Court noted that such sanctions existed, *i.e.* Public Health Law § 2806(1)(a), which authorizes the Department of Health to revoke, suspend, limit, or annul an ambulatory surgery center's operating certificate for failing to comply with the law or its rules and regulations; and the State Board for Professional Medical Conduct, which has statutory power to impose sanctions for fee-splitting arrangements that violate statutory prescriptions. As neither agency was involved in this matter, and there is no overarching public policy that mandates voiding the contract, the Court of Appeals held that the provision was valid and enforceable. It therefore remitted the matter to the trial court for a consideration as to whether Defendants are entitled to a setoff derived from their contractual share of fees from Plaintiff's off-site anesthesia services.

DOH Barred From Exercising Common-Law Right of Recoupment to Correct Computational Errors After Rates Have Become Final Under Its Regulations

DMN Mgmt. Servs., LLC d/b/a Capital Living & Rehab. Centers v. Daines, __ N.Y.S.2d __, 2010 WL 4342076 (3d Dep't Nov. 4, 2010). In this proceeding, the Appellate Division addressed a matter of first impression: whether the Department of Health ("DOH") may exercise its common-law right of recoupment to correct an undisputed computational error in a facility's reimbursement rate after the mistaken rate had become final for auditing purposes.

Petitioner operated several residential health care facilities, which had filed rate appeals seeking revisions to its Medicaid reimbursement rates for the years 1999 through 2005 as a result of mortgage refinancing. In 2007, the DOH acted upon those rate appeals, but simultaneously discovered and recouped overpayments stemming from an unrelated error in the DOH's calculation of petitioner's 1998, 1999 and 2001 rates.

Petitioner commenced an Article 78 proceeding seeking to annul the DOH's retroactive recoupment of the reimbursements for the 1998 rate year, which was the only year not included in the rate appeals. The motion court granted Petitioner's application to annul the recoupment as untimely. Upon a review of the DOH's auditing regulations (*see, e.g.*, 10 NYCRR 86-2.7; 18 NYCRR 517.3) and the cases applying the common-law right of recoupment, the Appellate Division affirmed.

Under the auditing regulations, the DOH is entitled to commence an audit of a provider's statistical and cost reports within six years after such reports are due or filed, during which time providers must maintain their books and records for inspection. Based upon the audit, the DOH may then correct any erroneous reimbursement rates, which are provisional until an audit is completed, or until the expiration of the six-year period if no audit is commenced. 18 NYCRR 517.3(a)(1).

Generally, under the common-law right of recoupment, a municipal administrative agency, such as the DOH, may retroactively recoup payments erroneously made as a result of computational or technological errors that do not involve the exercise of judgment (*i.e.* issues that do not require an agency's interpretation or expertise). Significantly, the DOH argued that there was no time limitation on exercising this common-law right, and the regulatory time limitation for audits did not apply to this common-law remedy.

However, the Court pointed out that the common-law right of recoupment appeared to be based, in part, on the provisional nature of the reimbursement rates. In the cases upholding the common-law right to recoup overpayments, the rates were still subject to revision and retroactive readjustment under the regulations because the DOH had either commenced a timely audit or corrected the error before the audit period elapsed.

Therefore, the Court logically inferred that, if the DOH fails to timely commence an audit, such that the rates have become final, "the provider's right to payment becomes vested, and the Department may no longer make readjustments or recover overpayments resulting from errors that could have been corrected by conducting an audit." Here, the DOH conceded that it could no longer conduct an audit of petitioner's 1998 reimbursement rate.

In sum, the Court held that the DOH could not rely on the common-law right of recoupment to circumvent its own regulatory time limitations, which established finality for a provider's reimbursement rates. Notwithstanding the usual deference given to an agency interpreting its own regulations, the DOH thus could not recoup petitioner's 1998 Medicaid reimbursement payments, which had become vested.

Appellate Division Holds Employees of Group Home Immune From Civil Liability for Reporting Alleged Sexual Abuse of Resident

Marilyn S., et al. v. Independent Group Home Living Program, Inc., et al., 73 A.D.3d 895 (2d Dep't 2010). Plaintiffs' son, a mentally challenged adult residing at Defendant group home, stated that his mother had sexually abused him. Three of the group home's employees, also individual Defendants, were present during the statement and reported it to their supervisor. The group home then reported the alleged sexual abuse to the Suffolk County Police Department, the Commission on Quality of Care and Advocacy (the "Commission"), and the Long Island Developmental Disability Services Office. An investigation by the Commission determined that the allegations were inconclusive.

Thereafter, Plaintiffs sued the group home and its employees to recover damages for defamation and intentional infliction of emotional distress in connection with the reporting of the sexual abuse allegations. The motion court granted Defendants' motion for summary judgment in part.

Citing *Mantis v. United Cerebral Palsy Association of Nassau County, Inc.*, 173 Misc.2d 778 (Sup. Ct., Nassau Co. 1997), the Appellate Division held that Plaintiffs' claims against Defendant and its employees for intentional infliction of emotional distress and defamation could not stand, as they were, by statute, immune from any liability for reporting the alleged sexual abuse. Social Services Law § 473-b provides that any person who in good faith believes that someone eighteen years of age or older may be an endangered adult or in need of protective or other services shall have immunity from any civil liability that might otherwise result by reason of making a report. Defendants established that the home and its employees acted in good faith in reporting the sexual abuse allegations, and Plaintiffs failed, in their opposition, to raise a triable issue of fact with regard to this issue.

The Appellate Division further held that Plaintiffs' claim for intentional infliction of emotional distress against Defendant employees for conduct other than reporting the alleged sexual abuse also could not stand. None of this other conduct alleged by Plaintiffs was, as a matter of law, "so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community."

Court Precludes Expert Testimony to Bolster Witness Credibility Based on Results of Functional Magnetic Resonance Imaging Test

Wilson v. Corestaff Services L.P, et al., 28 Misc.3d 425, 900 N.Y.S.2d 639 (Sup. Ct., Kings Co. 2010). Plaintiff sued her employment agency alleging that she was retaliated against after she reported inappropriate conduct by another employee at the work site. Defendants filed a motion *in limine* to preclude plaintiff's expert witness from testifying regarding the results of plaintiff's witness' Functional Magnetic Resonance Imaging ("fMRI") test, which is akin to a polygraph test. Plaintiff opposed the motion and cross moved for a *Frye* hearing concerning the results of the fMRI test. Essentially, plaintiff sought to use the fMRI test to bolster the credibility of a key witness in this case.

The motion court granted defendants' motion *in limine* to exclude the testimony of plaintiff's fMRI expert, and denied plaintiff's motion for a *Frye* hearing.

In reaching its decision, the court followed well-established New York jurisprudence and the principles set forth in *Frye v. United States*, 29 F. 1013 (Ct. App. D.C. 1923), which provide that expert testimony is proper only if it is based on scientific principles, procedures or theory, and after the principles, procedures or theories have gained general acceptance in the relevant scientific field, proffered by a qualified expert and on a topic "beyond the ken of the average juror."

Applying *Frye* to this case, the court concluded that the opinion to be offered by plaintiff's expert is of a collateral matter, *i.e.*, the credibility of a fact witness based on the results of the witness' fMRI test. Because credibility is a matter solely for the jury and is clearly within the ken of the typical juror, the opinion of an expert is unnecessary and improper.

In addition, the court noted that there was no reported case in New York or the rest of the country which deals with the admissibility of the results of a fMRI test. However, the court found that even a cursory review of the scientific literature demonstrated the fMRI test has not been accepted in the scientific community as a reliable resource to show a person's past mental state or to gauge credibility.

Appellate Division Holds That Surrogate's Imposition of Monetary Limit on a Supplemental Needs Trust Was Abuse of Discretion

In re Estate of Woolworth, 76 A.D.3d 160, 903 N.Y.S.2d 218 (4th Dep't 2010). Petitioner, as administratrix of the estate of her husband ("decedent"), sought an order confirming the settlement of wrongful death suit, and approval of a supplemental needs trust ("SNT") to be funded by petitioner's share of proceeds from the settlement. The Surrogate's Court approved the settlement but denied funding the SNT with more than $100,000, as that would shelter available resources and make the government responsible to pay for petitioner's care.

Petitioner receives Medicaid benefits from the Oswego County Department of Social Services (DSS). Limiting the amount of the settlement proceeds to be placed in the SNT would render petitioner ineligible to receive Medicaid benefits. DSS consented to the establishment and terms of the SNT proposed by petitioner.

The Appellate Division concluded that the Surrogate abused his discretion in conditioning the approval of the SNT upon petitioner's agreement to limit the funding of the trust to $100,000. Accordingly, the court reversed the Surrogate's denial of the proposed SNT, and granted the petition in its entirety.

The court noted that an SNT "is a 'discretionary trust established for the benefit of a person with a severe and chronic or persistent disability' (EPTL 7-1.12[a][5]) that is designed to enhance the quality of the disabled individual's life by providing for special needs without duplicating services covered by Medicaid or destroying Medicaid eligibility." Specifically, the SNT is designed to "address the unique and difficult situation faced by severely disabled individuals with assets that are sufficient to end their Medicaid eligibility but insufficient to account for their medical costs." Under the pertinent statutes, 42 USC § 1396p (d)(4)(A) and Social Services Law § 366(2)(b)(2)(iii)(A), neither the corpus nor the income of an SNT is considered a resource or income available to the disabled trust beneficiary.

In reaching its decision, the court first analyzed whether petitioner satisfied the eligibility requirements for a SNT, and whether the trust documents were in conformance with the relevant statutory law and regulations. The court acknowledged that the federal and state legislation governing the establishment and operation of SNTs allows a disabled person under 65 years of age who receives a lump sum of money to maintain Medicaid eligibility by transferring the funds into an SNT, provided that, in exchange, the state is given a priority interest in the balance of the SNT upon the beneficiary's death.

Here, the court found that there was no dispute that petitioner was disabled and under 65 years of age, or that the proposed SNT was in conformance with the requirements of EPTL 7-1.12(a)(5) and provided the State of New York with the remainder interest described in Social Services Law § 366(2)(b)(iii)(A).

By limiting the funding of the SNT, the Surrogate ensured that petitioner would lose her eligibility for Medicaid, a result that is inconsistent with the public policy underlying SNTs and the Surrogate's function in approving and supervising their establishment. In addition, the court pointed out that none of the pertinent statutes or regulations supported a limitation upon the amount of money that may be used to fund an SNT, and none of the cases construing those statutes and regulations had in fact imposed such a limitation.

Appellate Division Dismisses Wrongful Life Claim

DeChico v. Northern Westchester Hosp. Center, 73 A.D.3d 838, 900 N.Y.S.2d 743 (2d Dep't. May 11, 2010). The plaintiff, a mother of a child born with a rare, congenital birth defect, asserted claims against defendants to recover damages for wrongful life, the extraordinary costs of the child's medical care, and for lack of informed consent. The plaintiff's claims were based upon allegations that the defendants failed to advise her of the significance of certain test findings, failed to order additional tests, and failed to advise her regarding the possibility of terminating her pregnancy.

The Appellate Division reversed the trial court's decision denying summary judgment and dismissed all of the plaintiff's claims. The court found that the wrongful life claim should have been dismissed and noted that "no cause of action may be maintained…for 'wrongful life,' *i.e.*, that [the child] would never have been born but for the negligence of the defendant" (internal citations omitted).

The court also held that the plaintiff could not maintain her claim for extraordinary costs of the child's medical care. To sustain this claim, the plaintiff was required to establish that the defendants' negligence deprived her of the opportunity to terminate her pregnancy. Central to the court's dismissal of this claim was its analysis of Penal Law § 125.05, which makes it unlawful to terminate a pregnancy after the twenty-fourth gestational week, unless the mother's life is in jeopardy. Here, the birth defect did not reveal itself in tests until after the twenty-fourth gestational week nor did it endanger the plaintiff's life. Therefore, the court determined that "any negligence on the part of the defendants did not

proximately cause the complained-of-damages."

Furthermore, the court also observed that the plaintiff failed to raise a triable issue of fact regarding "whether the defendant physicians had a duty to advise [her] as to the legality of late-term abortions in states other than New York."

Lastly, the court dismissed the plaintiff's lack of informed consent claim, reasoning that she did not allege that "defendants failed to obtain her informed consent in connection with the performance of any affirmative treatment or testing involving a violation of her physical integrity."

Appellate Division Affirms Dismissal of Medical Malpractice Action Against Hospital Under New York Mental Hygiene Law

Lawlor v. Lenox Hill Hosp., 74 A.D.3d 695, 905 N.Y.S2d 60 (1st Dep't June 29, 2010). A former patient of Lenox Hill Hospital ("Hospital") brought a medical malpractice action, alleging that the Hospital departed from good and accepted medical practice during the patient's three previous alcohol-related hospitalizations by failing to, among other things, psychiatrically evaluate the patient. A month after the patient's last hospitalization, he suffered an alcohol-related seizure, fell, and sustained permanent brain damage.

The Appellate Division upheld the lower court's decision, which granted summary judgment for the Hospital. The court observed that under New York's Mental Hygiene Law alcoholism is not considered a mental illness. Pursuant to this statute, the Hospital could not have involuntarily committed the patient solely for the treatment of his alcoholism. Therefore, the court found that the patient's expert had failed to raise an issue of fact to defeat the Hospital's motion for summary judgment.

The Appellate Division also noted that even if the Hospital had failed to properly examine or treat the patient during each hospitalization, it could not find that any of these alleged failures were the proximate cause of the patient's fall and resulting brain damage.

Appellate Division Holds That Peer Review Privilege Bans Discovery of Hospital's Medical Staff Credentialing Process

Stalker v. Abraham, 69 A.D.3d 1172, 897 N.Y.S.2d 250 (3d Dep't Jan. 21, 2010). Plaintiff brought a medical malpractice action against defendants, a hospital and a physician who was on its medical staff, alleging that the hospital knew or should have known that the physician was unfit to practice medicine but nonetheless allowed him to continue practicing. During discovery, the plaintiff sought to compel deposition testimony from a hospital representative regarding the hospital's medical staff credentialing process generally and specifically regarding defendant physician.

The Appellate Division affirmed the trial court's issuance of a protective order, which shielded the hospital from having to disclose information related to its medical staff credentialing process, and its decision to appoint and reappoint defendant physician. The court found that the issuance of the protective order was proper as the hospital had satisfactorily invoked the peer review privilege, which is described in Education Law § 6527(3) and Public Health Law § 2805-m.

To invoke the privilege, the hospital was required to show that it had a peer review procedure and that the information for which the privilege is claimed was obtained or maintained in accordance with that peer review procedure. Primary to the court's decision was the legislative policy underlying the peer review privilege, which supports "confidentially in order to encourage peer review [and] outweighs [a] plaintiff['s] need for evidence in order to prove [a] cause of action" (internal citations omitted).

The court also observed that the protective order did not completely foreclose plaintiff's ability to garner possible evidence in support of her claim. Any information obtained by the hospital beyond the bounds of the peer review and credentialing process which evidenced its knowledge of the physician's competence was discoverable. The court also remarked that the plaintiff here had already discovered evidence from public sources, which allegedly supported plaintiff's claim of the hospital's prior knowledge of the physician's alleged incompetence.

Physician's License Restricted for Failure to Keep Accurate Records

Bakshi v. N.Y. S. Dep't of Health, 71 A.D.3d 1233, 896 N.Y.S.2d 508 (3d Dep't 2010). Petitioner, a licensed physician, brought an Article 78 proceeding challenging the decision of the Administrative Review Board For Professional Medical Conduct ("ARB"), which, among other penalties, limited Petitioner's medical license to practice only in government licensed or government operated facilities because such facilities would ensure supervision and monitoring of Petitioner's practice of medicine.

The ARB's decision was based upon the Hearing Committee's findings that Petitioner was negligent and incompetent in his practice of medicine due to his failure to take adequate patient histories, and to keep accurate records and information regarding his referrals to another physician. The ARB found that Petitioner's failures were deficiencies in an essential diagnostic task.

The ARB agreed with the Committee's determination to suspend Petitioner's license for 18 months, and stay the suspension. The ARB, however, replaced the Committee's imposition of probation with a restriction that limited Petitioner's practice to only government licensed or government operated facilities because "such facilities would guarantee supervision and monitoring" of Petitioner's practice of medicine.

The Appellate Division affirmed the ARB's decision and held that, based upon the facts presented, the ARB penalty was not "so disproportionate to the offense that it [wa]s shocking to one's sense of fairness." The records showed that Petitioner failed to obtain and document the causes and effects of his patient's injuries, but instead used forms on which he merely checked off preprinted symptoms and boilerplate findings. The ARB felt Petitioner had also compromised coordination of patient care by failing to note his referrals to a pain management specialist and failing to maintain in the charts copies of the specialists' reports. The evidence provided a "rational basis" for the ARB's decision, and, given the nature of Petitioner's misconduct, was "not shocking to one's sense of fairness."

Compiled by Leonard Rosenberg, Esq. Mr. Rosenberg is a partner 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

As we prepare for a new Legislature in 2011, accompanied by a new Governor and Administration, we can anticipate a new dynamic health care agenda, much of which may relate to the implementation of federal health reform. While the Patient Protection and Affordable Care Act (PPACA) establishes a national framework, states play a key role in implementation of its proposals to expand coverage, to ensure access for the insured and uninsured and to enact payment and delivery system reform.

Background and fiscal context: Predicting how New York State might implement health reform would be a dangerous enterprise, at least as of late fall, 2010. Since many of the provisions of PPACA are phased in over several years and most will require some degree of federal regulatory clarification and implementation, certain elements of the federal health reform regime have not yet taken shape. Little definitive guidance has been provided by the federal government on many key provisions. At the same time, New York State officials are not yet in a position to provide definitive guidance on the shape of health reform, New York style. With a new Administration assuming the reins in Albany in January, many of the most significant policy decisions must await the arrival of the Cuomo team and the appointment of the key policy makers with responsibility for health care and health insurance issues.

Meanwhile, New York State is in the grips of what may be its worst fiscal crisis. New York State officials have already complained that the $1 million provided by the federal government to aid in the establishment of the required health insurance exchange will not be sufficient. Thanks to rounds of state layoffs and early retirement incentives, we have witnessed the departures of a whole

generation of State employees, including key and longstanding leaders within the Department of Health and the Insurance Department, as State government continues to downsize. The absence of State resources and a depleted State workforce—and an irretrievable loss of institutional memory—will make implementation that much more challenging.

Health Care Reform Advisory Committee: On August 31, 2010, Governor Paterson established an Advisory Committee to assist the relevant state agencies (referred to as the State's "Health Care Reform Cabinet") to provide guidance to the Administration on the implementation of PPACA and to ensure "stakeholder and public engagement in all aspects of federal health care reform." To augment the Advisory Committee's efforts, seven work groups have been convened to address the following issues:

- Health Benefit Exchange
- Commercial Market Reforms
- Public Health Insurance Programs
- Outreach and Enrollment
- Cost Containment / Delivery System Reforms
- Public Health
- Long Term Care

As of this writing, the full Advisory Committee has held two meetings and the workgroups have yet to convene, but were expected to begin meeting before the end of the year.

Key issues for New York State: While the answers may not be forthcoming for a while, some of the most important questions to be answered have become clear. A very abbreviated list of some of the more significant policy decisions would include the following:

The Health Insurance Exchange: By January 1, 2014, the State must establish a Health Insurance Exchange, through which individuals and employers may purchase health insurance coverage. The Exchange will act as a portal that will link purchasers to health insurance options. Small employers and small groups will be able to access coverage through the Exchange at its inception; the State may allow larger employers (those with more than 100 employees) to utilize the Exchange beginning in 2017. Among the issues that the State will have to resolve are the following:

- Will the Exchange be an active purchaser of insurance, a clearinghouse or a selective contracting agent?
- How will the Exchange define small and large groups and how and when will employer groups access insurance through the Exchange?
- Should there be one statewide Exchange or Regional Exchanges?
- What standards—relating to marketing, benefit and network adequacy, and quality improvement—will be imposed through the Exchange?
- How will the costs of the Exchange—which must be self-sustaining after 2015—be financed?
- How will the Exchange enable easy navigation of health insurance benefits through its consumer outreach and enrollment practices?

Benefit Issues: The coverage offered through the Exchange must satisfy a federally mandated "Essential Benefits Package," the bare outlines of which are contained in PPACA but are to be further defined by the HHS Secretary in a manner equal to the typical coverage provided by employers and that does not discriminate on the basis of age, disability or expected length of life. PPACA requires, at a minimum, coverage of ambulatory patients services, emergency services, inpatient care, maternity and newborn care, mental health and substance abuse services, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services, and pediatric services, including vision and oral care. While somewhat broad, benefits are still substantially less extensive than existing New York State health insurance benefit mandates—which include, for example, chiropractic care, eating disorder treatment, infertility treatment, and home health care. If, however, the State mandates benefits beyond the federally prescribed Essential Health Benefits, it will be required to defray cost of such mandates—a requirement that will be very difficult for New York to satisfy.

The key issues, then, are:

- Will New York simply accept the Essential Benefits Package as is?
- If not, which benefits will New York State be prepared to require—and to pay for?

Similar issues will arise under Medicaid: Newly enrolled mandatory Medicaid enrollees will receive a "benchmark benefit package" that must, at a minimum, satisfy the statute's "essential benefit package" but may be less generous than the current Medicaid benefit. The State will have to decide:

- Will the newly enrolled Medicaid enrollees be able to avail themselves of home health care and long-term care services, dental and vision care, emergency medical transportation and various other services that have long been part of Medicaid coverage?
- Will the State establish a Basic Health Program for persons with incomes between 133% and 200% of FPL and legal immigrants (otherwise ineligible for five years from enrolling in Medicaid) with incomes below 133% of FPL and, if so, what benefits will be available to these enrollees?

Reconciling PPACA with State Law requirements: A host of the federal health reform provisions may require some fine-tuning of pre-existing New York State requirements. As just one example, under PPACA, tax-exempt hospitals will be required to satisfy new federal community needs assessments (effective two years after the date of PPACA's enactment) and financial assistance policies (effective in the first taxable year post-enactment). The community needs assessment must be conducted every three years and must lead to the implementation of a strategy to meet unmet needs identified by the assessment. Hospitals must also implement a financial assistance policy that defines eligibility for free or discounted care, that limits charges for emergency and medically necessary care for uninsured patients to lowest amounts charged to insured patients and that precludes engaging in aggressive collection practices until assessing whether the patient qualifies for financial assistance. These provisions are very similar to, but slightly different from, existing New York State law requirements on hospitals that mandate a community services plan (PHL § 2803-l) and that require collection and financial aid policies as a condition for receipt of indigent care payments (PHL § 2807-k(9)). While nothing compels the State to take action, making the two varying sets of requirements compatible would seem to be a good idea.

Regulation of Accountable Care Organizations: One of the most significant system reforms involves creations of Accountable Care Organizations to coordinate and manage care. Early indications from CMS and from accrediting entities, such as NCQA, suggest that the development of ACOs will require a structure, quality assurance activities and information systems that may be comparable to what is required to operate a managed care organization—and how these entities will be regulated by the States remains to be seen.

Other payment and health system reforms: The federal act establishes a new Center for Medicare and Medicaid Innovations, which appears to be the focal point of the more systemic reform initiatives and has been appropriated $10 billion to spend over the next decade in efforts to enhance quality and "bend the cost curve." How New York State will seek to access these resources or mirror its activity remains to be seen: among the many other recommendations offered by Lt. Governor Ravitch on reforming the Medicaid program was a recommendation to establish a similar CMI at the State level.

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In the New York State Agencies

By Francis J. Serbaroli

Minimum Standards for the Form, Content and Sale of Medicare Supplement Insurance

Notice of adoption. The Department of Insurance amended Parts 52, 215, 360 and 361; and addition of Part 58 to Title 11 N.Y.C.R.R. to conform the regulations with the requirements of federal law. Filing date: April 20, 2010. Effective date: May 5, 2010. *See* N.Y. Register May 5, 2010.

Chemical Analysis of Blood, Urine or Saliva for Alcoholic Content

Notice of emergency rulemaking. The Department of Health amended Part 59 of Title 10 N.Y.C.R.R. in order to update technical standards for blood and breath alcohol testing conducted by law enforcement. Filing date: April 23, 2010. Effective date: April 23, 2010. *See* N.Y. Register May 12, 2010.

APG

Notice of emergency rulemaking. The Department of Health amended Subpart 86-8 of Title 10 N.Y.C.R.R. in order to make refinements to Ambulatory Patient Group (APG) methodology, including provisions for reimbursement of out-of-state providers. Filing date: May 3, 2010. Effective date: May 3, 2010. *See* N.Y. Register May 19, 2010.

Personnel Health Amendments and Medicare Conditions of Participation

Notice of adoption. The Department of Health amended sections 405.3, 405.9, 405.10, 415.26, 751.6, 763.13, 766.11 and 793.5 of Title 10 N.Y.C.R.R. in order to allow but not require facilities to use FDA-approved Blood Assay for TB testing in place of the tuberculin skin test, etc. Filing date: May 13, 2010. Effective date: June 2, 2010. *See* N.Y. Register June 2, 2010

Early Intervention Program

Notice of adoption. The Department of Health amended Subpart 69-4 of Title 10 N.Y.C.R.R. in order to make several changes to the standards for the provision of services in the Early Intervention Program. Filing date: May 18, 2010. Effective date: June 3, 2010. *See* N.Y. Register June 2, 2010.

HIV Uninsured Care Program

Notice of adoption. The Department of Health amended Subpart 43-2 of Title 10 N.Y.C.R.R. in order to receive and expend funds to provide medications, medical treatment and other supportive services to persons with HIV disease through the HIV Uninsured Care Program. Filing date: May 18, 2010. Effective date: June 2, 2010. *See* N.Y. Register June 2, 2010.

APG Methodology

Notice of adoption. The Department of Health amended Subpart 86-8 of Title 10 N.Y.C.R.R. in order to modify existing APG transition provisions for new providers and the listing of APG reimbursable and non-reimbursable services. Filing date: May 18, 2010. Effective date: June 2, 2010. *See* N.Y. Register June 2, 2010.

Environmental Testing for Critical Agents Using Autonomous Detection Systems (ADS)

Notice of adoption. The Department of Health amended Subpart 55-2 of Title 10 N.Y.C.R.R. in order to establish standards for certification of environmental labs using new technologies to analyze samples for critical agents. Filing date: May 28, 2010. Effective date: June 16, 2010. *See* N.Y. Register June 16, 2010.

APG Outpatient Rate Setting Methodology

Notice of adoption. The Department of Health amended Subpart 86-8 of Title 10 N.Y.C.R.R. in order to refine APG payment methodology regarding new APG weights, new procedure-based weights and minor changes in APG payment rules. Filing date: June 8, 2010. Effective date: June 23, 2010. *See* N.Y. Register June 23, 2010.

Palliative Care Certified Medical Schools and Residency Programs

Notice of adoption. The Department of Health added Part 48 to Title 10 N.Y.C.R.R. in order to define palliative care certified medical schools and residency programs to award grants according to PHL, section 2807-n. Filing date: June 8, 2010. Effective date: June 23, 2010. *See* N.Y. Register June 23, 2010.

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

Notice of adoption. The Office of Mental Health amended Part 577 of Title 14 N.Y.C.R.R. to reduce the growth of Medicaid reimbursement for licensed Article 31 private psychiatric hospitals. Filing date: June 8, 2010. Effective date: June 23, 2010. *See* N.Y. Register June 23, 2010.

Revisions to Certificate of Need (CON) Process for Threshold Levels

Notice of adoption. The Department of Health amended Parts 405, 410, 420, 600, 703, 705, 709 and 710 of Title 10 N.Y.C.R.R. to constitute the first phase of regulatory changes as part of the Department's review of the CON process. Filing date: June 22, 2010. Effective date: July 7, 2010. *See* N.Y. Register July 7, 2010.

State Aid for Public Health Services: Counties and Cities

Notice of adoption. The Department of Health amended Parts 40 and 42 of Title 10 of the N.Y.C.R.R. in order to achieve cost savings and to clarify eligible services for reimbursement of Article 6 of the Public Health Law for public health services. Filing date: June 22, 2010. Effective date: July 7, 2010. *See* N.Y. Register July 7, 2010.

State Aid for Public Health Services: Counties and Cities Reimbursement to Municipalities per PHL Article 6 for Home Health Services

Notice of adoption. The Department of Health amended Parts 40-1 and 40-3 of Title 10 of the N.Y.C.R.R. in order to achieve cost savings and to clarify eligible services for reimbursement of Article 6 of the Public Health Law for home health services. *See* N.Y. Register July 7, 2010.

Clinic Treatment Programs

Notice of adoption. The Office of Mental Health added Part 599 to Title 14 N.Y.C.R.R. to establish standards for the certification, operation and reimbursement of clinic treatment programs servicing adults and children. Filing Date: June 29, 2010. Effective Date: October 1, 2010. *See* N.Y. Register July 14, 2010.

Residential Health Care Facility (RHCF) Bed Need Methodology

Notice of adoption. The Department of Health amended section 709.3 of Title 10 N.Y.C.R.R. in order to update and expand the applicability of the RHCF bed need methodology. Filing date: July 6, 2010. Effective date: July 21, 2010. *See* N.Y. Register July 21, 2010.

Circulating Nurse Required

Notice of adoption. The Department of Health amended section 405.12 of Title 10 N.Y.C.R.R. to require Registered Nurses (RNs) to be assigned and physically present in the operating room when surgery is being performed. Filing Date: July 13, 2010. Effective Date: July 28, 2010. *See* N.Y. Register July 28, 2010.

Operation of Residential Treatment Facilities for Children and Youth

Notice of adoption. The Office of Mental Health amended Part 584 of Title 14 N.Y.C.R.R. to continue the existing capacity of Residential Treatment Facilities Serving Children and Youth who are residents in NYC. Filing Date: July 20, 2010. Effective Date: August 4, 2010. *See* N.Y. Register August 4, 2010.

Operation of Psychiatric Inpatient Units of General Hospitals and Operation of Hospitals for Persons with Mental Illness

Notice of adoption. The Office of Mental Health amended Parts 580 and 582 of Title 14 of N.Y.C.R.R to update provisions that reflect outdated statutory references, nomenclature, practices or principles. Filing Date: July 20, 2010. Effective Date: August 4, 2010. *See* N.Y. Register August 4, 2010.

Mental Health Services—General Provisions; Community Based Service System for Children of Outpatient Programs

Notice of proposed rule making. The Office of Mental Health gave its notice of intent to amend Parts 501, 507, and 587 of Title 14 N.Y.C.R.R. to add a definition for "serious emotional disturbance." *See* N.Y. Register August 4, 2010.

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

Notice of emergency rulemaking. The Department of Health amended Part 59 of Title 10 N.Y.C.R.R. in order to update technical standards for blood and breath alcohol testing conducted by law enforcement. Filing date: July 22, 2010. Effective date: July 22, 2010. *See* N.Y. State Register August 11, 2010.

Certified Home Health Agency Program

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend section 505.23 of Title 18 N.Y.C.R.R. in order to repeal provisions of the Department's home health services regulations that are obsolete due to expired statutory authority. *See* N.Y. Register August 18, 2010.

Rate Methodology for Non-Public Hospitals to Ensure Access for All Medicaid Patients Requiring Language Assistance

Notice of expiration. The State gave notice that a Department of Health Notice regarding rate methodology for non-public hospitals to ensure access for all Medicaid patients requiring language assistance expired and cannot be reconsidered unless the Department of Health publishes a new notice of proposed rulemaking in the N.Y. Register. Proposed date: August 5, 2010. Expiration date: August 5, 2010. *See* N.Y. Register August 25, 2010.

Prior Approval for Quality and Appropriateness

Notice of adoption. The Office of Mental Health amended Part 551 of Title 14 N.Y.C.R.R. to make minor technical corrections and clarify the intent of the regulation. Filing Date: August 18, 2010. Effective Date: September 8, 2010. *See* N.Y. Register September 8, 2010.

Hospital Inpatient Reimbursement

Notice of emergency rulemaking. The Department of Health amended Subpart 86-1 of Title 10 N.Y.C.R.R. to modify current reimbursement for hospital inpatient services due to the implementation of APR DRGs and rebasing of hospital inpatient rates. Filing date: August 31, 2010. Effective date: August 31, 2010. *See* N.Y. Register September 15, 2010.

Lead Poisoning Control—Environmental Assessment and Lead Hazard Control

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend Subpart 67-2 of Title 10 N.Y.C.R.R. to create consistency with Federal regulations and guidelines on environmental assessment and lead hazard control. *See* N.Y. Register September 15, 2010.

Hospital Minimum Standards and Appropriateness Review

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend sections 405.6, 405.7, 405.19 and 708.5 of Title 10 N.Y.C.R.R. in order to decrease look-back period for credentialing from 10 to 5 years; extend the physician coverage time for EDs from 20 to 30 minutes. *See* N.Y. Register September 29, 2010.

Post Anesthesia Evaluations at Free-Standing and Hospital Off-Site Ambulatory Surgery Centers (ASCs)

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend section 755.6 of Title 10 N.Y.C.R.R. in order to authorize those individuals who can administer anesthesia in Free-Standing and Hospital Off-Site ASCs to do post anesthesia evaluations. *See* N.Y. State Register September 29, 2010.

Consumer Directed Personal Assistance Program

Notice of proposed rulemaking. The Department of Health gave notice of its intent to add section 505.28 to Title 18 N.Y.C.R.R. to establish regulations for the administration and operation of the Consumer Directed Personal Assistance Program (CDPAP). *See* N.Y. Register September 29, 2010.

Standards of Construction for Health Care Facilities

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend of Parts 711, 712, 713, 714, 715 and 716 of Title 10 N.Y.C.R.R. to update and clarify construction and physical environment standards for hospital, nursing home and certain ambulatory care facilities. *See* N.Y. Register September 29, 2010.

Financial Statement Filings and Accounting Practices and Procedures

Notice of emergency rulemaking. The Department of Insurance amended Part 83 (Regulation 172) of Title 11 N.Y.C.R.R. to update the regulation to conform to NAIC guidelines, statutory amendments, and to clarify existing provisions. Filing date: September 14, 2010. Effective date: September 14, 2010. *See* N.Y. Register September 29, 2010.

Audited Financial Statements

Notice of emergency rulemaking. The Department of Insurance repealed Part 89 and added a new Part 89 (Regulation 118) to Title 11 N.Y.C.R.R. in order to implement provisions of Insurance Law, section 307(b), and add provisions required pursuant to the Federal Sarbanes-Oxley Act of 2002. Filing date: September 21, 2010. Effective date: September 21, 2010. *See* N.Y. Register October 6, 2010.

Expedited Partner Therapy to Treat Chlamydia Trachomatis

Notice of adoption. The Department of Health added section 23.5 to Title 10 N.Y.C.R.R. in order to allow use of expedited partner therapy to treat the partner of persons infected with Chlamydia Trachomatis. Filing date: September 28, 2010. Effective date: October 13, 2010. *See* N.Y. Register October 13, 2010.

Potentially Preventable Readmissions

Notice of emergency rulemaking. The Department of Health added section 86-1.37 to Title 10 N.Y.C.R.R. to implement a revised reimbursement policy related to hospital readmissions that are determined to be potentially preventable. Filing date: September 29, 2010. Effective date: September 29, 2010. *See* N.Y. Register October 20, 2010.

Ambulatory Patient Groups (APGs) Payment Methodology

Notice of emergency rulemaking. The Department of Health amended Subpart 86-8 of Title 10 N.Y.C.R.R. to refine the APG payment methodology. Filing date: September 29, 2010. Effective date: September 29, 2010. *See* N.Y. Register October 20, 2010

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 serves on the Executive Committee of the New York State Bar Association's Health Law Section. **The assistance of Whitney M. Phelps and Caroline B. Brancatella of Greenberg Traurig's Health & FDA Business Group in compiling this summary is gratefully acknowledged.**

New York State Fraud, Abuse and Compliance Developments

Edited By Melissa M. Zambri

NOTE—The *Health Law Journal* is pleased to introduce this new regular column, and to welcome Melissa M. Zambri to our roster of columnists—The Editor, NYS Bar Association *Health Law Journal*.

New York State Department of Health OMIG Audit Decisions

Compiled by Eugene M. Laks

Rite Aid of New York, formerly d/b/a Eckerd Corporation Store 10839 (DOH administrative hearing decision dated July 7, 2010, John Harris Terepka, Administrative Law Judge)

In a setback for the OMIG, the use of the extrapolation methodology to extrapolate to the universe of claims from findings of overpayments in an audit sample in a pharmacy audit was reversed by the ALJ. The ALJ held that the failure of the OMIG to provide the formula methodology to the provider deprived the provider of a full opportunity to exercise its right to challenge the validity of the methodology. This is the only case in New York where a provider's challenge to extrapolation of audit findings was sustained. The OMIG had withdrawn various sample audit findings prior to the hearing. The remaining contested findings were sustained and the audit recovery was reduced from $600,250 in the Final Audit Report to $433.

Lemberg Home & Geriatric Institute (DOH administrative hearing decision dated January 19, 2010, Frederick Zimmer, Administrative Law Judge)

In this case, the ALJ sustained OMIG audit findings that the provider owed with interest over $400,000 in Medicaid overpayments resulting from Medicaid claims by the nursing facility for reserved bed days that did not meet documentation standards acceptable to the OMIG. In an earlier case on nursing facility bed-hold reservations, *Metropolitan Jewish Geriatric Center* (DOH administrative hearing decision dated November 4, 2009, William J. Lynch Administrative Law Judge), the ALJ reversed the audit findings as contrary to the Department of Health policy and regulations regarding documentation requirements in effect during the audit period.

In the *Lemberg* case, the ALJ observed that "[H]ad Lemberg responded in a timely manner to the Draft Audit Report, preserved its issues, and presented relevant documentation and / or testimony, a different outcome may have been justified in this matter." The ALJ also noted that Lemberg was in the process of closing down and had limited, if any, resources.

New York State Attorney General Press Releases

Compiled by Charles Z. Feldman

North Country Nursing Home—Nurses Arrested For Patient Abuse—1/15/10

Two Employees of an Elizabethtown, New York Nursing Home face charges for failing to seek timely medical care for an elderly patient who started to bleed after a routine catheter change. The nurses were charged with misdemeanors including reckless endangerment in the second degree, endangering the welfare of an incompetent and physically disabled person and willful violation of the health laws for allowing the bleeding to continue for hours after the catheter change.

Licensed Practical Nurse, Queens Rehabilitation Center for Patient Abuse and Stealing of Medication—4/22/10

A Medicaid Fraud Control Unit investigation that commenced at a Queens rehabilitation center following the disappearance of prescription narcotics led to charges of both larceny and patient abuse. The investigation revealed that the licensed practical nurse took between 21 and 24 percosate pills from a resident of the Rehabilitation Center. Moreover, as a result of this investigation, a video surveillance tape was discovered revealing that this same nurse knocked a resident out of her wheelchair, causing a broken hip, and then left the injured resident on the floor until she was found by another employee. The nurse faces a maximum seven (7) years incarceration.

Drug Manufacturer Settles Multi-State Claim Involving Off-Label Drug Marketing and Illegal Kickbacks—4/27/10

Drug manufacturer AstraZeneca paid a settlement relating to its marketing and promotion of Seroquel for unapproved uses. Seroquel is an anti-psychotic medication but AstraZeneca targeted not only psychiatrists but also primary care physicians to "advise" the company about how to market the drug. The Company paid the physicians to ghostwrite articles and to conduct studies regarding the unapproved uses of the drugs. Part of the promotional activities included all-expense-paid trips to resorts for the physicians. The Company was alleged to have violated the anti-kickback statute, as well as regulations regarding drug manufacturers

that prevent a manufacturer from promoting a drug for a use that is not approved by the FDA, and agreed to pay a fine of $45 million.

Provider of Services for Children With Special Needs Pleads Guilty to Scheme to Steal Hundreds of Thousands of Dollars from Business—5/20/10

The former CEO and CFO of a non-profit provider of services for children with developmental disabilities were charged for writing checks to a family owned business. The CEO was sentenced to four weekends in jail, five years of probation and $350,000.00 in restitution, and the CFO was sentenced to 6 months in jail, five years of probation and $128,000.00 in restitution. The Attorney General's Office stated that self-disclosure from the current administration of the non-profit brought this matter to the Attorney General's attention.

New York Dentists Charged For Giving Referral Fees to Recruiters and for Fee-Splitting Issues—6/2/10

MFCU filed a civil complaint and a criminal complaint alleging that a Brooklyn dental practice paid individuals to hand out flyers to encourage Medicaid recipients to receive dental care. The complaint also alleged that two of the owners of the practice are not dentists, leading to charges of improper fee splitting. The practice had many dentists involved with it and the investigation continues.

Allegations of Falsification on Physician's Application to Become a Diagnostic and Treatment Center—6/10/10

A dermatologist settled a whistleblower lawsuit that alleged that he falsely obtained a certification that his practice was a "diagnostic treatment center" and not merely a dermatologic practice. The Complaint alleged that this change substantially increased his rate of Medicaid reimbursement. In violation of the terms of the application for approval to be a "diagnostic treatment center," the practice remained primarily a dermatological practice, leading to a $2.75 million settlement with the Attorney General's Office.

Home Health Care Agency and Ambulette Service Company Were Run by a Disqualified Individual and Pay $44,000,000 in Restitution—7/14/10

A physician who has been excluded from the Medicaid program since 1997 pleaded guilty to larceny for running two companies that collected at least $44 million from Medicaid. The disqualified physician allegedly created and owned various shell corporations including a construction company which he used to collect payments from Medicaid, and he also directed funds from a home health care agency for his personal use.

Personal Care Assistants Jailed for Medicaid Fraud—7/15/10

A mother-daughter team of personal care assistants ("PCAs") were sentenced for fraudulently billing Medicaid. The PCAs billed Medicaid while they traveled overseas and admitted to billing Medicaid by signing time sheets for care that was never provided. The mother was sentenced to one year and the daughter sentenced to ten days, and the family paid $105,768.00 in restitution.

Guilty Plea in Western New York for a Hospital Debt Collecting Company for Bribery—7/19/10

A hospital debt collecting company pleaded guilty to bribing a Niagara County DSS employee in exchange for Medicaid client identification numbers that allowed the Company's hospital clients to unknowingly obtain reimbursement for Medicaid claims that would not otherwise be paid. The owner and operator of the Company faces up to seven years in prison and a fine of $10,000.00 or twice the amount of the Company's gain from the crime, whichever is greater.

Licensed Practical Nurse Arrested for Conspiring to Bill Medicaid for Services That Were Not Provided—7/22/10

The mother of a sick child and a licensed home health aide were arrested in a scheme to bill Medicaid for $32,000.00 of services that were never provided. The investigation, part of the Attorney General's "Operation Home Alone," showed that the licensed practical nurse was not present at the home for the hours she billed Medicaid.

New York State Office of the Medicaid Inspector General Update

Compiled by the Editor

- Joint Release—Manhattan U.S. Attorney Charges Nine Members of Oxycodone Distribution Ring—Doctor-Led Drug Ring Allegedly Distributed Approximately 11,000 Oxycodone Pills Purchased with Close to $1 Million in Medicaid Funds—August 12, 2010
- OMIG Compliance Webinar #2: Mandatory Reporting of Medicaid Overpayments Under the Obama Health Program—July 14, 2010—Still Available on the OMIG Website—covered responsibilities under the Patient Protection and Affordable Care Act to "report and return" overpayments
- OMIG Compliance Webinar #1: Addressing Excluded Persons in Medicaid Employment, Ordering and Contracting—June 8, 2010—Still Available on the OMIG Website—covered New York State and federal laws governing exclusion and provided examples of several exclusion cases
- Press Release—April 26, 2010—New York State Recovers Nearly $450,000 in Restitution as a Result of Pharmacy Fraud—Joint Investigation

with FBI, OMIG and NYC HRA Lead to Recovery

- Press Release—April 5, 2010—Office of the Medicaid Inspector General to Recover More Than $270,000 from Long Island-Based Pharmacy for Filing False Claims for Deceased Patients in Nursing Home
- Press Release—March 24, 2010—Three Podiatrists and a Pharmacy Owner Arrested on Health Care Fraud Charges

Corporate Integrity Agreements with the New York State Office of the Medicaid Inspector General

Compiled by the Editor

- Lawrence D. Jaeger, D.O., Advanced Dermatology of New York, P.C.—5/28/10—Physician
- FOBRA Dental—1/15/10—Dental Providers
- Medical Answering Services—12/22/09—Transportation
- Extended Nursing Personnel CHHA—12/16/09—Home Care
- Excellent Home Care Services—12/16/09—Home Care
- B & H Healthcare Services, d/b/a Nursing Personnel—12/16/09—Home Care

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Compiled by the Editor.

For Your Information

By Claudia O. Torrey

The following information highlights items of interest:

- On October 7, 2010, Judge George Steeh of the United States District Court for the Eastern District of Michigan[1] delivered the opinion on the first case to address the merits of whether or not the "minimum coverage requirement" in the Patient Protection and Affordable Care Act of 2010[2] ("ACA") is unconstitutional. Declaring the requirement constitutional, some of the issues addressed by Judge Steeh included the Commerce Clause, the overall Health regulatory scheme as it relates to adverse selection, and the justification of the ACA via the potential use of Congress' taxing and spending power.

  The minimum coverage requirement provides that beginning in 2014, if you are not covered by health insurance from your job and are not eligible for Medicare or Medicaid; if you do not have a religious objection to having health insurance or belong to a health care sharing ministry; if you have been uninsured for 3 months or more; if you are not Native American; if you earn more than the tax filing limit (currently $18,700 for a couple); if you can find a health insurance policy for less than 8 percent of your income; and if it does not otherwise cause you a hardship, you must purchase a basic, high cost-sharing health insurance policy or pay a tax penalty. If you do not pay the penalty, you cannot be criminally prosecuted and the IRS cannot place a lien or levy on your property. Tax credits will also be available to help many of those subject to the mandate (a small minority of Americans) to purchase the required insurance.[3]

- The American College of Physicians ("ACP") and Cientis Technologies have teamed up and launched an interactive website to help medical entities select, compare, and implement electronic health record technology; use of the website is currently free. The goal of the site is to be a resource as healthcare professionals attempt to qualify for "meaningful use" funds from the federal government. The American Health Information Management Association is a website partner; other participants include some vendors, the Society of General Internal Medicine, and the American Osteopathic Association of Medical Informatics.

  The "Hospital Compare" website, overseen by the federal Center for Medicare and Medicaid Services, has been expanded to include eleven new coordination of care outpatient measures, as well as updated 30-day mortality / readmission information concerning: heart attack, heart failure, and pneumonia.[4]

Endnotes

1. http://www.mied.uscourts.gov/News/Docs/09714485866.pdf.
2. Pub.L.111-148, 124 Stat.199 (2010) [as amended by the Health Care and Education Reconciliation Act, Pub. L. 111-152, 124 Stat. 1029 (2010)].
3. Timothy Jost, http://healthaffairs.org/blog/2010/10/08/a-victory-for-health-reform-and-good-law/.
4. *See* www.healthleadersmedia.com.

Claudia O. Torrey, Esq. is a member of the Health Law Section and is a sustaining member of the New York State Bar Association.

Payment and Delivery System Reform—

An Excerpt from Implementing Federal Health Care Reform: A Roadmap for New York State

Prepared for the NYS Health Foundation by Patricia Boozang, Melinda Dutton, Alice Lam and Deborah Bachrach

ACA includes pilots and demonstration projects intended to test and rapidly deploy new care and payment models that reduce health care costs and improve quality of care for Medicaid and Medicare beneficiaries, dual eligible New Yorkers, and by virtue of their broad application across the health care delivery system, all consumers of health care in New York State. Several of these new initiatives are centered on state Medicaid programs, and many require or encourage active state partnership with care providers. These new opportunities for states to drive value in the health care delivery system through reducing unnecessary costs and improving clinical outcomes will require high-level strategy, planning, implementation infrastructure, and nimble evaluation and deployment capacities at the state level.

The newly created CMS Center for Medicare and Medicaid Innovation (described below) will oversee the implementation and evaluation of the demonstration projects at the Federal level and the HHS Secretary has been given new authority to expedite the expansion of programs. But, states will be responsible for on-the-ground deployment and evaluation, and ultimately will have a key role in identifying effective models of care delivery and deploying them across multiple providers and payers. Additionally, because many of the demonstrations required by ACA involve multiple care providers across the continuum of care and introduce new payment methodologies, states—including New York—will face significant implementation challenges.

Following is an overview of key programs providing significant funding opportunities for New York.

MULTI-PAYER DELIVERY SYSTEM REFORM INITIATIVES

The ACA creates two new Federal entities charged with driving health care reimbursement and delivery system reform in both Medicaid and Medicare.

Center for Medicare and Medicaid Innovation (§ 3021)

ACA provides $10 billion over 10 years to establish by January 1, 2011 a new Center for Medicare and Medicaid Innovation (CMI) within CMS. CMI's charge is to develop, evaluate, and where warranted, expand innovative payment and delivery system models that reduce Medicare and Medicaid expenditures while preserving or enhancing quality of care. CMI will focus on populations for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The law requires the CMI to consult with representatives of relevant Federal agencies and clinical and analytical experts in medicine and health care management to carry out its duties. CMI is also directed to use open door forums or other mechanisms to seek input from interested parties. The new law outlines 20 patient care and payment reform innovation models for CMI's consideration, but authorizes the HHS Secretary to select additional or alternative pilots that would advance the goals laid out above. The models are designed to support the development and use of medical homes, coordinated care strategies, and more effective post-acute hospital services, with a particular focus on comprehensive and salary-based payment structures as alternatives to fee-for-service based reimbursement. These models would incentivize professional and institutional collaborations, encourage the use of evidence-based standards, and allow greater flexibility to reward innovation. In addition, states would have the flexibility, by working with CMI, to integrate care for "dual eligibles," or individuals who are covered by both Medicaid and Medicare, by assuming the management and oversight of both Federal funds for Medicare and Medicaid services, as well as state funds for services covered by Medicaid and other state-based programs. States would also have the flexibility to test and evaluate all-payer systems of reform.

Federal Coordinated Health Care Office (§ 2602)

For better integration of service delivery and payment mechanisms for dual eligibles, ACA directs the establishment of the Federal Coordinated Health Care Office within CMS to facilitate a working relationship between Medicare and Medicaid at the Federal level and Medicaid offices at the state level. The new office is specifically charged with ensuring that these beneficiaries have better access to all services to which they are entitled and improved quality of health care and long-term care services. Specific responsibilities of the Coordinated Health Care Office include:

- providing states and other relevant parties with education and tools for developing programs that align Medicare and Medicaid benefits for dual eligibles;

- supporting state efforts to coordinate and align acute and long-term care services for dual eligibles with other Medicare benefits;
- supporting coordination of contracting and oversight by the states and CMS;
- consulting and coordinating with the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC);
- studying the provision of drug coverage for new full-benefit dual eligibles; and
- monitoring and reporting total expenditures, health outcomes and access to benefits for all dual eligibles.

MEDICAID DELIVERY SYSTEM REFORM OPPORTUNITIES

The ACA establishes several new Medicaid-related demonstration projects, grant programs, and state options. Several of these new opportunities will become available on January 1, 2011, and some have the potential to bring new Federal funding to New York State. For each of these new projects and funding opportunities, New York State faces significant tactical work that must be managed, including:

- strategic analysis, request for proposals (RFP) submission (and potential State-level RFP creation or application process development for state providers);
- harmonization of regulations and possible legislative changes, most notably with respect to licensure and rate setting requirements;
- data collection; project monitoring and evaluation; and
- broad, rapid expansion across Medicaid, CHPlus, and possibly a Basic Health Program, of those efforts likely to yield a positive return on investment.

Further, the State faces a range of implementation issues. Most significantly, New York must determine how these program innovations can be implemented within—or coordinated with—the State's Medicaid managed care program and existing demonstration projects, including the State's Medical Home Demonstration. New York's immediate task will be to consider how these new program opportunities may influence current operations and planning, with an eye to demonstrating readiness and leveraging current operations to attract new funding as these initiatives are implemented at the Federal level.

Payment Adjustment for Health Care-Acquired Conditions (§ 2702)

Effective July 1, 2011, ACA prohibits state Medicaid programs from paying for services that relate to health care-acquired conditions (HACs)—preventable conditions resulting from treatment in a hospital.[1] The Secretary is charged with promulgating regulations that define HACs based on Medicare definitions and current state practices. New York is one of only 12 states to have implemented a statewide "never event" program in Medicaid to prohibit payment for HACs, and will likely need to cross-walk HAC regulation with its existing "never event" policy in Medicaid and align state policy with new Federal regulations, as required.

Elective Demonstration and Pilot Opportunities

State option to provide health homes for enrollees with chronic conditions (§ 2703)

Beginning on January 1, 2011, states will have the option to amend their Medicaid state plans to create health homes for people with chronic conditions who are covered by Medicaid, including dual eligibles. This demonstration is designed to promote a coordinated, team-based approach to providing health care to individuals with multiple, chronic illnesses.

Through the demonstration, eligible consumers select a provider or a team of health care professionals as their health homes. The designated provider or team health home would provide comprehensive care management; care coordination and health promotion; comprehensive transitional care, including appropriate follow-up, from inpatient to other settings; patient and family support; referral to community and social support services, if relevant; and, as feasible, use health information technology to link such services. Medicaid beneficiaries eligible for the demonstration include those who have:

- at least two chronic conditions;
- one chronic condition and at risk of developing another; or
- at least one serious and persistent mental health condition.

Qualifying providers would have to meet certain standards established by HHS, including demonstrating that they have systems and infrastructure in place to provide comprehensive and timely high-quality care either in-house or by contracting with a team of health professionals. Teams of providers could be freestanding, virtual, or hospital-based. They could also be community health centers, community mental health centers, clinics, physician's offices, or physician group practices. Designated providers would be required to report to the State on all applicable quality measures in the State Medicaid program.

ACA provides an enhanced match of 90% FMAP for all Medicaid costs for health home enrollees for the first two years of program operation. Small planning grants may also be available to states beginning in 2011.

The health home option has the potential to provide additional financial resources to Medicaid providers for coordinating care for Medicaid beneficiaries with chronic conditions. If New York opts to participate in the program, payment could be structured to fund a broader set of professional services and patient supports than are currently reimbursed in the fee-for-service Medicaid program. For its part, New York State Medicaid will seek a return on investment for the more expansive service and payment model in the form of quality improvement, better clinical outcomes, and long-term avoidance of acute, episodic care and related costs. Enhanced FMAP will bolster the State's ability to fund the new care model in the short term, but such funding will only be sustainable in the long term if the health home program has demonstrable success.

New York also has an existing patient-centered medical home program authorized by Chapter 58 of the Laws of 2009, which applies to providers that serve both Medicaid fee for-service and managed care enrollees. This program includes a financial incentive for providers who meet medical home standards, with the goal of improving health outcomes through better coordination and integration of patient care for individuals enrolled in New York Medicaid. The State Department of Health is in the process of implementing the initiative and recently received CMS approval to implement the program with office-based practitioners, FQHCs, and diagnostic and treatment centers (D&TCs).[2] The State chose to adopt medical home standards that are consistent with those of the National Committee for Quality Assurance's (NCQA's) Physician Practice Connections®—Patient-Centered Medical Home Program (PPC-PCMH™). While additional guidance is required from HHS regarding particulars of the ACA health home for enrollees with chronic conditions, the program promises to be a strong complement to New York's existing plans, and New York Medicaid's choice to model its medical home program around accepted national standards may make it easier to harmonize Federal program requirements.

STATE IMPLEMENTATION: CHART 20.
State Option to Provide Health Homes for Enrollees with Chronic Conditions

SUMMARY	ACA authorizes a new state plan option under which eligible Medicaid enrollees with chronic conditions, including dual eligibles, could designate a provider or health team as their health home. The health home would be responsible for providing comprehensive medical and care coordination services.
EFFECTIVE DATE	January 1, 2011: State option available and HHS may award planning grants to states for the purposes of developing a state plan amendment to create health homes.
FEDERAL FUNDING	▸ States opting to create the program would receive an enhanced match of 90% FMAP for two years.
	▸ The law allocates $25 million for small planning grants to help states intending to take the option. FMAP rules would apply.
RESPONSIBLE PARTIES	▸ CMS will issue guidance to states on the new state option.
	▸ Secretary of HHS is required to survey states and report to Congress.
	▸ New York State Department of Health.
	▸ New York State Legislature.
STATE IMPLEMENTATION TASKS/ISSUES	**Tasks**
	▸ Amend State Plan to provide health home services to chronically ill persons covered by Medicaid and articulate plan for tracking program outcomes.
	▸ Apply to HHS for planning grant and secure funding for State match.
	▸ Develop provider health home payment mechanism.
	▸ Develop mechanisms to segment eligible beneficiaries.
	▸ Establish a tracking mechanism for health home quality reporting.
	Issues
	▸ How will the program be integrated with New York's existing medical home program?
	▸ How will beneficiaries be segmented for health home participation from the Medicaid managed care and/or Medicaid fee-for service programs?

Pediatric Accountable Care Organization Demonstration Project (§ 2706)

Beginning on January 1, 2012 and through December 31, 2016, ACA establishes a new demonstration to allow pediatric providers to form Accountable Care Organizations (ACOs). ACOs represent a new category of contractors created by ACA that are able to share in program savings that result from using new patient care models that coordinate care. ACO requirements articulated in ACA include clinical and administrative systems needed to support evidence-based medicine, coordinated care—including the use of telehealth and other enabling technologies—and the ability to report quality and cost measures and to meet patient-centeredness criteria, such as the use of patient and caregiver assessments or the use of individualized care plans.[3] States may seek participation in this demonstration through an application process to be developed by the Secretary.

The Pediatric ACO demonstration opportunity raises significant implementation questions for New York where the vast majority of children covered by public health insurance are enrolled in either a Medicaid managed care or Child Health Plus plan. Roughly 20 health plans throughout the State receive capitated premium payments for managing and arranging care for more than 2 million children. A major challenge for New York with respect to pursuing the Pediatric ACO program would be how to integrate the program with the State's extensive managed care infrastructure, or whether plans themselves are not, in effect, ACOs.

Demonstration project to evaluate integrated care around a hospitalization (§ 2704)

ACA directs the Secretary to establish a demonstration project to evaluate the use of bundled payments in Medicaid for the provision of integrated care during an episode of care, including a hospital stay and concurrent physician services provided during hospitalization. The demonstration is effective on January 1, 2012 through December 31, 2016, and is limited to eight states to be selected by the Secretary through a competitive application process.

The Secretary is given authority to waive any Medicare or Medicaid provision of Title XI of the Social Security Act to accomplish the goals of the demonstration, ensure beneficiary access to acute and post-acute care, and maintain quality of care. A state selected to participate in the demonstration project may target the project to particular categories of beneficiaries, beneficiaries with particular diagnoses, or particular geographic regions of the State. A state selected to participate in the demonstration project must specify the one or more episodes of care the state proposes to address in the project, the services to be included in the bundled payments, and the rationale for the selection of such episodes of care and services. To participate in this program, New York would have to determine not only the service definition of bundled payments, but also how to cross-walk provider and beneficiary participation across both the fee-for-service and Medicaid managed care programs. The state would have to evaluate whether a managed care population demonstration should be conducted in partnership with Medicaid managed care plans or whether this demonstration would be tested in the fee-for-service program only.

Provider and Consumer Targeted Grant Programs to Support Medicaid Reform

Quality improvement technical assistance grants (§ 3501)

ACA authorizes technical assistance grants to provider organizations, provider associations, and other entities for the purpose of offering technical assistance to providers for quality improvement activities. Grants will be awarded based on applications. Federal funding must be matched by grantees at a ratio of $1 from the grantee: $5 from the Federal government.

Community health teams to support the patient-centered medical home (§ 3502 as modified by § 10321)

ACA establishes a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams (''health teams'') to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. Grantees must submit a plan for achieving long-term financial sustainability within three years, and incorporate prevention initiatives and patient education and care management resources into the delivery of health care that are integrated with communitybased prevention and treatment resources, where available, with a focus on chronic conditions.

Medication management for individuals with chronic diseases (§ 3503)

The HHS Secretary, acting through the newly established Patient Safety Research Center, is authorized to establish a program to provide grants for medication management services provided by licensed pharmacists and targeted to people with chronic illnesses. The goal of the grant program, which the HHS Secretary was directed to launch by May 1, 2010, is to improve the quality of care and reduce overall cost in the treatment of chronic diseases. New York has an existing pilot, called the medication therapy management program, which serves Medicaid beneficiaries with certain chronic illnesses. New York State's program appears consistent with the ACA initiative; New York may seek a grant to support and expand existing program operations.

Expansion of the Patient Navigator Program (§ 3510)

ACA also reauthorizes demonstration programs to provide patient navigator services within communities to assist patients with overcoming barriers to health services by coordinating health services and provider referrals, assisting community organizations in helping individuals receive better access to care, providing information on clinical trials, and conducting outreach to health disparity populations starting as early as 2010.

MEDICARE DELIVERY SYSTEM REFORM OPPORTUNITIES

The ACA also provides authority and funding for numerous Medicare grant and pilot programs to promote delivery system innovation.

Medicare Shared Savings Program/Accountable Care Organizations (§ 3022)

A new Medicare Shared Savings Program authorized by the ACA will be established in January 2012 to promote accountability for providing high-quality and efficient health care services to a defined population of patients. Through the program, Accountable Care Organizations (ACOs) that meet quality targets established by the Secretary will be able to receive savings that result from a reduction in the average per capita costs for an assigned population of Medicare enrollees compared to a target per capita rate established by the Secretary. A participating ACO must be willing to become accountable for the quality, cost, and overall care of its enrolled Medicare fee-for-service beneficiaries, and must participate in the program at least three years. Providers and insurers may seek participation in this demonstration through an application process to be developed by the Secretary.

Payment Bundling Pilot (§ 3023)

A five-year pilot program, the payment bundling pilot would create episode of care payments for acute care services provided to Medicare beneficiaries with one or more of 10 chronic conditions. Payments would include pre-admission services provided in the three days prior to hospitalization, hospital services, and 30 days of post-discharge services. Bundled services will be determined by the Secretary of HHS, but will include acute care, inpatient and outpatient physician services, outpatient care, home health, and long-term care. Provider organizations participating in the pilot will be required to submit data on quality measures that will be used to evaluate program efficacy.

Hospital Readmissions (§ 3025)

Effective October 1, 2012, Medicare will reduce payments to hospitals with high rates of readmissions for three high-volume, high-cost conditions when patients are admitted within 30 days of discharge. This reform to hospital reimbursement will require hospitals to implement or enhance community-based care transition efforts designed to reduce readmissions and avoid financial penalties.

Community-Based Care Transitions Program (§ 3026)

The ACA provides $500 million to establish collaborative partnerships between hospitals with high readmissions and community-based organizations. The program will encourage evidence-based care transitions services for Medicare beneficiaries at high-risk for hospital readmission. HHS will prioritize entities that serve medically underserved populations, small communities, and rural areas.

DUAL ELIGIBLES

The ACA includes provisions targeted to integrating and coordinating care for dual eligibles—generally low-income seniors and people with disabilities. Dual eligibles are the most medically complicated and expensive populations for both Medicaid and Medicare; yet, 80% of these beneficiaries receive their care through uncoordinated fee-for-service models.[4] Financial and administrative responsibility for dual eligibles care is fragmented, leading to significant access and quality issues for people who rely on both Medicare and Medicaid for services.

New York has approximately 650,000 dual eligibles enrolled in its Medicaid program, the second highest number of dual beneficiaries in the country after California. While dual eligibles represent just 16% of New York's Medicaid beneficiaries, they generate 40% of total expenditures, or $16 billion annually.[5] Nationally, more than half of Medicaid expenditures for dual eligible beneficiaries are related to long-term care services.[6] Several health insurance models operating in New York State are designed to integrate payment and coordinate benefits for dual eligible individuals. These programs include:

- *Medicaid Advantage*: a Medicaid managed care companion program to Medicare Advantage (Medicare managed care) that allows beneficiaries to enroll in the same health plan for most of their Medicare and Medicaid benefits, excluding long-term care.
- *Medicaid Advantage Plus*: a Medicaid Advantage program that covers long-term care services.
- *Program for All-Inclusive Care for the Elderly (PACE)*: a national managed care program for people who require long-term care, but wish to remain in their communities and receive adult day care services. PACE covers all medical needs for its enrollees.

Enrollment in these programs is voluntary and, to date, they collectively cover a relatively small number of New Yorkers: 8,574 or 1.3% of full dual eligibles in the State.[7] The balance of dual eligible individuals in New York is served through a Medicaid's fee-for-service program.

New York is in the early stages of developing a "Federal-State Medicare Shared Savings Partnership" waiver to seek Federal approval to allow the State to implement a series of demonstration proposals to integrate care for dual eligible New Yorkers, and share in the Medicare savings generated through these initiatives.[8] The State Legislature enacted law in June 2010 authorizing the State to develop the partnership program.

TABLE 19. New York State Programs for Dual Eligibles

PROGRAM	ENROLLMENT
Medicaid Advantage	5,639
Medicaid Advantage Plus	531
PACE	3,405

Source: New York State Monthly Managed Care Enrollment Report, May 2010

ACA provides a policy mandate and framework for CMS to drive integration and coordination of care for dual eligibles. The law provides opportunities for New York to make delivery system improvements for dual eligibles through enhanced Federal funding, technical support, and rapid deployment and testing of innovation. The changes in ACA appear to be aligned with New York's goals and objectives in its planned Federal-State Medicare Shared Savings Partnership waiver, and may enable the State to more rapidly deploy a strategy with respect to care and funding integration for dual eligibles.

Five-Year Period for Dual Eligible Demonstration Projects (§ 2601)

New waiver demonstration authority is created for states to conduct five-year waivers related to dual eligible beneficiaries under Social Security Act § 1115 Research & Demonstration Projects, § 1915(b) Managed Care / Freedom of Choice Waivers, § 1915(c) Home and Community-Based Services Waiver, and § 1915(d) Waivers. This provision authorizes dual eligible waivers to be conducted over longer periods of time to allow states to capture longer-term savings. These waiver programs are currently two- to three-year initial authorization periods, with a maximum three-year renewal.

Extension of Special Needs Plan (SNP) Program (§ 3205)

ACA extends SNP program authority through December 30, 2013 and allows HHS to apply a frailty payment adjustment to fully integrated, dual eligible SNPs that enroll frail populations. The law also requires dual eligible SNPs to contract with state Medicaid programs beginning 2013. Finally, ACA requires SNPs to be NCQA-approved.

LONG-TERM CARE

ACA includes several provisions targeted to making long-term care accessible and affordable and to shift care from institutional to community settings to the largest extent possible. The law creates the nation's first government–sponsored, long-term care insurance program, and provides authority and funding for a series of projects and pilot programs that develop, integrate, and pay for home- and community-based long-term care services. In 2009, long-term care spending in New York's Medicaid program was $12.3 billion, 28% of total Medicaid expenditures for the year.[9] New York has several programs and demonstrations that promote long-term care reform goals that are consistent with the goals of ACA. The State operates the Long Term Home Health Care Program (LTHHCP), a Social Security Act § 1915(c) Home and Community Based Medicaid waiver program serving seniors and individuals with disabilities who are medically eligible for nursing home care, but seek to remain in their communities. LTHHCP provides care coordination and supportive services through a network of contracted agencies. The program serves 24,000 individuals throughout the State.[10]

More recently, the New York State Department of Health launched several initiatives to reform the State's long-term care delivery system, including:

- The Nursing Home "Rightsizing" Demonstration: Allows nursing homes to convert beds to longterm care home health, adult day care and / or assisted living "slots." The agency is seeking CMS authority to expand the demonstration from 2,500 to 5,000 beds.
- County Long-Term Care Demonstration: A five-county demonstration to promote conversion of county nursing homes to alternative long-term care settings.
- Money Follows the Person Rebalancing Demonstration: Provides the State with $4.7 million annually in additional FMAP funding to assist individuals in avoiding long-term care institutionalization and transitioning from nursing home to community-based settings.

ACA includes a number of key long-term care provisions that align with and support New York's current approach to restructuring long-term care delivery, and provide new funding to expand LTC reform efforts in the State.

CLASS Program (§ 8001)

The health care reform law establishes a new, national and voluntary long-term care insurance program called the Community Living Assistance Services and Supports (CLASS). The program is designed to promote independent and community-based living for older adults and individuals with disabilities through financial assistance. Participants become eligible for the program after contributing premiums for five years (either directly or through payroll deductions initiated by an employer). Once eligible, participants will receive at least $50 per day paid, either daily or weekly, to support needs, including home modifications, assistive technology, accessible transportation, homemaker services, respite care, personal assistance services, home care aides, and nursing support. Institutionalized residents are eligible for the payment; all but 5% of the benefit will go toward payment of the institutional care. Individuals enrolled in Medicaid home- and community-based services, or the PACE program, will similarly be eligible for the payment; 50% of the payment will go to the State to cover the cost of care.[11] New York currently operates the Partnership for Long-Term Care, a program originally funded by the Robert Wood Johnson Foundation, which combines long-term care insurance and Medicaid Extended Coverage. Its purpose is to help New Yorkers financially prepare for the possibility of eventually needing nursing home care, home care, or assisted living services. The program allows New Yorkers to protect some or all of their assets (resources), depending on the insurance plan purchased, if their long-term care needs extend beyond the period covered by their private insurance policies. New York will likely seek to re-evaluate and possibly align or integrate its current Partnership for Long-Term Care program with the new Federal CLASS program.

Payment and Care Delivery Demonstration, Grant, and Pilot Programs

ACA provides new plan options and demonstration programs to encourage and incentivize State innovation in payment reform, and delivery system integration in long-term care and care for dual eligible beneficiaries. CMS will provide guidance on the structure of these programs. New York State will need to determine how it can best leverage these programs to support its existing and planned demonstrations, and maximize Federal funding for additional long-term care delivery system innovations.

Endnotes

1. A HAC is defined as "a medical condition for which an individual was diagnosed that could be identified by a secondary diagnostic code described in § 1886(d)(4)(D)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(4)(D)(iv))."
2. New York State Department of Health, Medicaid Update, Vol 26; No 7. May 2010.
3. § 3022.
4. Center for Health Care Strategies. Options for Integrating Care for Dual Eligible Beneficiaries. March 2010. Available at: http: / / www.thescanfoundation.org / sites / default / files / CHCS%20Options%20for%20Integrating%20Dual%20Eligible%20Care.pdf.
5. Kissinger, M. "New York State Department of Health Office of Long Term Care: 2010-11 Executive Budget Summary" Presentation at the New York State Public Welfare Association, January 27, 2010.
6. Kaiser Family Foundation. Kaiser State Health Facts. Distribution of Medicaid Spending for Dual Eligibles by Service (in millions), 2005.
7. Kaiser Family Foundation. Kaiser State Health Facts: New York State. Dual Eligible Enrollment, 2005. Full dual eligibles are defined as qualifying for full Medicaid benefits, including long-term care provided in both institutions and in the community as well as prescription drugs. For this group, Medicaid may also pay Medicare premiums and cost-sharing.
8. Kissinger, M. "New York State Department of Health Office of Long Term Care: 2010–11 Executive Budget Summary" Presentation at the New York State Public Welfare Association, January 27, 2010. Spending includes long-term care expenditures related to OMRDD related services.
9. Kissinger, M. "New York State Department of Health Office of Long Term Care: 2010-11 Executive Budget Summary" Presentation at the New York State Public Welfare Association, January 27, 2010.
10. Hokenstad, A., Shineman, M., and Auerbach, R. An Overview of Medicaid Long-Term Care Programs in New York, United Hospital Fund, April 2009.
11. Effective dates of this program vary. While tax treatment of the program begins January 1, 2011, HHS Secretary must design an eligibility assessment program by January 1, 2012.

This report was prepared in August, 2010 by Patricia Boozang, MPH, Melinda Dutton, JD and Alice Lam, MPA of Manatt Health Solutions and Deborah Bachrach, NYS Health Foundation Visiting Fellow, for the NYS Health Foundation.

***This report was originally published in August 2010 and is reprinted with permission of the NYS Health Foundation. The full report is available from the NYS Health Foundation and can be downloaded from the following link: http://www.nyshealthfoundation.org/userfiles/file/RoadmapPaper_Aug2010.pdf.**

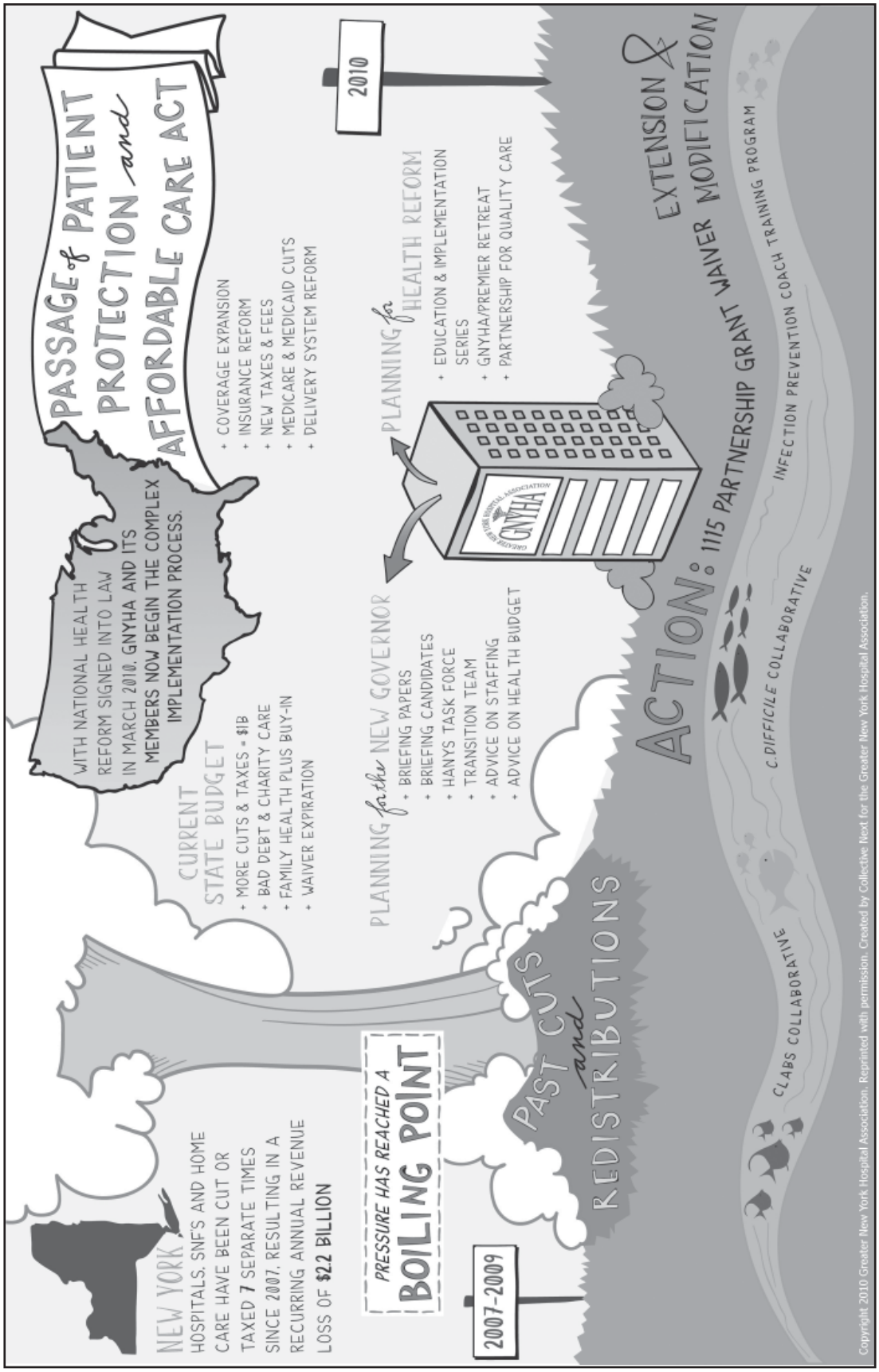
TABLE 20. New State Options and Demonstration Programs Related to Long-Term Care Available under Health Reform			
PROGRAM OPTION	**DESCRIPTION**	**NEW FEDERAL FUNDS**	**EFFECTIVE DATE**
Medicaid Community First Choice Option § 2401	State plan amendment option to provide coverage of home- and community-based attendant services and supports, such as assistance to accomplish activities of daily living, to those who meet the State's nursing facility clinical eligibility standards. Threshold issues for New York with respect this option include determining whether the State's current personal care program qualifies for reimbursement under this program.	6% FMAP increase	October 1, 2011
Home- and Community-Based Services State Plan Options § 2402	Provision simplifies home- and community-based services through a State plan option rather than pursuing more onerous Federal waiver authority. Provides a full range of Medicaid services to individuals whose income does not exceed 300% of the Supplemental Security Income (SSI) standard.	Regular match rate	April 1, 2010
Balancing Incentive Payments Program § 10202(a)	Expands and diversifies Medicaid coverage for home- and community-based long-term care services (HCBS) and makes structural changes to improve coordination and access to such services. Creates new financial incentives for states to shift Medicaid beneficiaries out of facilities and into HCBS. Only states with less than 50% of long-term care being provided in community-based settings will be eligible to participate in this program, with further guidance expected from HHS on the definition of "community-based." Whether New York will meet this threshold will depend on the definition of community-based long-term care, as well as the populations included in the calculation, pursuant to HHS guidance.	2–5% FMAP increase Allocates up to $3 billion for Medicaid home- and community-based services.	October 1, 2011 through September 30, 2015

TABLE 20. New State Options and Demonstration Programs Related to Long-Term Care Available under Health Reform

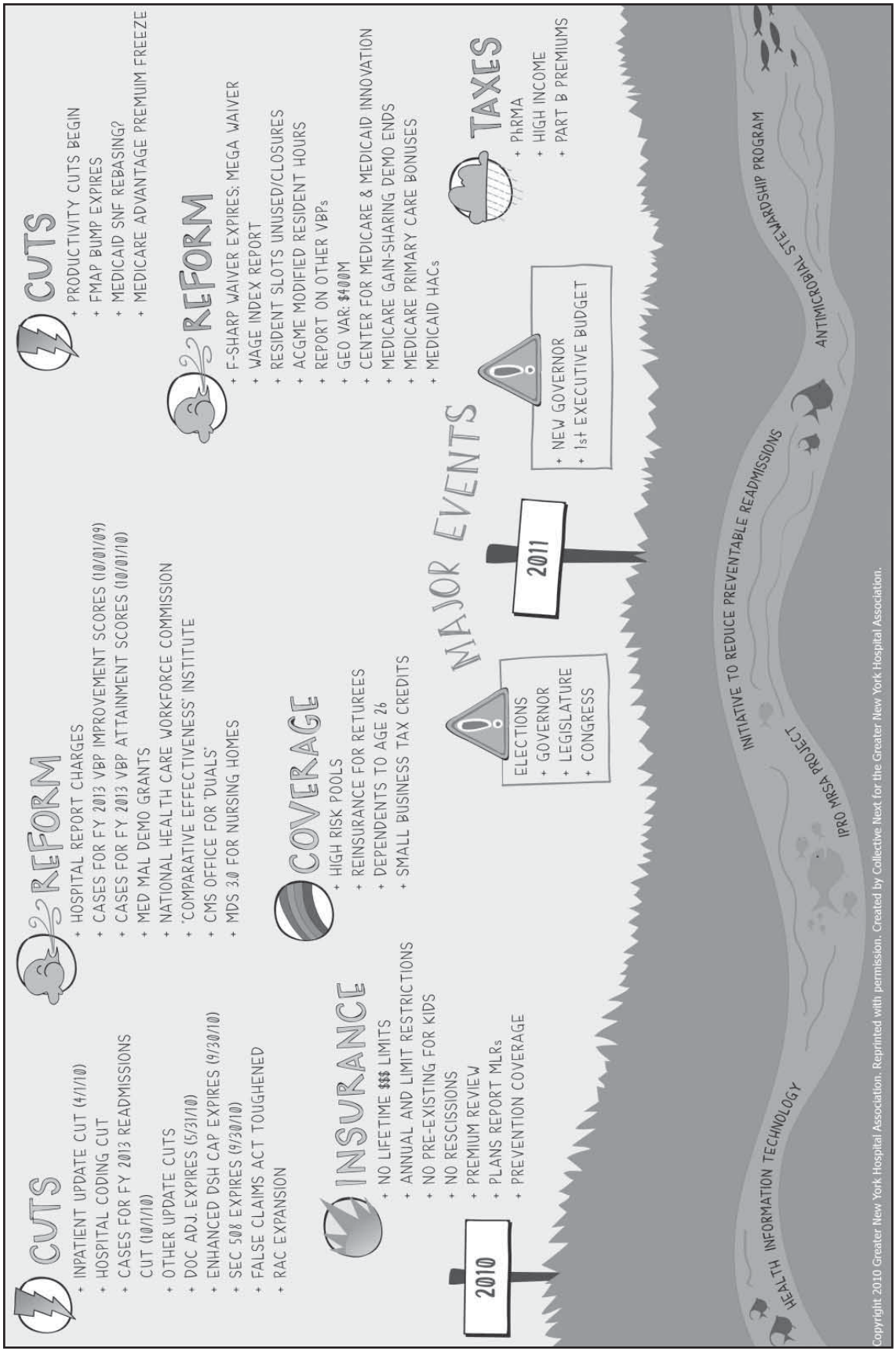
PROGRAM OPTION	DESCRIPTION	NEW FEDERAL FUNDS	EFFECTIVE DATE
(CONTINUED) Medicaid Money Follows the Person (MFP) Rebalancing Demonstration § 2403	Demonstration established through the Deficit Reduction Act of 2005 (P.L. 109-171) to reduce reliance on institutional care and develop community-based systems of care. ACA modifies eligibility rules to require that individuals reside in an inpatient facility for no fewer than 90 days. New York receives $4.7 million annually for the Nursing Home Transition and Diversion program, for the five-year project term from 2008–2012. The project aims to transition 2,800 individuals from institutional to community-based settings. On June 22, 2010, CMS released a State Medicaid Director letter that provides clarification and guidance on the MFP Demonstration Program. Benefits of the ACA MFP Demonstration Program provisions to states like New York that are already participating in the program include: Enhanced FMAP for home- and community-based services and demonstration services; use of the American Recovery and Reinvestment Act of 2009 enhanced FMAP rate as the base from which to calculate states' MFP-enhanced FMAP rate through December 31, 2010, subject to a 90% cap; technical assistance (TA) provided by CMS contracted experts in the long-term care; HCBS and demonstration services reimbursed at the enhanced MFP FMAP; supplemental services reimbursement for services only be available for the MFP Demonstration Program period and not covered by Medicaid; and full reimbursement for certain MFP Demonstration administrative costs, including key personnel; MFP travel, training, outreach and marketing; IT infrastructure to accommodate the MFP reporting requirements; and completing the Quality of Life survey requirements. CMS will post a grant solicitation in summer 2010 to www.grants.gov to offer states not currently participating the opportunity to apply for an MFP Demonstration Program Grant through a competitive award process.	ACA extends demonstration through September 30, 2016, bringing new aggregate Federal funding of $450 million each year for FY 2011–2016.	30 days after enactment of ACA (April 22, 2010)

Sources: Patient Protection and Affordable Care Act (P.L. 111-148) and Modifications by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152); The Scan Foundation, Policy Brief No. 2. March 2010.

2010 Health Care Reform, A Timeline
Greater New York Hospital Association



2010 Health Care Reform, A Timeline
Greater New York Hospital Association



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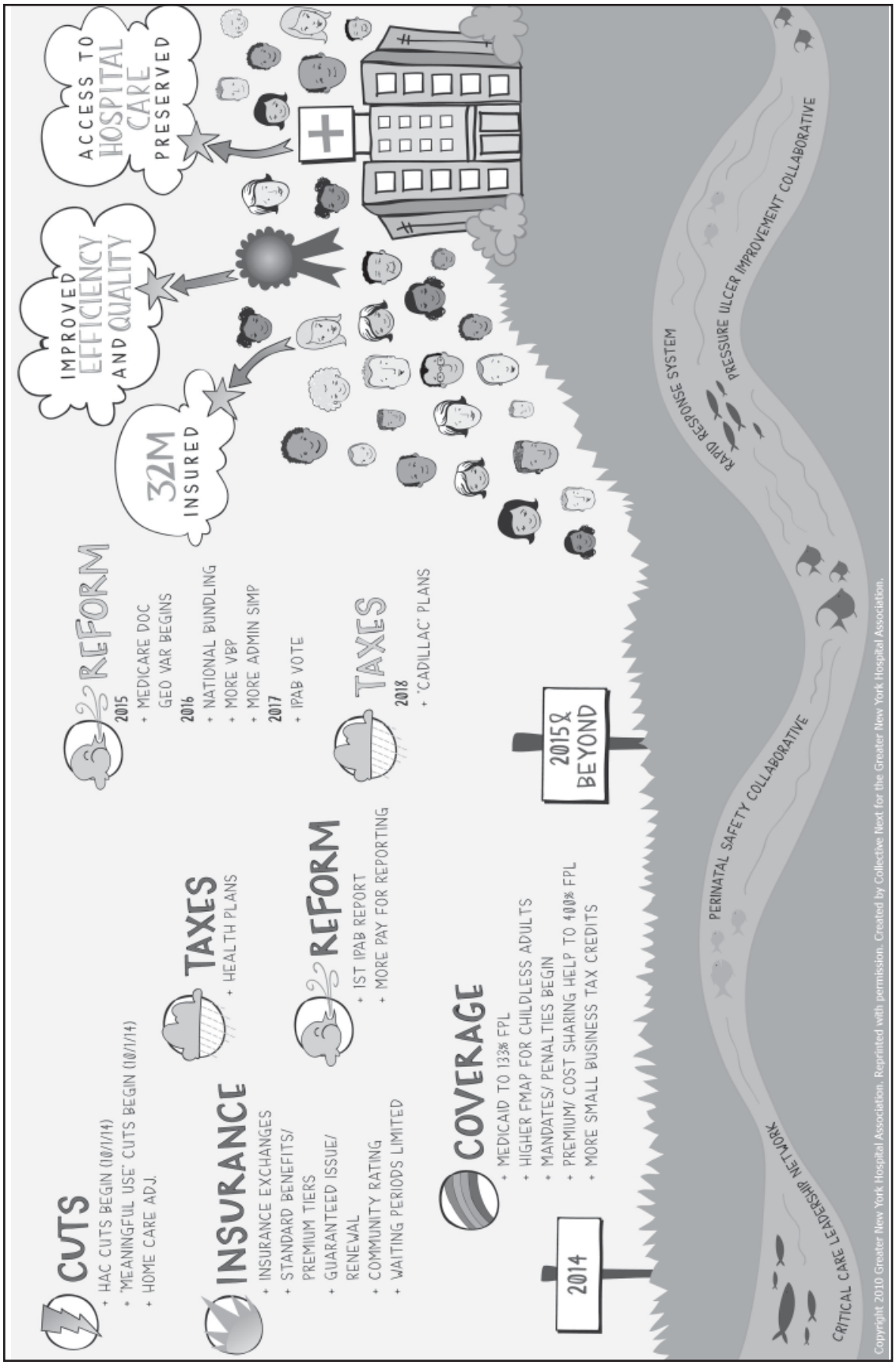

2010 OMIG Reform Legislation: "Wait'll Next Year"

By Brian T. McGovern

What is "OMIG"?

As health care lawyers, by now you or one of your clients has probably encountered the New York State Office of Medicaid Inspector General ("OMIG"), perhaps on more than one occasion and in more than one context. For a primer, OMIG was established by the New York State Legislature in 2006 with the statutory charge of (among other things) the "prevention, detection and investigation of fraud and abuse within the medical assistance [Medicaid] program."[1] OMIG's authority was further expanded to include oversight of the State's mandatory compliance program, requiring Medicaid providers to adopt and implement a comprehensive compliance program.[2] In furtherance of that authority, OMIG has promulgated regulations, codified at 18 N.Y.C.R.R. Part 521, which largely track the statutory language and establish the eight elements of an effective compliance program.

OMIG's powers over providers were again magnified by its adoption of a provider "self-disclosure" protocol in 2009 coupled with the mandate in the federal Patient Protection and Affordable Care Act ("PPACA"), enacted in March 2010, that providers disclose and refund overpayments within 60 days.[3]

OMIG Audits

To date, however, OMIG's greatest impact on the health care provider community has been felt through its recoveries and recoupments from Medicaid providers under the auspices of its statutory authority to "review and audit contracts, cost reports, claims, bills and all other expenditures of [Medicaid] program funds to determine compliance with applicable federal and state laws and regulations and take such actions as authorized by federal or state laws and regulations."[4] In its annual report for 2009, OMIG touted $500 million in audit recoveries in the fiscal year ending September 3, 2009—in excess of the $322 million it needed to meet the targets set forth in the Federal-State Health Reform Partnership ("F-SHRP") entered into between the State of New York and the Federal government in 2006. (F-SHRP, which expires on September 30, 2011, calls for the investment of $1.5 billion of federal dollars in New York State over a five-year period, to improve the efficient operation of the State's health care system.)

According to OMIG, last year, the office initiated 1,852 audits and completed 1,053 audits. OMIG's audits have reached just about every provider along the care spectrum—whether regulated by the Department of Health ("DOH"), the Office of Mental Health ("OMH"), the Office of Mental Retardation and Developmental Disabilities ("OMRDD") (now known as the Office of People with Developmental Disabilities), or any other State agency overseeing a program funded by Medicaid, plus individual Medicaid providers who billed Medicaid for professional medical services such as physicians.

While much press and public attention has been given to OMIG's role in ferreting out "fraud and abuse," including such notorious examples as billing for deceased patients, many if not most of its audit initiatives over the past four years have actually not been premised on allegations or findings of fraud. Rather, the more fruitful audit initiatives are those with the broadest reach among a given provider class, involving more common, prosaic lapses in documentation and technical errors in billing. The logic for that stratagem is straightforward: investigating, identifying, and proving fraud against specific bad actors (in my opinion, the exception rather than the rule) involves enormous staff and resources, with sometimes relatively modest financial recoveries. On the other hand, auditing provider compliance with documentation and other technical requirements is far less labor-extensive, and can often be done with little factual investigation—literally behind an auditor's desk. What is more, under OMIG's approach, those audit initiatives can yield 100% recoveries of Medicaid claims based on a single technical defect.

OMIG Audit "Process"

Providers have complained of the fundamental unfairness of OMIG's imposing such a severe penalty—*total* disallowance of a claim—for a single and arguably minor documentation or technical flaw, especially when, as is often the case, there is no issue that the services billed for were in fact provided and were medically necessary. Providers have also protested what some have characterized as "abusive" auditing practices, such as overbearing and burdensome document demands and the auditor's myopic focus on overpayments, to the exclusion of underpayments discovered in the course of audits.

In light of a groundswell of concerns raised by providers, the State's provider associations this past year advocated for legislation to reform the OMIG audit process and rein in some of the more egregious auditor conduct experienced by providers. Those efforts spawned two pieces of legislation, introduced in the Assembly and Senate this past Spring, that attempt to establish a greater degree of provider "due process" and fairness as well as proportionality of audit recoveries in the OMIG audit process.

Assembly Bill No. A10630 (Assembly Member Richard Gottfried, Sponsor)

On April 13, 2010, Assembly Member Richard Gottfried introduced Assembly Bill No. 10630 with the express intent to "balance the ability of the state to ensure the integrity of the [Medicaid] program with the need to afford due process to providers and recipients…in order to ensure that such actions are conducted in a fair and consistent manner," and to conduct audits and payment recoveries pursuant to "established statutory standards." Summarized below are some of the more salient reform measures included in Assembly Bill No. 10630:

- **Stay of OMIG audit recoupments pending the outcome of ALJ hearing requested by the provider**. Currently, OMIG can begin recouping audit adjustments 20 days after a final audit report has been issued, despite a provider's challenge of the audit findings through the administrative hearing process.[5]
- **10% cap on audit recoupments**. Under current practice, OMIG will typically recoup alleged overpayments at a rate of 15% of a provider's Medicaid receivables—so long as the provider timely requests repayment terms—but reserves the prerogative to recoup at a higher rate; no statute or regulation limits the percentage or amount of audit recoupments. The proposed 10% cap would apply to all OMIG audit recoupments except in the case of fraud, or when the provider and OMIG agree upon different terms.
- **No OMIG authority to audit cost reports or claims that "were the subject of a previous audit or review" by OMIG or another state or local agency completed within the prior three years**. This provision was intended to address the frequently cited complaint that OMIG is reauditing areas already covered in prior audits by OMIG or another state agency. Under this provision, OMIG could only audit the same issues reviewed in the past three years if OMIG's audit is based on new information, the prior review or audit was erroneous, or the scope of audit is significantly different.
- **Limit of scope of OMIG audits to three-year period**. Currently, there is no temporal limit on OMIG audits other than the six-year audit limitations period contained in 18 N.Y.C.R.R. § 517.3. This provision would limit the periods under audit to three years, except where fraud or intentional misconduct is alleged.
- **Standards for audit based on "laws, regulations, policies, guidelines, standards and interpretations" applied by the primary regulatory agency "in place at the time the subject claim arose or other conduct took place."** This provision addresses the concern expressed by many providers that OMIG is reinterpreting policies and even changing the "rules of the game" retroactively on audit, and in a manner contrary to the interpretations and understandings relied upon by providers based on contemporaneously communications and directives given by the primary regulatory agency, such as DOH or OMRDD. OMIG would now be required to apply on audit the regulatory agency's contemporaneous standards, and not its own *post-hoc* standards.
- **OMIG's respect for a prior "determination of compliance by a governmental agency with jurisdiction to make such a determination."** If the primary regulatory agency has already found the provider's cost reporting or billing practices to be compliant, this provision would bar OMIG from revisiting those practices and second-guessing the agency's determination, except when the prior determination was based on "misinformation, was clearly erroneous, or was effected by fraud or other intentional conduct."
- **OMIG duty to produce any "evidence that…that would support the allowability or propriety of the provider's cost reporting, billing or other practice or practices at issue in the hearing or is otherwise exculpatory."** This "due process" reform would require OMIG to turn over to the provider during the audit process, any documentary or other evidence OMIG possesses or discovers that might support the allowability of a disallowed cost or claim.
- **No authority for audit recoveries based on the "actions or the responsibility of another provider or governmental agency."** This provision would relieve a provider from liability on audit on account of regulatory lapses committed by another provider, except when the provider knew or should have known it was not entitled to claim payment.
- **Limit on OMIG audit recoveries to 10% of claim in the case of administrative or technical defects**. This provision embodies the notion that the remedies imposed by OMIG on audit should be "proportionate" to the nature of the regulatory violation. Specially, this measure would address providers' objection to OMIG's practice of disallowing a claim in full based on mere technical or documentation defects by limiting the amount of the recovery to 10% of the claim at issue, and only after the provider has been notified by OMIG of the alleged defect and given 60 days to correct the defect and resubmit the claim. In the case of a billing-

coding error, the recovery would be limited to the difference between the correct level of payment and the amount mistakenly paid to the provider. The 10% cap would not apply where there was intent to defraud the Medicaid program.

- **Limit on overpayment "extrapolations" to audit findings where "the category of error or defect in the billing or other practice…exceeds the rate of 5% within the sample of claims."** Many providers have complained about OMIG's reliance on sampling and extrapolation to convert what may be a handful of sampled claims found defective into a six-figure or larger audit liability by extrapolating, exponentially, from a sample 100 or 200 claims to a universe of claims in the tens or hundreds of thousands in the audited period. Before resorting to extrapolation, OMIG would have to find that the claimed error or defect identified in the sample was not an "outlier," but was at least prevalent enough to meet a base line threshold of a 5% error rate.
- **Written explanation of the extrapolation/sampling methodology**. This provision would require OMIG to furnish the provider with information in writing about the sample and the extrapolation methodology utilized by OMIG, in "sufficient detail to permit the provider to test and recreate the methodology in order to properly and fully defend any determination of overpayment which is based on [the extrapolation] process."
- **Provider refunds within 90 days, with interest**. This provision would achieve a modicum of balance and fairness between auditor and audited entity, by introducing reciprocity in the assessment of interest. Thus, if it is later determined by an ALJ or a court of law that the OMIG's audit findings were invalid, and its recoupments improper, OMIG would have to repay the recouped funds to the provider within 90 days of the invalidation of its audit findings, and pay interest on the recouped funds at the same rate that OMIG had charged the provider for the alleged overpayment.
- **Employment of OMIG auditors or contractors "with appropriate training, education or experience."** Providers have frequently complained that some OMIG auditors, particularly among the newer initiates, often lack experience or knowledge of cost reporting or billing practices, resulting in wasted time and effort on the part of the provider and staff in responding to unnecessary requests and producing extraneous information, educating them about basic cost-reporting or billing processes and, worse, having to address patently erroneous audit adjustments being considered by the auditors. Given the substantial stakes involved for the Medicaid provider and program alike, providers believe that it is critical that OMIG deploy auditors who are competent to perform the audits entrusted to them.
- **Rebuttal presumption that a provider's clinical records are valid**. This provision would give the benefit of the doubt to, rather than against, the provider, and would shift the burden to OMIG to effectively "impeach" a provider's clinical records when a disallowance or recoupment is based on alleged lack of medical necessity or otherwise involves clinical judgment or standards. Also, in no circumstance would disallowances based on any clinical findings serve as the basis for an overpayment extrapolation.
- **Effective Repeal of the 90-day claims submission rule**. Currently, under Social Services regulations (18 N.Y.C.R.R. § 540.6(a)), a provider must submit a claim for Medicaid reimbursement within 90 days of providing the services (with certain limited exceptions)—which has proven to be a formidable challenge for many providers, given the myriad reasons why a claim may not be ready for submission within that 90-day time frame. Nevertheless, OMIG has identified noncompliance with the 90-day billing rule and / or the exception codes for extending the 90-day period as the basis for disallowing claims on audit. This provision would permit the submission of Medicaid claims past the 90-day period for up to 2 years after the date of service.
- **Provider notice and 60-day period to cure alleged deficiencies in mandatory compliance program**. OMIG now possesses the authority to review mandatory provider compliance programs and sanction providers for failing to maintain an effective compliance program. Yet there is currently no requirement that OMIG notify the provider of any alleged deficiencies in its compliance program and afford it an opportunity to cure the deficiencies identified by OMIG, prior to the imposition of sanctions. This provision would "cure" that due-process shortcoming in the compliance review process.

Senate Bill No. 7821 (Senator Craig Johnson, Sponsor)

On the Senate side of the New York State legislative branch, Senator Craig Johnson introduced his own legislation (Senate Bill No. 7821) on May 13, 2010, incorporating much of the same or substantially similar reform measures included in Assembly Member Gottfried's bill. Among the salient additional provisions in Senator Johnson's bill are the following:

- **No OMIG authority to enforce provider operating standards and conditions of participation**. OMIG appears to hold the view that provider operating standards and conditions of participation, including programmatic, clinical, and quality of care standards, are in all cases subject to review and enforcement by OMIG as conditions of payment and, thus, fair game for disallowances and recoupments on audit. However, it is the primary regulatory agency that has the duty to ensure compliance with, essentially, its own promulgated regulations and operating standards. That compliance is reviewed and enforced through a host of enforcement mechanisms, such as licensure-revocation proceedings, patient-care surveys, and fines and sanctions for any noted clinical or operating deficiencies. This provision would remove OMIG's authority to also determine and enforce compliance with operating standards and conditions of participation as the basis for audit recoveries.
- **Confidentiality of compliance programs, reports, self-evaluations, audits and investigations, and corrective actions**. This provision would confer confidentiality on a provider's activities and deliberations undertaken as part of its compliance program, similar to the confidentiality that attaches to a hospital's quality assurance committee activities and deliberations. The rationale is the essentially same: to encourage self-reporting and self-examination of compliance issues and concerns and to thereby foster a robust and effective compliance program, the participants in the process should not have to worry that their activities and work product may be subject to disclosure and perhaps used against them as the basis for a civil action for damages or otherwise.

The Fate of OMIG Reform Legislation in 2010

Assembly Member Gottfried's and Senator Johnson's bills were each referred to the respective Health Committees in the Assembly and Senate and later conformed with each other, but were not included in the State's Budget Bill adopted in June 2010. I am no "sausage-maker," *i.e.*, a legislator or lobbyist, and do not know the events that led to the demise of these two bills. I understand that estimates of the fiscal impact of the legislation, in the range of $200 to $300 million, were being circulated. I do not know the sources for these estimates, and what portion is attributable to the effects of curbing or preventing some of the more problematic audit initiatives, premised on technical or documentation lapses, that the legislation sought to redress.

Maybe Next Year

In any event, OMIG reform legislation is expected to be revived and reintroduced in the upcoming 2011 Legislative session. The political landscape will have changed somewhat. New York State will have a new Governor, and control of the Legislature will be divided between Democrates (the Assembly) and Republicans (the Senate). What is more, the OMIG reform legislation will have lost is chief sponsor on the Senate side, Craig Johnson, who lost his bid for re-election in one of the closest electoral contests this past November. My understanding is that the provider associations still remain cautiously optimistic that, come next year, the OMIG reform legislation, or some modified version thereof, will become law. In the meantime, OMIG continues to audit and recoup Medicaid dollars unchecked by the reforms proposed in last session's legislation.

Endnotes

1. Public Health Law § 31 subd. 1.
2. Social Services Law § 363-d.
3. PPACA § 6402.
4. Public Health Law § 32 subd. 14.
5. 18 N.Y.C.R.R. § 518.8(a).

Uniform Plan-Provider Contracts: A Proposal to Reduce Expenses of Health Plans, Health Care Providers and the Public

By Robert N. Swidler

States, including New York, could significantly cut expenses by health plans, health care providers and the public by developing uniform plan-provider contracts without rate sheets, and requiring the use of those contracts by health plans and health care providers. Plans and providers would still negotiate reimbursement methodologies and rates, but all or most other terms would be prescribed. For some contractual matters the uniform plan-provider contracts could offer alternative terms, but with prescribed language for those alternatives. Parties could also add non-conflicting terms.

This approach would:

(i) dramatically reduce the currently significant expenditures by plans and providers in the review, negotiation and implementation of plan-provider contracts;

(ii) in New York, reduce the significant amount of NYS Department of Health (NYSDOH) staff resources devoted to reviewing such agreements,

(iii) reduce or eliminate unclear provisions, unfair provisions and non-compliant provisions that find their way into these contracts; and

(iv) make it possible for provider clinical and administrative staff to actually learn and follow requirements in plan-provider contracts, something they now cannot do when they are confronted with conflicting terms of many contracts,

(v) reduce interpretive disputes, through the development of interpretive precedents; and

(vi) help plans meet their medical loss ratio requirements under the federal health care reform law.

The potential benefit for the public is very significant. Uniform plan-provider contracts would offer a rare way to achieve significant health care savings with no diminution of quality of care or access to care. The proposal targets activity that is expensive and pervasive, yet adds little benefit for the public or the parties.

Plan-Provider Contracts

A contract between a health plan ("plan") and a health care provider ("provider") memorializes a simple bargain: the provider agrees to provide covered health care services to members of the plan, and the plan agrees to pay the provider for those services at an agreed-upon rate. Plan-provider contracts generally include two distinct parts: (i) contract terms other than rates of payment, which form the main body of the contract; and (ii) rates of payment, which usually are set forth in an appendix, sometimes called the "rate sheet."

The part of plan-provider contracts that sets forth terms other than rates of payment tends to address these topics, among others:

1. ***Definitions***—This section sets forth the definitions of key terms, including "covered service," "emergency" and "medically necessary."
2. ***Provider representations and obligations***—This usually states the provider's obligation to provide care (within provider's license) to plan members, as well as the obligation to comply with the plan's provider manual.
3. ***Plan representations and obligations***—This should state the plan's obligation to pay for services provided at the agreed-upon rates, an obligation that often is subject to the provider meeting various claims submission and other administrative requirements.
4. ***Compensation***—This sets forth the obligation of the plan to pay for covered services, and the obligation of the provider to accept as payment in full payment at the agreed-upon rate. (The rate itself typically is set forth in an appended rate sheet.) The clause may also describe the claims submission process, and the claims payment process.
5. ***Utilization review***—This sets forth requirements for prior approval of services and the process for appealing denials. Generally, it will also allow the plan to review claims retrospectively, conduct audits, and require repayment of alleged overpayments. It may also include provider rights to recover underpayments.
6. ***Coordination of benefits***—This states the rules that apply when a plan member has coverage by more than one health plan.
7. ***Constraints on provider billing members.*** This constrains the provider from billing a member in the event a claim for a covered service is denied, or in the event the plan (or another payor, if the plan acts as a third party administrator) fails to pay for some other reason such as insolvency.

8. ***Term and termination***—This specifies when the contract expires or can be terminated, and the responsibilities of the provider for continuing patient care in the event of termination.

9. ***Confidentiality requirements***—This addresses the need for the provider to secure consent from patients to release health information.

10. ***Dispute resolution***—This generally prescribes steps that must be taken to resolve disputes either prior to litigation, or in lieu of litigation (e.g., arbitration).

11. ***Amendments***—This describes how the contract may be amended, and may give the plan certain rights to impose amendments upon notice.

12. ***Miscellaneous/boilerplate provisions***—This includes such matters as requirements to maintain liability insurance, mutual indemnification, notification procedures, governing law, subcontracting and assignment rights, and third-party beneficiary rights.

13. ***Medicare Advantage plan addendum***—This sets forth provisions required by the Center for Medicare and Medicaid Services (CMS) in its contract with the plan.

To be sure, contracts may use different titles for these sections, or address them in different order or in various combinations. They may also include provisions addressing topics beyond these standard topics. But these topics and a few others form the core of plan-provider contracts in New York.

Increasingly, New York state statutes and regulations impose requirements that impact contract terms. For instance, prompt pay requirements narrow the ground for differences in clauses on the timing of payment.[1] Also, in New York, most plan-provider contracts are required to include "Standard Clauses for HMO and IPA provider Contracts"—a set of mandatory terms largely aimed at protecting the rights of patients in these arrangements.[2] The federal health care reform act will impose additional requirements, narrowing differences in other provisions.[3] But the growing realm of legal requirements has not reduced the need for constant, tedious, time-consuming, expensive drafting, review and negotiations over the provisions identified above, or for expensive disputes over the meaning of such customized terms.

The Development, Review, Negotiation and Implementation of Terms Other Than Payment

Generally a health plan will develop a series of standard contracts. It may need more than one contract both because it contracts with different types of providers (e.g., hospitals, physicians, home care) and because it offers different product lines (e.g., its commercial managed care plan, its third party administrator plan, its Medicare Advantage Plan). The development of these contracts by attorneys and health plan contracting departments requires significant administrative expenditures by plans.

In New York, managed care contract terms, and significant modifications of approved terms, must be approved by NYSDOH.[4] Accordingly the next step for the plan is to forward its contracts to NYSDOH for its review and approval—a process which may involve some back-and-forth with the plan.

The health plan will then send the applicable contracts to each health care provider that it seeks to include (or continue to include) in its network. The provider must then devote significant resources, including its contracting and/or finance staff and its in-house or outside attorneys, to carefully review the contract.

Then comes the hard part. A provider, if it has the resources and any negotiating ability, will identify provisions that are disadvantageous to it and seek to change them. For instance, it may object to a clause that would allow the plan to pay "the lesser of" negotiated rates or published charges. It may object to provisions that obligate it to comply with changes in the plan's "provider manual" but do not give the provider practical notice of such changes. It may object to a provision that allows the plan to amend the contract unilaterally, upon notice to the provider and the provider's failure to object within a notice period.

The plan and the provider will then have to devote significant resources to painstakingly negotiate each of the disputed terms. This process will require further time and effort of contracting staff and/or in-house or outside attorneys. If the negotiations result in significant modifications to the contract, it may be necessary for the plan to submit the modifications to NYSDOH again.

Once a plan-provider contract is agreed-upon and signed, variations among contracts will continue to impose expenses on both plans and providers. A provider will find it difficult to train its staff to understand and implement the requirements of the contract, which are likely to differ from the requirements in its contracts with other plans. A plan will find it difficult to learn and implement any unique changes that a provider secured through negotiations.

This burdensome process of contract development by a plan, contract review by NYSDOH, contract review by the provider, negotiation by both parties, approval of modifications by NYSDOH, and implementation of variations by both parties is not an isolated or occasional event. A hospital or health system will have to go through this same process with twenty, thirty, or maybe fifty or more contracts. A plan will to go through this process with

hundreds, perhaps thousands of contracts. Accordingly, plans and providers in New York are devoting enormous resources each year to developing, reviewing, negotiating, and striving to implement these contracts.

It is difficult to discern significant value to health plans, providers or the public from this activity. To be sure, in each individual negotiation, a plan or provider may gain some incremental advantage over the other party, or over competing plans or providers. But in the aggregate there is probably not a great deal of difference in these contract terms from plan to plan. The enormous resources devoted to this process could be spent more productively on the provision of health care, or not spent at all.

The Uniform Plan-Provider Contracts (UPPCs)

New York should consider developing a series of "Uniform Plan-Provider Contracts" (UPPCs) and mandate their use by health plans and health care providers. These contracts would accomplish wholesale what is now being done retail at enormous transactional expense. Specifically, state-mandated uniform contracts would reduce expenditures:

- by plans for contract development
- by the NYS Department of Health for contract review
- by providers for contract review
- by plans and providers for contract negotiations
- by plans and providers for implementation of unique terms
- by plans and providers, in interpretive disputes

Plans and providers would continue to negotiate rates, as well as other terms that do not conflict with the UPPC terms.

The process for developing UPPCs. It is not difficult to envision a process to develop UPPCs in New York. The most straightforward approach would be for NYSDOH or the NYS Insurance Department (NYSID) or both, after securing authorizing legislation, to develop UPPCs and promulgate them as regulations. But health plans, health care providers, and consumer groups may question the ability of those agencies to recognize and protect their interests when performing this task. A better approach would be for the empowered state agency to convene a task force, with representatives of health plans, health care providers, and consumers, to develop and propose draft UPPCs to the agency. The Task Force should require a consensus, or at least a supermajority, before recommending any draft UPPC. Thereafter the agency could consider those recommendations and, if it agrees, mandate the UPPC by regulation. Participation by competing plans and competing providers in this process would likely be protected from antitrust exposure under the Noerr-Pennington doctrine, which protects persons who advocate for laws and regulations even if the laws and regulations would have an anticompetitive effect.[5]

The process of developing a series of complete UPPCs may be long and difficult. However, it will not take very long, or be very difficult for a UPPC Task Force to agree upon discrete, simple clauses, and achieve some quick accomplishments. For example, if the UPPC Task Force were to agree upon a coordination of benefits clause, by that step alone it would free up enormous resources now required to draft, review, negotiate and implement these clauses (which, incidentally, are especially taxing to read). A standard Medicare Advantage Addendum should also be a relatively easy, noncontroversial task that will reduce custom drafting, review and negotiation work. With each new series of agreed-upon clauses, the Task Force would remove more costs, and come closer to achieving the goal of creating complete UPPCs. The UPPC Task Force could continue to meet to review and recommend modifications to UPPCs as necessary.

Alternative uniform clauses. In many instances, it will be reasonable to offer the contracting parties alternative uniform clauses. For example, the UPPC could allow the parties to choose between a compensation clause that requires payment at "the rates set forth in Appendix A" or an alternative clause that requires payment "at the lesser of the rates set forth in Appendix A or provider's published charges." Even if a UPPC were to offer choices such as this, it would still achieve most of the advantages noted previously: it would relieve the parties of drafting and reviewing unfamiliar language. The presence of optional clauses would create some additional items for negotiation, but the negotiation would be greatly simplified: the choices would be fixed, limited and clear. And as a result, the parties would be better able to recognize the financial implications of each alternative, and the relationship between the selection and the negotiated rates.

Need for legislation. Legislation would be necessary to facilitate the development and implementation of UPPCs. Even if DOH or SID could claim regulatory authority to convene task forces and create UPPCs, they clearly do not have the authority to mandate the exclusive use of such contracts.

Judicial interpretation. Currently, a court decision that interprets a disputed clause in a plan-provider contract has little precedential value; it is not relevant to other contracts that have different terms. But a court decision interpreting a disputed clause in a UPPC will operate as a precedent, and reduce the potential for future disputes and lawsuits on that same term.

Through this process, plans and providers would be liberated from the expensive, low value task of developing, reviewing, negotiating, implementing, and disputing the meaning of plan-provider contract terms.

Possible Objections to UPPCs

Various objections to UPPCs can be anticipated.

1. *UPPC terms would unduly favor plans or unduly favor providers.* Both health plans and providers are apt to fear that the process described above will result in contracts that are unfavorable to them. But the UPPC Task Force process would provide ample protection against contracts that are skewed toward one side or the other—especially if it requires a consensus or supermajority for recommendations. Moreover, the value of standardization would more than make up for the presence of provisions that are less-than-optimal from a plan or provider's standpoint.

2. *Opposition to government interference in plan-provider negotiations.* Persons who oppose any increase in government involvement in health care will object to this proposal, because it undeniably increases government involvement in what are now private negotiations. But those willing to look beyond mere form will see that in this instance government will be helping the parties achieve their own aims more efficiently, which coincides with the public interest in reducing health care costs. This is similar to government's role in mandating electronic data interchange protocols for plans and providers.[6] It is even more closely akin to state government's role in adopting uniform commercial codes, which benefit both sides in private contracting.[7] And like the uniform commercial code, the UPPC leaves untouched the heart of the commercial negotiation—rates of payment. In this regard, this proposal is wholly unlike a call for the return to NYPHRM,[8] where the state displaced the very heart of plan-provider negotiations by setting commercial rates of payment for providers.

3. *Health care reform will eliminate the need for UPPCs.* The Patient Protection and Affordable Care Act (PPACA)[9] strives in many ways to push plans and providers away from contracting on a fee-for-service basis, and toward other reimbursement mechanisms that reward providers for value. A key delivery model envisioned to achieve this shift is the accountable care organization (ACO), a collaboration of providers who strive to control costs and improve quality of care for a defined population. In all likelihood, plan-ACO contracts will look very different from UPPCs, which will reflect today's largely fee-for-service environment.

   But the emergence of ACOs, if it occurs, will actually enhance the need for UPPCs. As providers form ACOs, and as plans and providers move more members into that structure, it will become even more inefficient to expend resources on developing, reviewing and negotiating fee-for-service contracts on a contract-by-contract basis: contracting-related costs will be spread over a shrinking base. In sum, health care reform, rather than eliminating the need for UPPCs, makes them essential, and makes the retail approach to plan-provider contracting untenable.

   Moreover, PPACA will place additional pressure on plans to reduce administrative expenses in order to meet new medical loss ratio requirements. The UPPC could prove quite helpful to plans in that regard.

   As an interesting aside, some conservative groups that oppose PPACA argue that access to care would be improved more, and costs would be controlled more, by allowing individuals to buy health insurance "across state lines," i.e., from any state, without regard to the insurance laws of the state of their residence.[10] That may or may not be true. But if that approach were adopted, New York health care facilities would start seeing more and more patients with insurance from plans licensed in places like Utah, Kentucky or Guam. The need for each New York facility to participate in burdensome contract and rate negotiations would jump from twenty or thirty localized instances to thousands of nationwide instances. Plans would face a similar exponentially increased contracting burden. It is hard to envision accomplishing this without UPPCs or some variation.

4. *The UPPC would disrupt standardization of a plan's contracts across states.* Plans that operate in several states have an interest in using the same contract, or as close to the same contract as possible, in all those states. To the extent the plan is required to use a New York specific contract, that requirement will disrupt standardization from its perspective. This is true, but it is fair to say that New York laws and regulations already require plans to prepare a lengthy appendix of special clauses, as well as many other provisions do not appear in their contracts in other states. The UPPC is an incremental extension of that process.

5. *State laws cannot require ERISA plans to use UPPCs.* This is probably correct: ERISA's pre-emption clause constrains state efforts to regulate health insurance operated by employee benefit plans subject to ERISA.[11] But state insurance laws are efficacious within their sphere. Moreover, if UPPCs prove valuable for state-regulated plans, federal policymakers should consider a similar initiative for ERISA-regulated plans.

Certainly other objections will be identified. But absent some significant new concern not identified here, it seems on balance the advantages of implementing UPPCs far outweigh the objections.

Accordingly, health care policymakers in New York should start to consider the merits of developing a series of Uniform Plan-Provider Contracts (UPPCs) and mandate their use by health plans and health care providers. The use of UPPCs promises to cut significantly expenditures by health plans and health care providers associated with developing, reviewing, negotiating, and striving to implement plan-provider contracts. Those expenditure reductions will advance the public's compelling interest in controlling health care costs, with no impact on quality of care or access to care.

Endnotes

1. NY Public Health Law § 3224-a.
2. See http://www.nyhealth.gov/health_care/managed_care/hmoipa/appendix.htm.
3. See, e.g., Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 Fed. Register 43330 (July 23, 2010).
4. See Provider Contract Guidelines for MCOs and IPAs. http://www.nyhealth.gov/health_care/managed_care/hmoipa/guidelines.htm See also 10 NYCRRR § 98-1.13 Assurance of access to care. (a) All covered services must be directly provided or arranged for within the approved provider network pursuant to written contracts developed and maintained in a form and manner prescribed by the commissioner, except that when services are unavailable within the provider network, such services must be arranged for outside of the approved provider network.
5. See *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 135 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965).
6. See, e.g., Health Insurance Reform: Standards for Electronic Transactions, 65 Fed. Register 50312 (August 17, 2000).
7. NY Uniform Commercial Code.
8. New York's Prospective Hospital Reimbursement Methodology (NYPHRM) regulated hospital rates for all in-patient care, except for services provided to Medicare beneficiaries. N. Y. Pub. Health Law § 2807-c (McKinney 1993). It was allowed to expire on December 31, 1996.
9. The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111–148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111–152, was enacted on March 30, 2010.
10. See, e.g., "Let Health Insurance Cross State Lines, Some Say," NY Times, Feb 13, 2010, available at http://prescriptions.blogs.nytimes.com/2010/02/13/let-health-insurance-cross-state-lines-some-say/.
11. See *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers*, 514 U.S. 645 (1995).

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New York's New Council on Public Health and Planning

By Francis J. Serbaroli

Out of the budget battles taking place in Albany has emerged historic legislation[1] that combines two powerful health care regulatory councils into one. As of Dec. 1, 2010, the 50-year-old State Hospital Review and Planning Council (SHRPC) and the nearly century-old Public Health Council (PHC) will be combined into what will be known as the Public Health and Health Planning Council (PHHPC).

History

The PHC and SHRPC have broad authority over health facilities and public health matters in New York. The Public Health Council was created by the Legislature in 1913.[2] It has statutory authority to approve the establishment of medical facilities such as those licensed under Public Health Law (PHL) Article 28 (general hospitals, nursing homes, diagnostic and treatment centers, rehabilitation centers, dental clinics, ambulatory surgery centers, and renal dialysis facilities); Article 36 (certified and licensed home health agencies); and Article 40 (hospices).

In reviewing applications for the establishment of these providers, the PHC is required to consider:

a) the public need for the existence of the provider at the time and place and under the circumstances proposed;

b) the character, competence and standing in the community of the proposed incorporators, directors, sponsors, stockholders, members, or operators;

c) the financial resources of the proposed provider and its sources for future revenues; and

d) such other matters as the PHC shall deem pertinent.

The PHC also has the authority to:

- review and approve any transfer, assignment or other disposition of 10 percent or more of the stock or voting rights of a corporation that is the operator of an Article 28, Article 36 or Article 40 facility;
- revoke, limit or annul the establishment of an Article 28 or Article 40 facility;
- approve the establishment of any business corporation or not-for-profit corporation that has among its purposes raising funds for the establishment or operation of an Article 28 facility;
- approve a change in the name of any Article 28 facility; and
- approve any certificate of amendment that makes a substantial change in the corporate purposes and powers set forth in the certificate of incorporation of an Article 28 facility.

The PHC has statutory authority to enact and amend the Sanitary Code, the state's health code, subject to the approval of the Commissioner of the Department of Health.[3] The PHC has broad authority to promulgate regulations in the Sanitary Code to: "deal with any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York, and with any matters as to which the jurisdiction is conferred upon the [PHC]."

Thus, the Sanitary Code sets forth requirements and standards for such important matters as:

- the standards for drinking water supplies;
- the qualifications of public health personnel;
- the practice of nurse mid-wifery;
- the provision of maternal and child health services;
- the standards for clinical laboratories;
- the designation of and reporting requirements for communicable diseases;
- the issuance of permits for migrant laborcamps;
- the sanitary and safety standards for public events likely to attract large crowds; and
- the sanitary and safety standards for swimming pools, bathing beaches, children's summer camps, and food service establishments.

Under PHL § 2801-b, the PHC also has responsibility for reviewing and investigating complaints concerning medical staff appointments and privileges in Article 28 facilities, and can direct the facility involved to review the case. A physician, podiatrist, optometrist, dentist or licensed midwife who has been denied medical staff privileges, or who has had his / her privileges curtailed, suspended or terminated, must first exhaust the facility's internal due process procedures, and then can file a complaint with the PHC. New York's courts repeatedly have held that before a practitioner can challenge the facility's action in a court proceeding, the practitioner must first avail him / herself of the PHC's complaint process.[4]

Lastly, the PHC has a broad general mandate under PHL § 225 that has been summarized by the Court of Appeals as follows: "[The PHC] has the duty, at the request of the Commissioner, to consider any matter relating to

the preservation and improvement of public health and it may also advise the Commissioner and recommend action concerning matters of public health."[5]

There are 15 members of the PHC, including the Commissioner of the Department of Health who is a voting member. Members of the PHC are nominated by the Governor subject to approval by the State Senate. Other than the commissioner, who is a member as long as he or she is in office, member terms are six years, and there is no term limit. A PHC member can remain in office beyond the expiration of the member's term until such time as a successor is appointed to fill the member's slot. The PHC's enabling legislation requires that its membership be reflective of the diversity of the state's population including its various geographic areas and population densities.

SHRPC was created by the Legislature in 1960.[6] SHRPC reviews and makes recommendations to the PHC regarding the establishment of Article 28, 36 and 40 facilities. It also reviews and has final approval over Certificate of Need (CON) applications involving construction projects, and has rulemaking authority, subject to the approval of the commissioner, over operating standards for hospitals and other health care facilities, reimbursement and fiscal policy, and facility construction.

There are 31 members of SHRPC, including the commissioner, who is a voting member. SHRPC members are nominated by the Governor and subject to approval by the State Senate. Other than the commissioner, members serve three-year terms and can be reappointed, but may not serve for more than six years within a 12-year-period.

As with the PHC, SHRPC's membership must reflect the diversity of the state's population including geographic areas. Unlike the PHC, however, SHRPC's enabling legislation requires that its members must include representatives of consumers, physicians, hospitals and nursing homes, a representative of home health care, and two members of the state's Mental Health Services Council.

With respect to CON applications for establishment, the roles of the PHC and SHRPC have long overlapped. The long and cumbersome CON process entails a thorough review of the CON application by the Department of Health, then review by SHRPC's Project Review Committee, followed by a recommendation by the full SHRPC to the PHC. The application is then presented and reviewed by the PHC's Establishment Committee, followed by review and approval by the full PHC. Due in part to the unnecessarily duplicative review process, CON applications can take anywhere from six months to two years or more to receive final approval.

New Council

As of Dec. 1, 2010, the new PHHPC will have all of the powers and responsibilities previously assigned to the PHC and SHRPC. The PHHPC will consist of the commissioner and 24 members appointed by the Governor with the approval of the Senate. The enabling legislation retains the requirement that the PHHPC be "reflective of the diversity of the state's population including, but not limited to, the various geographic and population densities throughout the state." The law requires that the PHHPC include:

- representatives of public health systems;
- health care providers; and
- individuals with expertise in the clinical and administrative aspects of health care delivery, issues affecting health care consumers, health planning, health care financing and reimbursement, health care regulation and compliance, and public health practice.

The law specifically allocates member slots to various industry interests: at least four to general hospitals or nursing homes and at least one each to:

- home health care agencies;
- diagnostic and treatment centers;
- health care payors;
- labor organizations for health care employees; and
- health care consumer advocacy organizations.

At least 2 members of PHHPC must also be members of New York State's Mental Health Services Council.

PHHPC members serve for a term of six years, or until a successor has been appointed and approved. However, the legislation provides staggered terms for 10 of the PHHPC's 24 initial members as follows: three members—six years; three members—five years; two members—four years; two members—three years.

By December 2016, all PHHPC members will be appointed for a term of six years.

There are no term limits for PHHPC members. However, the law does limit the "holdover" period for members whose terms have expired. Formerly, PHC and SHRPC members whose terms had expired could remain members—sometimes for years—until the Governor nominated and the Senate approved a replacement. The new law requires the Governor to appoint (or re-appoint) members of the PHHPC within one year of the expiration of a term or within one year of any vacancy.

The consolidation of the powers and duties of the PHC and SHRPC into the new PHHPC is set forth in a new PHL § 224-b:

> The [PHHPC] shall have such powers and duties as are set forth in this chapter, including the consideration of the applications for the establishment and construction of health care facilities, home care agencies and hospices licensed under article twenty-eight, thirty-six or forty of this chapter. In carrying out its powers and duties, the council shall take into account the impact of its actions and recommendations on the quality, accessibility, efficiency and cost-effectiveness of health care throughout the state.

That second sentence could serve as a helpful clarification to the existing provision allowing the consideration of "such other matters as [the PHC] shall deem pertinent in establishment applications." Occasionally, when certain CON applications have faced opposition, this vague and open-ended "such other matters" provision has caused considerable difficulty. An applicant that passed the first three establishment tests (i.e., need, character and competence, and financial feasibility) and met all other DOH requirements, might find itself having to deal with standards or criteria that other similarly situated applicants had not faced.

The misuse of this "such other matters" provision, which remains in the PHHPC's enabling legislation, could easily give rise to Article 78 proceedings challenging disapprovals of establishment applications as arbitrary, capricious and unreasonable. Thus, the new wording, requiring the PHHPC to consider quality, accessibility, efficiency and cost-effectiveness, should clarify the applicable standards and reduce the possibility of unfair outcomes.

The new PHL § 224-b goes on to add another important new responsibility:

> The council shall undertake a comprehensive review of regulations and council procedures governing the establishment and construction of such health care facilities, home care agencies and hospices and shall submit to the commissioner any recommendations for the revisions of such regulations. Such review shall be conducted every five years, and the first set of recommendations shall be submitted to the commissioner on or before December first, two thousand sixteen.

This is a long-needed and welcome requirement for the new PHHPC to periodically evaluate its procedures for reviewing and approving establishment and construction CONs so that applicants do not face unreasonable delays and unnecessary expenses, and the approval process is as fair, objective, and efficient as possible.

Conclusion

The Department of Health estimates that the combination of these two councils will result in considerable savings to the state by eliminating unnecessary meetings, Health Department staff support, travel costs, and other expenses.

More importantly, it should help to shorten and streamline the unnecessarily burdensome regulatory review process for CON applications, thereby saving applicants significant amounts of time and money, and contributing to a reduction in health care costs.

The new PHHPC, like its predecessors, has critically important responsibilities with regard to the state's health care delivery system. Its members are also the guardians of the health and safety of all New Yorkers. The Governor should choose wisely in selecting the members of this important body, and the members of PHHPC should always keep in mind that they represent all of the people of the state, and not just particular health care industry interests. We wish them much success.

Endnotes

1. New York State Senate 6608-B; Assembly 9708-c; Chapter 58 of the Laws of 2010, signed July 2, 2010.
2. The PHC's enabling legislation is found in New York Public Health Law PHL §§ 220 et seq.
3. PHL § 225.
4. See, e.g., *Gelbard v. Genessee Hospital*, 87 NY2d 691 (1996).
5. *Matter of New York State Society of Surgeons v. Axelrod*, 77 NY2d 677, 682 (1991) (citations deleted).
6. The enabling legislation for SHRPC is found in PHL § 2904.

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Joint Commission MS.01.01.01: A Golden Opportunity for Physicians to "Level the Playing Field" at Intra-Hospital Hearings

By David A. Zarett and Craig D. Bloom

Imagine this very realistic, and unfortunate, scenario: A physician client comes into your office one day with a certified mail letter from the only hospital where he has a medical staff appointment, advising that all of his privileges have been "summarily suspended, effective immediately." The letter continues that this action was taken by the Departmental Director (who happens to be your client's number one competitor), after he determined that despite a 15 year unblemished professional record, your client has suddenly become an "imminent risk of harm" to patients, having just experienced his first meaningful complication in the operating room.

As the physician's attorney, you must explain to him that as a result of the action by the hospital—taken before he even knew there was an "investigation" on going in the first place—he is no longer able to admit patients to the hospital, a restriction that could last for months. As this is the only hospital where he has privileges, it will have the effect of practically shutting down his medical practice. Even worse, you'll explain that: (1) he will likely be reported to the National Practitioner Data Bank, where information about the summary suspension is forever accessible by any hospital, licensing agency, professional board, or health care organization to which he applies in the future;[1] (2) he has already been, or will most likely be, reported to the Department of Health's Office of Professional Medical Conduct ("OPMC"), which will initiate its own investigation, potentially resulting in charges of professional misconduct;[2] (3) the summary suspension may eventually have to be disclosed to the New York Physician Profile website, where it will be available to anyone who "Googles" his name;[3] (4) the summary suspension could be relied upon by the managed care plans to remove him from their panels; (5) the summary suspension could be used by his malpractice insurance carrier to nonrenew or terminate his liability coverage; and (6) even if he had been smart enough to get privileges at more than one hospital, if both are part of a larger "health system," his privileges at the other hospital within the same system could be adversely affected as well.

To make matters even worse, you must explain to your physician client that due to the scarlet-letter effect of a "summary suspension"—which is only supposed to be implemented when a physician truly poses a real, tangible and imminent risk of harm to patients—he will most likely not get privileges at a "substitute" hospital at least until the summary suspension is removed or resolved. Finally, you may not be able to immediately run to Court to seek an injunction to challenge the suspension, since in virtually all instances you must first exhaust the "procedural due process rights" set forth in the hospital's medical staff bylaws and an administrative review process before the New York State Public Health Council—which could take months.[4]

Rather, your client's only hope to right this wrong is to go forward with the intra-hospital hearing process to challenge the "summary suspension" internally, and hope to prove that the Departmental Director either jumped the gun based on faulty conclusions; or worse, is acting out another agenda having nothing to do with your client's skills as a physician. Thus, you and your client sit down and crack open the hospital's Medical Staff Bylaws to determine his "rights" at the hearing, and the ground rules applicable to this "due process" procedure.[5] And this is where you will likely have to explain to your client that the procedure leading up to the imposition of the suspension and the process for challenging it could be characterized as far from fair. For example, you learn that prior to implementing the summary suspension, neither the Departmental Director nor anyone else at the hospital had an obligation to advise the physician of the investigation, get your client's input on the matter, or have an outside independent expert review of the chart. You may also learn that at the upcoming hearing:

- The physician is presumed guilty, and it is his burden to prove by "clear and convincing" evidence that the action by the hospital was "unreasonable" or "arbitrary and capricious."
- The physician has no rights to pre-hearing disclosure, so the hospital is not required to provide you with any information in advance, such as the medical records at issue or any exculpatory information that would prove the suspension was not warranted in the first place.
- The physician is not guaranteed an advance preview of any outside expert reports obtained by the hospital, or knowledge of what information was provided to the outside "expert" if one was obtained (oftentimes, relevant information is not received by the hospital's outside expert, such as office records and diagnostic tests, which would have led to differing conclusions of the care rendered by the target physician).

- To your chagrin, while allowing you to "represent" your client at the hearing, some hospitals limit the lawyer's role to attending only, but not speaking at the hearing.

So much for "due process," your client says, as he heads home to share the news with his spouse and loved ones.[6]

While we are not questioning the legitimate value and importance of meaningful and effective peer review and quality assurance, one wonders why medical staff members throughout the state have allowed such inequities in the process to persist for years when so much is at stake. This problem persists due to a trend for medical staff members to avoid active involvement in their own bylaw process. Fortunately, the Joint Commission has recently implemented new requirements that are effectively requiring all hospitals to revamp their medical staff bylaws to implement a series of changes designed to give more power and control to the medical staff body as a whole. Specifically, in March 2010, the Joint Commission approved a revised "Medical Staff Standard" MS.01.01.01 (formerly MS.1.20), which addresses the organized medical staff's self-governance and its accountability to the governing body.[7] According to the Joint Commission, the new standard "contributes to patient safety and quality of care through the support of a well-functioning, positive relationship between a hospital's medical staff and governing body."[8] All hospitals and critical access hospitals are expected to be in full compliance by March 31, 2011.[9] The revised MS.01.01.01 will require significant changes to most hospitals' medical staff bylaws, and other similar governance documents, to be made over the next few months.

While a large portion of the Joint Commission's requirements pertain to the parliamentary aspects of medical staff bylaws, and attempts to re-balance the power sharing between the medical staff rank and file versus the few elected committees thereof (such as "Medical Board" or the "Medical Executive Committee"), the practical result of MS.01.01.01 is that all hospitals, and their lawyers and administrators, are going to be hustling to substantially revise their bylaws and make major revisions to comply with the new Joint Commission standard.

This is therefore a perfect opportunity for members of the medical staff (*i.e.*, your physician clients) to effect more than just the bare minimum changes to comply with MS.01.01.01—but also meaningful changes to the bylaws to enhance the procedural protections to a "target" physician in a peer review hearing. These modifications could include: (i) adding a "presumption of innocence" in favor of the target physician, and requiring the hospital to carry a burden of proof justifying the imposition of its disciplinary action and penalties; (ii) requiring the hospital to make reasonable information available to the target physician in advance so that he can prepare for the hearing (such as being given prior access to the medical records and expert reviews); and (iii) requiring that the hospital produce exculpatory evidence. The modifications could also require that before a physician is summarily suspended, he be given an opportunity to "meaningfully" respond to the charges of misconduct. "Shoot first and ask questions later," is not a responsible way to manage the professional career of medical staff members.

If the purpose of a hospital's due process rules is to get to the truth of matter, then a fair hearing process is the only way to achieve such goals if one accepts the basic premise of an adversary system of justice. Indeed, like any system of justice, procedural fairness helps to assure the integrity of the process as a whole. The medical staff bylaw overhaul required by MS.01.01.01 presents a golden opportunity for the physicians of the organized medical staff to propose amendments to the medical staff bylaws to address these inequities. The organized medical staffs of hospitals should take this opportunity to implement changes to the bylaws to protect the rights of all its members so that fair hearings will take place.

Remember, no matter how popular, well-liked, or "in" your physician client may be with the hospital crowd today, the tables can and always do turn. Your client could find himself being the recipient of a "summary suspension" letter, which with the stroke of a pen will adversely affect the rest of his professional career. Now is the opportunity to implement changes to the rules of the road so that a hearing to challenge this potentially catastrophic disciplinary action is done in a fair, even-handed and objective fashion.

Endnotes

1. The National Practitioner Data Bank ("NPDB") is an electronic repository of all payments made on behalf of physicians in connection with medical liability settlements or judgments, as well as adverse "peer review" actions against medical licenses, clinical privileges, and professional society memberships of physicians and other health care practitioners. The NPDB was established by Congress as part of the Health Care Quality Improvement Act of 1986 ("HCQIA"). 42 U.S.C. §§ 11101, et seq.
2. 10 N.Y.C.R.R. § 405.3(e); N.Y. Pub. Health Law § 230(10)(a).
3. N.Y. Pub. Health Law § 2995-a.
4. Public Health Law § 2801-b(2) sets forth the appropriate procedural framework whereby an aggrieved physician may invoke the jurisdiction of the Public Health Council when the governing body of a hospital terminates or impairs a physician's privileges "without stating the reasons therefor, or if the reasons stated are unrelated to standards of patient care, patient welfare, the objectives of the institution or the character or competency of the applicant." Public Health Law § 2801-b[1]. New York courts have repeatedly dismissed actions brought by physicians who sought to have their medical staff privileges restored without first pursuing their administrative remedies before the Public Health Council. *Gelbard v. Genesee Hosp.*, 87 N.Y.2d 691, 664 N.E.2d 1240 (1996).

5. The following is a hypothetical set of procedures and guidelines that we typically see in medical staff bylaws when representing physicians in these types of matters. However, medical staff bylaws do vary from hospital to hospital.
6. The Health Care Quality Improvement Act establishes a minimum threshold for procedural due process for professionals subject to peer review by providing those involved in the peer review process with near complete immunity from claims for monetary damages arising from peer review actions, so long as these standards are met. In order to receive this immunity, only the following four safe harbor provisions set out in 42 U.S.C. § 11112(a) must be met: that the professional review action was taken (1) in a reasonable belief that the actions was in furtherance of a quality health care, (2) after a reasonable effort to obtain the facts of the matter, (3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirements of paragraph (3).
7. Approved: Revision to Medical Staff Standard MS.01.01.01, 30(4) Perspectives, The Official Newsletter of the Joint Commission 1 (April 2010), at 1.
8. Revisions to Hospital Medical Staff Standard S.01.01.01 (formerly MS.1.20) (presentation slides), The Joint Commission, available at http://www.jointcommission.org/NR/rdonlyres/81A0E2F3-CA04-4DC6-905B 64449A76339B/0/MS010101FINAL40810.pdf (last visited September 27, 2010).
9. Approved: Revision to Medical Staff Standard MS.01.01.01, 30(4) Perspectives, The Official Newsletter of the Joint Commission 1 (April 2010), at 1.

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Electronic Signature Act Permits Online Registration for Organ and Tissue Donation

By Wendy J. Luftig

In July of 2010, Governor Paterson signed legislation that will amend Section 4310 of the NYS Public Health Law, permitting individuals to use an electronic signature for requesting consent to make an anatomical gift in New York State. Simply put, this law (S. 4999/A. 10664) enables New Yorkers to sign the Department of Health "Donate Life Registry" online.

For those in the New York State organ donor and transplant community, this law signifies a welcome advance from the current cumbersome registry process. Until now, those interested in affirming their consent to organ donation had to visit the registry website, download a physical form and return it by mail to the NYS Department of Health in order for registration to be effective. Of course, New Yorkers can register in the traditional manner by declaring consent on a license or identification card renewal, but online registration dramatically streamlines the registration process.

Moreover, the Electronic Signature legislation was urgently needed. As of this writing, New York State has one of the lowest organ donor designation rates in the country. Approximately, 9,559 and an estimated 632 New Yorkers die each year while waiting. New Yorkers typically make up 10% of the national waiting list. One of the motivations for the legislation was that donation rates are consistently higher in states where registry enrollment is a straightforward and one-step process.

A consortium of groups, New York Alliance for Donation, committed to boosting the state's organ donor consent rates, worked together to promote this legislation. One member of the consortium, the New York Organ Donor Network ("NYODN"), the federally-designated organ procurement organization for the greater New York City metropolitan region, was among the groups active in campaigning for the Electronic Signature Act. According to Elaine R. Berg, President and CEO of NYODN, "it is important to educate all attorneys, particularly those practicing in the area of Trusts and Estate, about this new legislation and to encourage them to alert interested clients about this easy procedure for consenting to an anatomical gift online."

Wendy J. Luftig, a member of the NYSBA Health Law Section, serves on the Public & Professional Education Committee, reporting to the Board of the New York Organ Donor Network.

Addressing Excluded Persons in Medicaid Employment, Ordering and Contracting

Excerpt from Office of Medicaid Inspector General, Compliance Webinar 1

Editor's Note—New York State Medicaid Inspector General James G. Sheehan presented the first in a series of OMIG Webinars on June 8, 2010. Entitled "Addressing Excluded Persons in Medicaid Employment and Contracting—New York," the session covered New York State and federal laws governing exclusion and provides examples of several cases in which exclusion from the Medicaid program has been applied to individuals.

This excerpt from the Webinar is a list of questions and answers on the obligation of Medicaid providers to identify and to avoid billing Medicaid for the services of persons excluded from Medicaid. It is printed with permission from the New York State Office of the Medicaid Inspector General. Further information about exclusions, including the complete list of people and organizations excluded from the New York Medicaid program, is available on the OMIG Web site: http://omig.ny.gov.

OMIG Compliance Webinar #1 Questions and Answers

Addressing Excluded Persons in Medicaid Employment and Contracting—New York June 8, 2010

1. When does this take effect?

Answer: *It is in effect now.*

2. Where specifically does it say that providers are required to be aware of Medicaid Updates?

Answer: *As part of the conditions of participation in the Medicaid program, providers are required to keep current with changes in Medicaid regulations and statutes. Medicaid Updates from the Department of Health (DOH), as well as information posted on the OMIG, DOH and eMedNY Web sites, are valuable sources of information about regulatory and statutory changes.*

Additionally, when submitting a Medicaid claim, providers attest that "I (or the entity) shall be subject to and bound by all rules, regulations, policies, standards, fee codes and procedures" as set forth in Title 18 of the Official Compilation of Codes, Rules and Regulations of New York State and other publications of the Department, including Medicaid Management Information System Provider Manuals and other official bulletins" of the department. Please see attached sample (paragraph four) for complete language.

3. Can you define the term "employee"—in other words, who is considered an employee for purposes of screening for exclusion?

Answer: *Anyone who provides a service for which a claim is submitted to Medicaid, or anyone who is compensated out of Medicaid funds, would be considered an employee for the purposes of the list. However, as set forth in www.irs.gov/businesses/small/article/0,,id=99921,00.html, providers should also understand that they should screen independent contractors if they are billing for Medicaid services.*

4. This is for ALL employees, not just licensed professionals, correct?

Answer: *It applies to all employees, vendors and referral sources whose functions are a necessary component of providing items and services to federal program beneficiaries.*

5. How does a criminal conviction that causes exclusion get conveyed to OMIG and/or OIG? Are courts required to do this?

Answer: *The OMIG receives the majority of its convictions from the Medicaid Fraud Control Unit (MFCU) and actions by the state's two licensing boards—the Office of Professional Medical Conduct (OPMC) and the Office of Professional Discipline (OPD). We also obtain information from the United States Department of Justice (DOJ) and local district attorneys.*

6. Are departments of social services required to check for excluded persons? They receive Medicaid administrative funds, but they do not provide or order medical services. Federal funds are received for eligibility determinations and transportation coordination.

Answer: *The local DSS should see if their employees are on the exclusion list. Definitely, however, any employee who is providing direct care services and is on the county payroll (e.g., nursing home staff, home care staff, etc.) must be checked. The OMIG is currently reviewing legal responsibilities in this area.*

7. Is there a Web site or other way to check if a person is excluded from several states? Or do you have to check each state's Web site separately?

Answer: *At this time, states are not cross-linked. The federal Health and Human Services (HHS) Office of the Inspector General (OIG) exclusion list is also not linked to the states at this time. You should check New York State's list, the OIG list, and the GSA list (as noted on www.omig.state.ny.us). However, if a potential employee's resume indicates that he or she has*

worked in another state, you should also check that state's individual list.

8. What mechanisms are available to perform the monthly exclusion check in an expedited fashion? This is very time-consuming if done manually, even five at a time. Are there software programs to expedite this?

Answer: *The list is downloadable in Excel format and can be manipulated by using Excel software. You can check with your information technology staff on how this may work in your individual organization.*

While there is no definitive requirement, we recommend that you check the master list quarterly and then perform updates at 30-day intervals. Once you have performed your initial check of your employees, you can check new employees and then refer to the list on our Web site that is called the "30-day" list, which will give you the latest names that have been added in the last 30 days. You should do checks on the OIG and GSA lists on a 30-day basis as well.

9. Can the OMIG list be formatted to clearly contain last name and first name fields?

Answer: *Not at this time.*

10. How are these lists populated? For example, who provides information on exclusions?

Answer: *The OMIG's Division of Medicaid Investigations (DMI) adds names to the OMIG list and updates the list on a daily basis during the five-day work week (holidays and weekends excluded). Names of individuals who are reinstated through an application process to the Medicaid program are removed the same way. We are not in a position to comment on either the OIG or GSA processes.*

11. As a school, are we required to check the exclusion status of a practitioner who prescribes physical therapy or occupational therapy that will be billed to Medicaid?

Answer: *Yes.*

12. What about foster parents? Do they need to be checked against the list?

Answer: *As far as we understand, foster parents are not Medicaid providers and do not receive Medicaid funding. The children and/or adults under their care receive support through the Medicaid program for their health care needs.*

13. If an individual is excluded from one list but not the other two, can an agency still hire that person?

Answer: *It depends on what services they will be providing and the type of reimbursement they may seek.*

14. Why do providers appear on the OMIG excluded provider list and not the OIG excluded provider list? Is the information shared between both?

Answer: *The OMIG automatically excludes persons if they are excluded by the OIG. However, the opposite is not always true. The OIG does not adopt all state exclusions at this time.*

15. Should we check the exclusion lists for all employees of an agency with multiple contracts and services, or only those employees who work in programs involved in Medicaid/Medicare billing?

Answer: *You should check all employees, contractors or service providers who are involved in generating a claim to bill for services or being paid by Medicaid (including if their salaries are included on a cost report submitted to the Medicaid program).*

16. What penalties would a county face for contracting with a provider who employs an excluded person?

Answer: *The county facility involved in the services rendered by that excluded person would face repayment of reimbursement for those services and may be subject to a variety of other administrative remedies, if the county knew or should have known of the exclusion. The county's contractual agreement should contain a clause in its standard agreements that clearly states that all people working for a county contractor have been screened against the various lists.*

17. Most chain pharmacies receive hundreds of thousands, if not millions, of prescriptions each year. How can the pharmacies check that many individuals each month? It seems almost impossible!

Answer: *We expect pharmacies to have a system reasonably designed to prevent submission of prescriptions from excluded providers. In addition, through the eMedNY claiming system, when a prescription is presented, one that has been written by an excluded provider will not be approved. Most pharmacies punch in the information, and the pharmacist will get a red or green light. Don't fill the prescription if you get a red light, indicating that the prescriber has been excluded.*

18. Does Computer Sciences Corporation (CSC) regularly update their database with excluded provider information? If they do, pharmacies that would be submitting claims including the prescriber's name might be able to expect a rejection if the prescriber had been excluded.

Answer: *Yes, they update on a regular basis. The information gets into eMedNY to assist pharmacies in the process. However, as mentioned in the answer to question #18, we expect pharmacies, pursuant to NYCRR 18, part 521, to have a system in place through their compliance efforts, reasonably designed to prevent submission of prescriptions from excluded providers.*

19. My company employs personal care aides (PCAs). Is it necessary to screen these individuals on a monthly basis as well?

Answer: *Yes. Any direct-care staff whose salary is paid for in any part through Medicaid funding must be checked against the state, federal and GSA lists when he or she is initially hired and every 30 days thereafter.*

20. We consult for psychiatric services through a group. Are we expected to check the group or each individual psychiatrist within the practice?

Answer: *Each individual psychiatrist and the group should be checked.*

21. When does this take effect?

Answer: *It is in effect now.*

22. What about a physician who signs a level of care (LOC)? If the physician was not excluded when it was signed and then became excluded, how long would it be effective? (This is an OMRDD-related question.)

Answer: *The LOC is effective for as long as the LOC would have been effective under the original orders, assuming that the patient's need do not change. The physician would not be able to sign a new LOC, if he or she had been excluded in the meantime.*

23. Can you give me the names of some organizations that we can hire to check the lists for us?

Answer: *Several such companies exist, but we are unable to endorse private entities.*

24. On the issue of checking every 30 days, is there any federal law or regulation that requires that, or is it based on an interpretation? If the latter, does that interpretation have the force and effect of law?

Answer: *The 30-day requirement is not in a regulation or statute, but is contained in a letter from the Center for Medicare and Medicaid Studies (CMS). Providers should follow that directive, which recommends that each Medicaid provider check each employee as a "foundation," then quarterly thereafter, using the 30-day list to determine whether the provider knew or should have known about an exclusion.*

25. You mentioned that the list can be automatically accessed. Does that mean that our human resources and billing system can directly interface with the list?

Answer: *HR and billing can access the OMIG, OIG and GSA lists. See the answer to question #9, above.*

26. Is there a definition for a "referral source"? Can you provide an example of what constitutes a referral source?

Answer: *A "referral source" is any provider who sends a Medicaid client to another provider for additional services or second opinion related to medical condition. An example might be a physician who refers a patient for an ancillary service (e.g., X-ray, lab, etc.) or to a specialist (e.g., surgeon or therapist) for a particular form of care.*

27. Regarding referral sources: Are we expected to screen entities from referring providers?

Answer: *Yes, if there is a "referring provider" field on the resulting Medicaid claim form, and if you are relying on the referral to support the medical necessity of the service (i.e., lab, X-ray).*

28. When using the GSA Web site, if multiple names come up on the list, I was told that GSA needs the Social Security number of the provider being checked. What if it is not possible to obtain the Social Security number?

Answer: *Any questions about the GSA and OIG lists and processes should be directed to the federal government.*

29. What if an excluded provider is working for a physician enrolled in a managed care organization without the MCO's knowledge? How would the MCO have a way to know about that?

Answer: *The MCO should have a contractual agreement with all physicians that indicates they have not been excluded, and that all contractors are checking the OMIG's list on a regular basis. If the MCO learns that an excluded person is working for it, both the MCO and the physician must self-disclose this fact to the OMIG for resolution.*

30. How should a managed long-term care plan, an organization that receives capitation for care management services and is not a direct provider but provides services through contracts with vendors, comply? Is proof of the contractors checking sufficient?

Answer: *The managed care plan is ultimately responsible regardless of who is actually performing the function.*

31. Is a managed long-term care provider responsible for collecting information from contracted vendors regarding names, owners, administrators and staff and checking directly?

Answer: *While the MCO is ultimately responsible, it can either check the list itself or have a contractual agreement that the contracted vendors will be responsible for checking. Pursuant to Part 521 regulations, which took effect on October 21, 2009, providers must have a system in place reasonably designed to assure compliance.*

32. Is it necessary to run ALL employees each month, or just those assigned to government assignments?

Answer: *It all relates to payment source for compensation. Any employee who causes a claim to be generated, and whose income derives all or in part from Medicaid funds, must be checked at initial hiring and on a monthly basis for exclusion.*

33. When a John Smith (or other common name) shows up on the exclusion list, how do we know if it's our "John Smith" or another one with a similar name?

Answer: *In this instance, you would have to call the OMIG's exclusion staff at 518-474-9739 for clarification. Staff at this number is able to verify Social Security numbers and/or dates of birth for individuals being screened. For privacy purposes, the OMIG is unable to post Social Security numbers, dates of birth, or location of last-known position for individuals on our Web site. The OIG and GSA have similar processes in place.*

34. We are a residential program. Do we have to check each private pharmacist who fills a prescription for one of our residents? These pharmacists are private and separate entities, for the most part.

Answer: *No. That is the pharmacy's responsibility's to check unless the residential program bills for the prescription.*

35. Will we have to ask each of our vendors the names of their employees in order to comply with this requirement? For example, device vendors and their employees—will we be responsible for ensuring that their employees have not been excluded?

Answer: *One way to handle this might be to put in your contractual agreements with your vendors that they will ensure that their employees have been screened and have not been excluded from Medicaid. Again, the question comes down to payment. If the vendor is compensated fully or in part with Medicaid funds, the vendor's employees must not have been excluded.*

36. What type of assurance are providers supposed to obtain from contractors to show that they are also checking for excluded entities? Do you have best practices for us to follow in this regard?

Answer: *In your contracts, you should place a provision requiring contractors to check all three exclusion lists before hiring staff and every 30 days thereafter to comply with Medicaid provisions.*

37. What type of verification are you looking for from billing companies that will prove that they are conducting the proper checks for excluded persons?

Answer: *Under 18 NYCRR Part 521, each provider who receives $500,000 or more in Medicaid funding annually must have an effective compliance program in place and certify to that fact annually. OMIG has begun reviewing compliance programs to assess their effectiveness, and, as part of that review, OMIG will, in appropriate cases, include assessing whether or not effective exclusion screenings were done.*

38. If an individual is working strictly in research and utilizing federal grants, would the exclusion provisions apply?

Answer: *Again, it comes down to payment. If the person is supported wholly or in part through Medicaid funding, exclusion provisions apply. This is for the OMIG list only. Check with the federal funding source and ask what their policy is for federal health care dollars.*

39. Do we have to keep all results of monthly searches, and, if yes, for how long?

Answer: *While there are no set requirements for retaining all results, they may be helpful in providing evidence of your compliance program effectiveness. Part 521 requires that providers maintain evidence of maintaining an effective compliance program, and screening for excluded providers is one component of an effective compliance program.*

40. If we are doing our own manual screening, how do you recommend we provide proof of our efforts? Do you want us printing out each search we do and the confirmation of our efforts if the person/entity is excluded or not?

Answer: *The process you use for your own record-keeping is up to you. Again, we recommend downloading your lists of employees, providers and contractors against the list of sanctioned/excluded providers.*

41. How is it in the best interest of the health care entity to self-disclose, if the excluded individual (i.e., vendor, etc.) has already been terminated upon the health care entity's knowledge of the exclusion? In particular, will the health care entity be fined, even upon self-disclosure?

Answer: *Providers are required by statute and regulation to repay identified overpayments. The OMIG's self-disclosure protocol (available on the Web site at www.omig.state.ny.us) outlines potential benefits of self-disclosures, including often waiving interest penalties and relaxing repayment terms. Failure to disclose your employment of or contract with an excluded individual can be the basis for a False Claims Act liability.*

42. Is it mandatory to notify CMS and OIG if you self-disclose to OMIG as well?

Answer: *Once you self-disclose to OMIG, we notify CMS and OIG via letter that we have received your self-disclosure.*

43. Does a prescription or order written by a provider who was not excluded at the time the prescription was written, but who was subsequently excluded at a later date, remain valid, or does the prescription or order become invalid as of the date of suspension?

Answer: *The prescription or order written prior to exclusion remains valid for 180 days. Anything written ON OR AFTER the individual is excluded will be rejected for payment under the Medicaid system.*

44. On the one hand, you are saying that any person involved in medical care needs to be run against these lists, excluding the person "who plows the road for a medical facility." On the other hand, you are saying that all vendors need to be run. Which is it?

Answer: *It is the Medicaid dollars related to claiming or payment, either directly or indirectly. It applies to all employees whose functions are a necessary compound of providing items and services to federal program beneficiaries.*

45. Please confirm that the OMIG exclusion list regulations supersede New York State Division of Human Rights legislation and/or OFCCP-Equal Employment Opportunity Commission anti-discrimination statutes.

Answer: *The Medicaid exclusion list applies to participation in the Medicaid program. We do not see a connection to EEOC or human rights legislation. A person's legal ability to participate in providing services covered by Medicare or Medicaid is a bona fide occupational qualification for working in these areas.*

46. If a monthly check reveals that an existing contractor is now on the excluded list, and that contractor is a sole-source supplier of services to the agency, what do we do?

Answer: *Self-disclose the specifics of the problem to OMIG, and then we can discuss how best to proceed to address the issue while meeting your agency's mission. The Medicaid statute requires the OMIG to consider the best interests of program recipients. Under the Public Health Law:*

§ 32. Functions, duties and responsibilities. The inspector shall have the following functions, duties and responsibilities:

6. to pursue civil and administrative enforcement actions against any individual or entity that engages in fraud, abuse, or illegal or improper acts or unacceptable practices perpetrated within the medical assistance program, including but not limited to: (a) referral of information and evidence to regulatory agencies and licensure boards; (b) withholding payment of medical assistance funds in accordance with state and federal laws and regulations; (c) imposition of administrative sanctions and penalties in accordance with state and federal laws and regulations; (d) exclusion of providers, vendors and contractors from participation in the program; (e) initiating and maintaining actions for civil recovery and, where authorized by law, seizure of property or other assets connected with improper payments; and entering into civil settlements; and (f) recovery of improperly expended medical assistance program funds from those who engage in fraud or abuse, or illegal or improper acts perpetrated within the medical assistance program. In the pursuit of such civil and administrative enforcement actions under this subdivision, the inspector shall consider the quality and availability of medical care and services and the best interest of both the medical assistance program and recipients.

47. If an excluded person is reinstated, does OMIG (and the other list maintainers) remove that name from the list?

Answer: *Yes. In New York State, a provider who has been excluded has to apply to be reinstated. OMIG does remove those names from the list. We update our lists daily every work day (except weekends and holidays). If you are reinstated by HHS, you are not automatically reinstated by OMIG, and vice-versa. You must reapply for consideration to be reinstated by OMIG.*

48. If a non-employed physician appears on the NYS OMIG list, should admitting privileges be revoked—at least temporarily—until the name no longer appears on the OMIG list, or can the provider have an agreement with the excluded physician that he/she will not treat any Medicaid patients?

Answer: *OMIG cannot advise you on whether or not to revoke or suspend privileges when dealing in a non-Medicaid environment. However, the physician in question cannot generate or cause to be generated any billing to the Medicaid program unless he or she applies for and is granted reinstatement to the program.*

49. Currently, we are allowed to hire employees on a temporary basis, pending receipt of their criminal background check. We use the HPN system (for criminal background checks) in New York State. If we hire someone temporarily and we learn at a later date through the HPN system that this person can no longer continue to provide personal care services due to a criminal background, are we obligated to pay back all claims filed under this employee prior to receipt of this information? If an agency hires a director of patient services who is excluded, does this mean the agency must pay back all claims since this person was director?

Answer: *Having a criminal background does not necessarily mean that the person has been excluded from the Medicaid program. In terms of compliance, existence on the OMIG list is key.*

If an agency were to hire a director of patient services who is excluded, then the agency would have to pay back all claims since this person was director.

Reprinted with permission from the New York State Office of the Medicaid Inspector General. Further information about exclusions, including the complete list of people and organizations excluded from the New York Medicaid program is available on the OMIG Web site: http://www.omig.ny.gov.

Editor's Selected Court Decision

Kevin Glassman M.D., Respondent v. ProHealth Ambulatory Surgery Center, Inc. et al., Appellants, 14 N.Y.3d 898; 930 N.E.2d 263; 904 N.Y.S.2d 342

No. 105

COURT OF APPEALS OF NEW YORK

Decided June 3, 2010

JUDGES: Chief Judge Lippman and Judges Ciparick, Graffeo, Read, Smith, Pigott and Jones concur.

OPINION

MEMORANDUM:

The judgment appealed from and the October 2008 order of the Appellate Division brought up for review should be reversed, with costs, and the matter remitted to Supreme Court for further proceedings in accordance with this memorandum.

Even assuming that the provision of the employment contract allowing defendant to collect fees emanating from plaintiff's off-site anesthesiology services is inconsistent with 10 NYCRR 401.2 (b), which provides that "[a]n operating certificate shall be used only by the established operator for the designated site of operation," we conclude that the provision is merely malum prohibitum and, therefore, enforceable in this breach of contract action (*see Lloyd Capital Corp. v. Pat Henchar, Inc.*, 80 NY2d 124, 127-128, 603 N.E.2d 246, 589 N.Y.S.2d 396 [1992]; [*2] *see also Charlebois v. Weller Assoc.*, 72 NY2d 587, 531 N.E.2d 1288, 535 N.Y.S.2d 356 [1988]). Forfeitures by operation of law are disfavored, and allowing parties to escape their contractual obligations, freely entered into, "is especially inappropriate where there are regulatory sanctions and statutory penalties in place to redress violations of the law" (*Lloyd Capital Corp.*, 80 NY2d at 128).

Here, Public Health Law § 2806 (1) (a) authorizes the Department of Health to revoke, suspend, limit or annul an ambulatory surgery center's operating certificate where it "has failed to comply with the provisions of this article or rules and regulations promulgated thereunder." Additionally, the State Board for Professional Medical Conduct has the power to impose sanctions for fee-splitting arrangements that violate statutory prescriptions (*see* Education Law § 6530 [19]; § 6531; *see also* Public Health Law §§ 230, 230-a). Neither agency has been involved in this matter, nor has plaintiff identified an overarching public policy that mandates voiding the contract (*see generally Albany Med. Coll. v. McShane*, 66 NY2d 982, 489 N.E.2d 1278, 499 N.Y.S.2d 376 [1985], *rearg. denied* 67 NY2d 757, 490 N.E.2d 1234, 500 N.Y.S.2d 1028 [1986]). For this reason, Supreme Court shall consider whether defendant is entitled, [*3] under the terms of the agreement, to a set off derived from the funds, if any, held by plaintiff, against the amount of recovery in this case. We see no reason to disturb the remaining conclusions of the courts below.

Judgment appealed from and the October 2008 Appellate Division order brought up for review reversed, with costs, and case remitted to Supreme Court, Nassau County, for further proceedings in accordance with the memorandum herein. Chief Judge Lippman and Judges Ciparick, Graffeo, Read, Smith, Pigott and Jones concur.

Upcoming Events

- **Health Law Section Annual Meeting**—Wednesday, January 26, 2011. The Section's Annual Meeting will be held as part of the NYS Bar Association's Annual Meeting at the Hilton Hotel New York, 1335 Avenue of the Americas, New York City. The program will be a review of developments in a range of areas of health law, including compliance / fraud and abuse, health care quality initiatives, accountable care organizations, conflicts of interest, health care information technology, tax exempt health care organizations, changes in the Public Health Council as well as other topics. The program is chaired by Tracy E. Miller of Cadwalder, Wickersham and Taft.

- **Doing the Deal with Health Care Providers—A Webinar / Teleconference Series**. The Section is sponsoring a five-part CLE series of webinars / teleconferences on major transactions with health care providers, such as purchases or mergers. The five sessions are as follows:

  – Session One—The Term Sheet, Letter of Intent and Business Terms
  Tuesday, November 16, 2010 | 12:30 p.m.–1:30 p.m.

  – Session Two—Major Regulatory Issues to Consider
  Monday, December 13, 2010 | 12:30 p.m.–1:30 p.m.

  – Session Three—Conducting Due Diligence
  Tuesday, January 11, 2011 | 12:30 p.m.–1:30 p.m.

  – Session Four—The Stock or Asset Purchase Agreement–Part I
  Monday, February 14, 2011 | 12:30 p.m.–1:30 p.m.

  – Session Five—The Stock or Asset Purchase Agreement–Part II
  Monday, March 14, 2011 | 12:30 p.m.–1:30 p.m.

The series is chaired by Ari J. Markenson, J.D., M.P.H. of Benesch Friedlander Coplan & Aronoff LLP**.** The speakers are Philip Gassel, Esq., Epstein Becker Green, P.C. and Ross Lanzafame, Esq., Harter Secrest & Emery LLP. For more information, and to register, go to the NYSBA.org and click on upcoming events.

- **Health Care Decisionmaking—**A program on Health Care Decisionmaking will be held at three locations across the state on May 6, 13 and 20. The program will address issues arising under the Family Health Care Decisions Act, special issues for persons with developmental disabilities or mental ilness, consent to treatment and related matters. Laurence Faulkner, Counsel to the Westchester Association for Retarded Citizens, is Program Chair. For more information see the Section's website.

Recent Events

- **Health Law Section Fall Meeting**. The Section held its Fall Meeting on October 22 -23, 2010 at the Equinox Hotel in Manchester, VT. The program, chaired by Edward Kornreich of Proskauer Rose, examined the new federal health care reform legislation and its impact in New York.

- **Membership Appreciation and Networking Reception**. This event, held at the offices of Epstein, Becker and Green, December 2—created educational and networking opportunities for members interested in the health law field. Karen Gallineri of Montefiore Medical Center organized the event.

Section Establishes New Standards for Committees and Committee Chairs

The following resolution was approved by the Executive Committee on November 11, 2010

Resolution of the Health Law Section
Executive Committee

November 11, 2010

Whereas, Article VI, Section 1 of the Bylaws of the Health Law Section of the New York State Bar Association (the "Bylaws"), grants to the Executive Committee of the Section the authority to adopt policies, rules and guidelines for Standing Committees and Special Committees;

Whereas, Article VI, Section 2 of the Bylaws grants to the Chair of the Health Law Section (the "Section") the authority to fill any vacancy or make additional appointments, in consultation with the Chair of the relevant Committee to his or her Committee;

Whereas, Article III, Section 4 of the Bylaws provides that Chairs of Section Committees are prohibited from serving more than two consecutive terms as Chair of a Committee, except that the Chair of the Section may waive this restriction in unusual circumstances for the best interests of the Section for only one year for a specific committee, and appoint a Committee Chair to serve a third term;

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

Whereas, the Executive Committee has determined that certain policies are needed to improve the functioning of the Section's Committees and establish procedures regarding the appointment of Vice Chairs of the committees;

Now therefore be it:

RESOLVED, that the Executive Committee of the Section hereby adopts the following policies for the Section Committees:

1. The term limits for the Chairs of Section Committees set forth in Article III, Section 4 of the Bylaws shall be consistently applied and enforced. The Section Chair shall appoint the Committee Chairs in writing, and shall communicate to the Committee Chairs at the time of appointment the responsibilities of the Committee Chairs and the limit regarding consecutive terms of office. The NYSBA Staff Liaison for the Section shall send each Committee Chair a notice in March preceding the end of the Committee Chair's second term advising of the Bylaw provision regarding term limits and requesting that the Chair take steps to assure an orderly transition of Committee leadership.
2. Each Section Committee shall prepare a written annual work plan and submit the plan to the Section Chair in the third week of January of each calendar year. The annual work plan for each Committee shall set forth the projects that the Committee will undertake during the year, and shall be updated and resubmitted to the Section Chair if the plan is revised. The Section Chair shall provide the Committee plans to the members of the Executive Committee in advance of the first Executive Committee meeting following the time for submission of the Committee plans.
3. Each Standing and Special Committee shall develop and complete at least one project every two years, which may include a CLE program, an article for the Section Journal or other legal publication, a legislative report, or other project.
4. The Chair of the Section, in consultation with the Chair of each Standing Committee, shall appoint a Vice Chair of each Committee to serve a term of one year, which may be continued for a second year, in consultation with the Committee Chair. The Vice Chair shall attend Executive Committee meetings in the absence of the Committee Chair and shall perform such other duties as determined by the Committee Chair. The Vice Chair of each Committee shall be given first consideration to serve as Chair of the Committee at the expiration of the term of the Committee Chair, subject to evaluation by the Section Chair and Committee Chair of the Vice Chair's participation and contribution during his or her term as Vice Chair. (I have not included Special Committees from this section on vice-chairs since if they carry over more than two years, they should be made regular committees).
5. Upon taking office in June, the Chair of the Section shall evaluate whether there is a continuing need for the Special Committees then in existence, and shall make a recommendation to the Executive Committee about the continuation of such Committees, after consultation with the Special Committee Chairs.

Adopted by the Executive Committee on November 11, 2010.

—Ari J. Markenson, Chair

Recent Supraspinatus Topics

- As Managed Care Plans Go, New York's Are Pretty Good
- NY To Create Nation's Largest Connected Electronic Health Record Exchange
- Autism Mandate Vetoed
- Gov. Paterson proclaims Oct. 6 as Stem Cell Awareness Day in NYS
- Vaccine design claims—Bruesewitz v. Wyeth, SCT
- SUNY Downstate Will Use State Grant to Acquire LICH
- DOJ Busts Largest Medicare Fraud Ring Ever
- Insurance Department Fines HealthNew $1.9 Million
- Long Island College Hospital to Merge With SUNY Downstate
- Closure of St. Vincent's Rains Fallout on Area Hospitals
- NY Asks Permission to Bar Food Stamp Use for Sugary Drinks
- NYS Comments on State-Based Health Insurance Exchange
- Insurance Department Fines Aetna $850K
- Governor signs more health bills
- Lt. Governor Calls for Medicaid Overhaul
- DOH Doles Out $109 Milliion in IT Grants
- Paterson vetoes health care proxy bill
- *New York Times* Hails Upstate Bassett Healthcare As Model of Efficiency
- NY Insurance Department Issues $716K in Prompt Pay Fines
- Insurance Department's 2010 Consumer Guide to Health Insurers Hits the Street

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.

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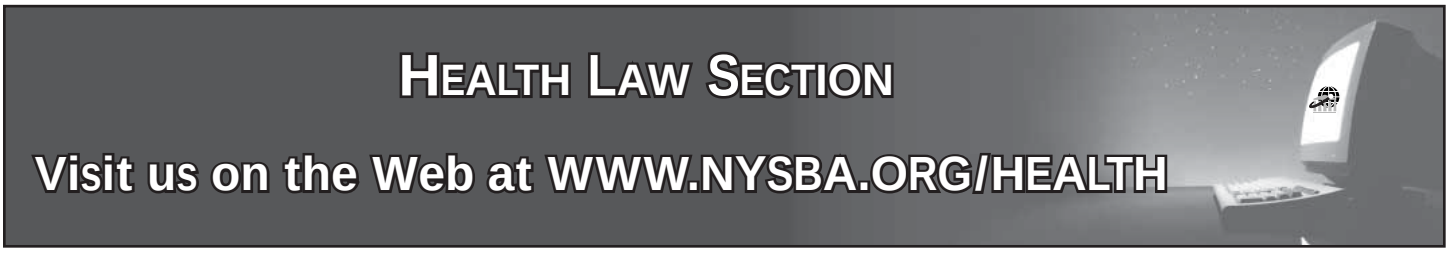

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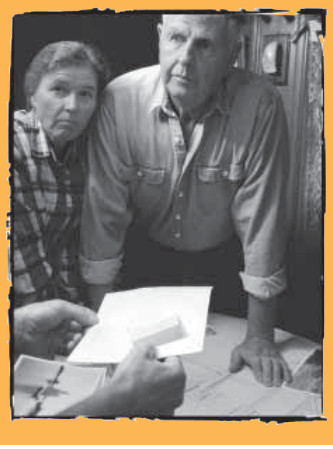

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