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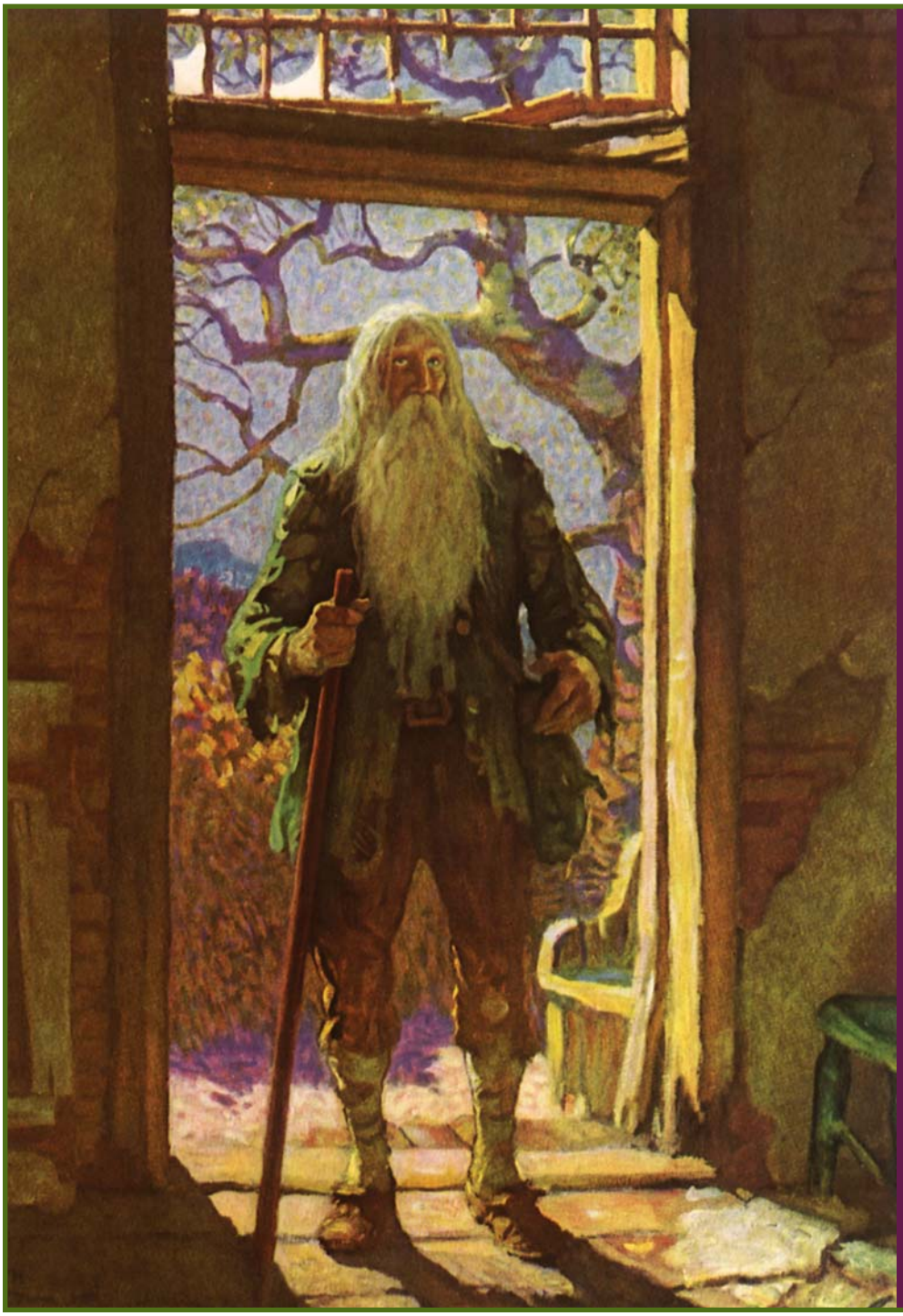
Health Law Journal

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



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Elder law is one of the most challenging and rewarding practice areas. With the aging of the baby boomers, and the rapid growth of the number of senior citizens, elder law practitioners have stepped in to fill the gaps in the more traditional practice areas. This text provides an introduction to the scope and practice of elder law in New York State. It covers areas such as Medicaid, long-term care insurance, powers of attorney and health care proxies, and provides an estate and gift tax overview.

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NYSBA

HEALTH LAW JOURNAL

SUMMER/FALL 2012

Vol. 17, No. 3

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

Table of Contents

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Rip Van Winkle by N.C. Wyeth

A Message from the Section Chair

I am pleased to be serving as Chair of the Health Law Section. The Section currently has over 1,260 members. Our initiatives include our legislative and regulatory agenda, our CLE programs, our committee work, and our participation in the NYSBA diversity challenge, which I will briefly discuss below.

I look forward to working with you in the coming year. Please do not hesitate to contact me with any suggestions for Section initiatives.

Legislative/Regulatory Agenda

Our Section plays an important role in proposing and commenting on legislation and regulations. We have been working on a variety of legislative and regulatory initiatives, including those described below. Thanks are due to the Chair of our Legislative Issues Committee, Jim Lytle, as well as to many other members of the Section who have contributed their time and expertise to these and other legislative and regulatory initiatives.

- **NY Practitioner Self-Referral Law amendments (A3551-A/S4660):** Our Section developed an affirmative legislative proposal that is designed to make Public Health Law 238-a consistent with the federal Stark law. Section members drafted the proposed amendments, worked with the leadership of the NYSBA and the legislature to achieve passage of the bill, and continue to work with the NYSBA to urge the Governor to sign the bill. [Editor's Note: On October 3, 2012, just as this edition was going to print, Governor Cuomo vetoed this bill. See Veto Message #153, http://public.leginfo.state.ny.us/menugetf.cgi.] The legislation would ensure that any arrangement permitted under federal law will also be permitted under State law, unless the Public Health Council and Commission of Health find that such arrangements pose a substantial risk of payer or patient abuse. This is an important piece of legislation, designed to get rid of the inconsistencies between state and federal law that have made compliance with state law nearly impossible.
- **Accountable Care Organization (ACO) Law amendments (A8869-B/ S6228-B):** Members of our Section worked with the legislature in crafting amendments to the State's ACO Law (Article 29-E of the Public Health Law). The amendments include provisions removing the limit on the number of ACOs that may be approved by the New York Department of Health (DOH), thereby entitling them to the protections afforded by the N.Y. law, aligns the State ACO governance requirements with those in Medicare regulations, and provides an expedited process for State certification of Medicare ACOs. The Section has drafted a letter to the Governor urging him to sign the bill, which has passed both houses of the legislature.
- **Executive Compensation regulations:** Our Section submitted comments on the proposed regulations issued by DOH (and other state agencies) designed to implement the Governor's Executive Order No. 38, which seeks to limit executive compensation and reduce administrative expenses for entities contracting with the state. The Section's comments appear in this edition of the *Health Law Journal*, and are listed on our website at http://www.nysba.org/ExecCompRegs.

CLE Programs

The Health Law Section sponsored two programs in the Spring 2012 season, both of which were held in New York City, with live webcasts:

- "The Sunshine Act and the Final Rule on Conflicts of Interest in Research: Issues, Implementation and Compliance Implications" held on April 4, and
- "Key Issues for Health Care Providers: In-House Counsels' Perspective," held on June 11.

In the Fall of 2012, the Health Law Section sponsored a program in Albany at the State Bar Center, with a live webcast option:

- "Health Information Exchanges & Electronic Health Record Systems: Infrastructure and Security in the Internet Model," on Sept. 20.

Also scheduled is a program in Albany at the State Bar Center, with a live webcast option:

- "HITECH for Lawyers," scheduled for Dec. 7.

In addition, the Section's Fall program is scheduled for Friday, October 26, at the State Bar Center in Albany. The program will focus on "New York Health Reform." The speakers include a number of state officials: Jason Helgerson, Deputy Commissioner, Office of Health Insurance Programs and New York State Medicaid Director; Assemblyman Richard Gottfried, Chair of the N.Y. State Assembly Health Committee; Lisa Sbrana, Counsel to the New York Health Benefit Exchange; and Jeremy Creelan, Special Counsel, Public Integrity & Ethics Reform for the

N.Y. Governor's Office. Other speakers include Harold Iselin, James Lytle, as well as Elisabeth Benjamin, Chair, Health Care for All New York.

Diversity

On May 10, 2012, the NYSBA honored our Section as a First Place Winner/Section Diversity Champion of the President's Diversity Challenge. Recognition is due to Lisa Hayes, Chair of our Diversity Task Force, and to Karen Gallinari, Chair of the Membership Committee, who have been working tirelessly on this important initiative.

Committees

The Section currently has 13 standing Committees:

Committee on Fraud, Abuse and Compliance

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Melissa M. Zambri, Esq., Co-Chair
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Committee on Institutional Providers

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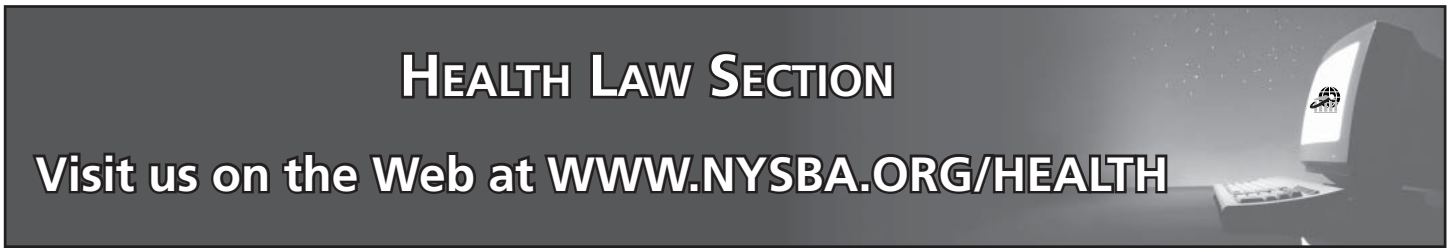
We also recently appointed an ad hoc committee on Strategic Planning.

I encourage all Section members to join a standing committee and to contribute. Participation in committee initiatives, including commenting on proposed regulations and legislation, as well as developing and presenting at CLE programs, can be rewarding in many ways, personal as well as professional.

Ellen V. Weissman
Chair
Health Law Section



In the New York State Courts

By Leonard M. Rosenberg

School Nurse's Allegation of Firing in Retaliation for Disclosure of Single Instance of School's Failure to Report Suspected Child Abuse Held Sufficient to Satisfy Labor Law § 740's "Danger to Public Health and Safety" Provision

Villarin v. Rabbi Haskel Lookstein Sch., 96 A.D.3d 1 (1st Dep't 2012). Plaintiff, a former school nurse, alleged that defendant terminated her employment in retaliation for her reporting of suspected child abuse, as she was required to do by Social Services Law § 413. Plaintiff alleged that the retaliatory firing violated Labor Law § 740, New York's "Whistleblower" statute. The school moved to dismiss the action, arguing that the complaint failed to state a claim under Labor Law § 740 because the single instance of failing to report a case of suspected child abuse did not present a "substantial and specific danger to public health or safety." Affirming the trial court, the Appellate Division, First Department, denied the school's motion to dismiss the retaliatory termination claim.

Analyzing the legislative history of Social Services Law § 413, which revealed the legislature's overriding concern for the protection of abused children and the prevention of further harm to children, the court rejected the defendant's argument that because the alleged violation posed a danger to a single individual or small group of individuals rather than the public at large, it did not present a "substantial and specific danger to the public health and safety." The court held that "there is no requirement that there be a…large-scale threat, or multiple potential or actual victims ... [rather] a threat to any member of the public might well be deemed sufficient." The court further held that because the plaintiff alleged that she had a duty to report suspected child abuse pursuant to

Social Services Law § 413, and that the school actively discouraged and later terminated her for reporting such abuse, the plaintiff sufficiently stated a claim under Labor Law Section § 740 as the school's practices "might result in further abuse or maltreatment" if, for instance, other nurses are discouraged from reporting any suspected child abuse.

The court also premised its decision on the dilemma posed by a contrary result: if the teacher remained silent, she would be subject to liability for failing to report under Social Services Law § 413; if she complied with her reporting obligations, she would be subject to termination without whistleblower protection. The court noted that Labor Law § 740 should be interpreted so as to avoid "such a manifestly unjust outcome." Two justices dissented, arguing that the plaintiff did not allege any facts that implicate a danger to the public health or safety as "public" refers to "an entire community, state or nation," rather than just one person. The dissent also argued that the single instance of suspected child abuse is not indicative of a schoolwide problem of child abuse or a schoolwide practice of failing to report such abuse.

Physician-Patient Privilege Did Not Bar Hospital's Disclosure of Deceased Inmate's Medical Records to New York State Commission of Correction

In re New York City Health and Hospitals Corporation v. New York State Commission of Correction, 969 N.E.2d 765, 19 N.Y.3d 239 (2012). Elmhurst Hospital, a healthcare facility operated by the New York Health and Hospitals Corporation (HHC), received a subpoena issued by the Commission of Correction (Commission), seeking the production of the medical records of an inmate in the custody of the City of New York who was treated at Elmhurst prior to his death. HHC opposed the subpoena, on the grounds that the physician-patient privilege shielded the information from disclosure, and that the Health Insurance Portability and Accountability Act (HIPAA), while it would permit disclosure, did not require the disclosure absent an authorization signed by the deceased prisoner's personal representative. The New York County Supreme Court concurred with HHC's argument, finding that HIPAA did not require production of the record absent an authorization, and that the physician-patient privilege codified at CPLR 4504 otherwise shielded the records from production. The Appellate Division, First Department, concurred with the Supreme Court, holding that, while the Commission's objectives in carrying out its statutorily mandated duty to investigate the deaths of inmates were "laudable," the clinical records of the patient, who was treated in a non-prison unit of the hospital, were subject to the physician-patient privilege. In addition, the Appellate Division held that there is no public policy exception to the physician-patient privilege and that any exception to the statutory privilege is for the legislature, and not the courts, to declare.

The Court of Appeals, reversing the lower courts, held that where there are countervailing legislatively sanctioned policies and practices militating in favor of disclosure, exceptions to the physician-patient privilege may be implied. By way of example, the Court of Appeals noted the line of cases including *Matter of Camperlengo v. Blum*, 56 N.Y.2d 251, 451 N.Y.S.2d 697, 436 N.E.2d 1299

(1982), in which the Court held that, although there is no express statutory exception to the physician-patient privilege for Medicaid records, Federal and State record-keeping and reporting statutes evidence a clear intention to abrogate the physician-patient privilege to the extent necessary to ensure that Medicaid funds are properly applied. Because the Commission is statutorily mandated to investigate inmate deaths, reasoned the Court, and because the Commission was not seeking a general exception to the physician-patient privilege, but rather a narrow exception reasonably and "indeed practically necessarily to be implied" from the Commission's statutory responsibilities and powers, the physician-patient privilege should not bar production of the requested records. The Court ultimately held that "[i]n light of the Legislature's authorization of such broad and intrusive investigatory authority [upon the Commission], there is no plausible contention that there is some residual privacy, record keeping or treatment interest effectively to be vindicated by asserting the [physician-patient] privilege." Finally, the Court rejected HHC's argument that HIPAA's privacy rule also required affirmance of the lower courts' decisions, because HIPAA permits disclosures "required by law" including those disclosures "pursuant to a subpoena… issued… by an administrative body authorized to require the production of information."

Based on Contractual Right to Audit Supplier, Human Tissue Distributor May Be Held Liable for Emotional Harm Caused by Supplier's Illegal Harvesting of Tissue

In re Human Tissue Litigation, 750000/08, NYLJ 1202568689933, at *1 (Sup. Court, Richmond County, August 16, 2012). Michael Mastromarino ("Mastromarino"), a former dentist who had entered into the business of harvesting human tissue, organs and bone for distribution in the healthcare industry, and his tissue harvesting company, Biomedical Tissue Services, Inc. ("BTS"), contracted with Defendants RTI Donor Services, Inc., RTI Biologics, Inc. f/k/a Regeneration Technologies, Inc. and Tutogen Medical (United States), Inc. (collectively the "Processors"), who were in the business of redistributing human tissue, organs and bones in the healthcare industry. Under the terms of the contract, Mastromarino and BTS were the Processors' exclusive provider of certain human tissue for processing and distribution.

Following the execution of the contract, the Processors conducted an internal investigation of Mastromarino which revealed that Mastromarino had an extensive criminal history, which included, among other things, a misdemeanor for unlawful use of a police uniform or emblem, and that Mastromarino continued to practice dentistry while New York State had suspended Mastromarino's dentist license. Based on the results of the investigation, Jerome Hoffman, the attorney who had conducted the investigation on behalf of the Processors, recommended that the Processors terminate their relationship with Mastromarino and BTS. Despite their knowledge of Mastromarino's criminal history and Mr. Hoffman's recommendation, the Processors renewed their contract with Mastromarino and BTS.

The contract was, however, amended on two separate occasions. Through the first amendment the Processors reserved the right to "audit/inspect" Mastromarino and BTS no less than once a year. The second amendment established that the human tissue, organs and bone being provided to the Processors from Mastromarino and BTS would meet the accepted criteria and quality control of the American Association of Tissue Banks (the "AATB"), by whom the Processors were accredited.

Following a criminal investigation, it was discovered that Mastromarino and BTS employees (the "Cutters") were unlawfully harvesting the remains of individuals entrusted to certain funeral homes. The elaborate scheme involved cutting open the corpses and harvesting tissue, bones and organs and replacing those body parts with materials purchased at local hardware stores, such as PVC pipes and rubber gloves. In addition, records indicate that Mastromarino and BTS provided the Processors with well over 1,000 forged donor consent files during their three-year business relationship. Following the investigation, Mastromarino was sentenced to 18-54 years in prison. Mastromarino is currently serving his prison sentence at Wende Correctional Facility, a New York State maximum security prison.

Plaintiffs, the next of kin of the decedents, commenced this consolidated action against Mastromarino, the Cutters, the Processors, and certain funereal homes, alleging negligence, negligent infliction of emotional distress, intentional and reckless infliction of emotional distress, negligent misrepresentation, violation of the New York consumer protection statute, loss of consortium, and loss of sepulcher (the right of the next of kin to recover for solely emotional damages which may arise as a result of interference with their loved one's body after death). The Processors brought a motion for summary judgment to dismiss the claims asserted for loss of sepulcher, negligence, negligent infliction of emotional distress, and intentional infliction of emotional distress. The Court granted in part and denied in part the Processors' motion.

The Court noted that in order to succeed in a loss of sepulcher claim there must be an interference with the next of kin's immediate possession of decedent's body and the interference has caused mental anguish, which is generally presumed. In support of its motion relating to plaintiffs' loss of sepulcher claim, the Processors argued that they did not owe a duty to the plaintiffs because they did not

actually interfere with the decedent's body, and that they did not have actual notice of Mastromarino's and BTS's acts as required under N.Y. Public Health Law § 4301(3) ("§ 4301(3)"). The Court, in rejecting the Processors' argument, held that the Processors failed to act on their unlimited right to "audit/inspect" Mastromarino and BTS's operation. Accordingly, the Court expanded the right to "audit/inspect" to include a duty on the part of the Processors to monitor Mastromarino and BTS for any misconduct, fraud, or illegal acts. Under this expansion, the Court held that the Processors interfered with the next of kin's immediate right of possession to the decedent's body by failing to monitor Mastromarino and BTS for illegal activity when the amount of tissue samples provided to the Processors escalated in a short period of time. Furthermore, the Court reasoned that this duty to monitor overcame the actual notice requirement § 4301(3), and that the Processors had constructive notice of Mastromarino's character through the internal investigation it had conducted.

Additionally, the Court held that since the Processors used their membership in the AATB to enhance their reputations in the human tissue marketplace, they raised their obligations to others, including plaintiffs, above the bare bones statutory and common law standards. In failing to "audit/inspect" Mastromarino and BTS, the Processors failed to certify that the activities and services performed by Mastromarino and BTS were performed in conformance with the standards of the AATB. Accordingly, even though there was no statutory or common law duty owed by the Processors to the plaintiffs, in acquiring accreditation to enhance their reputation with the AATB, the Processors adopted a duty to the plaintiffs under the higher AATB standards, and could thus be held liable for the plaintiffs' alleged loss of sepulcher claim.

Finally, the Court dismissed plaintiffs' claims as against the Processors for intentional infliction of emotional distress, negligent infliction of emotional distress, and negligence, because the causes of action were duplicative of plaintiffs' claim for loss of sepulcher.

Court of Appeals Holds That Provisions of Mental Hygiene Law That Grant Advocacy Groups Right to Access Clinical Records of Developmentally Disabled Persons Residing in State-Licensed Facilities Is Limited by Federal Criteria Set Forth in the Developmental Disabilities Assistance and Bill of Rights Act

Albany Law School, et al. v. New York State Office of Mental Retardation and Developmental Disabilities, et al., 945 N.Y.S.2d 613 (2012).

On a certified question, the Court of Appeals determined whether New York Mental Hygiene Law Sections 33.13(c) and 45.09(b) grant State Protection and Advocacy organizations unfettered access to the medical records of developmentally disabled individuals residing in State-owned facilities, without consideration of federal criteria for review of such records established by the Developmental Disabilities Assistance and Bill of Rights Act (the "DD Act").

Petitioners Albany Law School and Disability Advocates, Inc. ("Petitioners") contracted with the New York State Commission on Quality of Care and Advocacy for Persons with Disabilities, the agency that oversees New York's protection and advocacy system (the "Commission") to perform quality assessments of state-owned facilities housing developmentally disabled residents and to follow up on complaints made by those residents. Petitioners received a complaint that certain facilities operated by the New York State Office for People with Developmental Disabilities ("OPWDD") were denying residents the opportunity for discharge to less restrictive settings. In response, Petitioners requested the clinical records of those facilities. Petitioners claimed that they were entitled to those records pursuant to the Mental Hygiene Law sections noted above.

OPWDD disagreed, arguing that the Mental Hygiene Law provisions cited by Petitioners incorporate the codified records-access procedures established by the DD act at 42 USC § 15043(a) (which were enacted to balance the privacy rights of developmentally disabled persons with the need of protection and advocacy organizations to access residents' personal information).

Based on those standards, OPWDD agreed to provide records pertaining to residents for whom Petitioners had obtained authorizations, either from the individuals or their legal representatives (which, according to OPWDD, included actively involved family members), and for individuals who were unable provide authorization and did not have a legal representative.

Petitioners sued to obtain unfettered access to the records. Alternatively, Petitioners requested an order obligating OPWDD to provide the records of developmentally disabled individuals who did not have a legal representative, and for a declaration that "actively-involved family members" were not "legal representatives" for purposes of record access under the DD Act.

The Supreme Court held that the Mental Hygiene Law adopted the federal access procedures, and therefore did not grant Petitioners access to the records at issue absent compliance with the DD Act's requirements. The court also concluded that actively involved family members were equal to "legal representatives" for purposes of the DD Act.

The Appellate Division concurred that MHL § 33.13(c)(4) did not afford Petitioners with unrestricted access to clinical records without consideration of the DD Act, but held that Mental Hygiene Law § 45.09(b) authorized access to Petitioners upon receipt of a complaint. The Appellate Division

further disagreed with the Supreme Court's determination that actively involved family members can be "legal representatives" for purposes of the DD Act's notice provisions.

The Court of Appeals held that the Mental Hygiene Law incorporates the DD Act's standards, given that the MHL expressly ties the access rights of protection and advocacy organizations to the Commission's powers "*as provided for by federal law.*" Thus, the "most plausible reading of the two statutes is that [advocacy] organizations are entitled to review records in compliance with federal law." *See id.* The Court also considered amendments to the DD Act that require states to grant advocacy groups access to records under certain codified circumstances (so that the states can maintain funding under the federal program). The Court reasoned that advocate agencies' compliance with the DD Act when invoking their powers under the Mental Hygiene Law is necessary to avoid jeopardizing continued federal funding to the Commission.

Finally, the Court of Appeals ruled that actively involved family members can be considered "legal representatives" of developmentally disabled individuals such that the family member's consent to the release of clinical records (or failure to act on behalf of a developmentally disabled family member) would satisfy the DD Act's requirements.

General Standard of Care for Pharmacists in Filling Prescriptions Does Not Require Consideration of Patients' Individual Particularities and Subsequent Contact of Physicians for Prescription Verification

Brumaghim v. Eckel, 94 A.D.3d 1391 (3d Dep't 2012). Plaintiffs, the Decedent and her husband, commenced this action alleging malpractice and negligence against *Eckel*, the decedent's physician, and Rite Aid, the pharmacy that filled the Decedent's prescription. Plaintiffs alleged that *Eckel's* failure to prescribe an adequate dose of Coumadin, and Rite Aid's failure to inquire about the dosage, resulted in Decedent's stroke. Rite Aid moved to dismiss for failure to state a cause of action. The Supreme Court denied the motion, and Rite Aid appealed.

"The standard of care which is imposed on a pharmacist is generally described as ordinary care in the conduct of his [or her] business. The rule of ordinary care as applied to the business of a druggist means the highest practicable degree of prudence, thoughtfulness and vigilance commensurate with the dangers involved and the consequences which may attend inattention…Generally, a pharmacist cannot be held liable for negligence in the absence of an allegation that he or she failed to fill a prescription precisely as directed by the physician or was aware that the customer had a condition that would render the prescription of the drug at issue contraindicated."

Plaintiffs alleged that Rite Aid was negligent because it filled "an incorrect and inconsistent prescription medication of a contra-indicated dosage for plaintiff." Plaintiffs did not allege that the amount or dosage differed from what was prescribed by the physician, or that the medication itself was contraindicated for the decedent. They based their allegation of negligence on Rite Aid's failure to consider the particular needs of Plaintiff in its fulfillment of the prescription.

In reversing the lower court, the Third Department reasoned that that the circumstances at issue did not warrant deviation from the general standard of care imposed upon pharmacists:

"Imposing a duty upon a pharmacist to contact the prescribing physician whenever there has been a change in dosage—within medically acceptable ranges—of a particular patient's medication would, in essence, require the pharmacist to question the physician's judgment regarding the appropriateness of each customer's prescription." The Court noted that it is the duty of the prescribing physician to properly prescribe medication, the duty of the patient to advise the physician of what other drugs he may be taking, and the duty of the drug manufacturer to warn of adverse effects or other precautions. "Placing such duties on the pharmacist would serve only to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability."

Status as Primary Care Physician Alone Does Not Impose Duty to Assess Course of Treatment Initiated by Another Physician

Burtman v. Brown, 97 A.D.3d 156 (1st Dep't 2012). Plaintiff sued her primary care physician ("Defendant"), her obstetricians ("Brown" and "Langer"), and West Side Radiology, alleging malpractice. Specifically, she alleged that their failure to diagnose atypical lipoma caused her to require more invasive treatment than would have been necessary otherwise. On appeal, the Court considered whether status as a primary care physician is dispositive on the issue of whether a physician has a duty to supervise or override a course of treatment initiated by another physician actively treating the patient. In a four-to-one decision, the Court held that this fact is not dispositive, and under the circumstances of this case, Defendant was under no independent duty.

Since 1997, Plaintiff had been a patient of West Care, a rotating group obstetrical practice. In 1999, Brown treated Plaintiff for an underarm mass. After biopsy, Brown diagnosed her with benign lipoma.

On August 2, 2005, when she first visited Defendant, Plaintiff was three months pregnant and under the care of Brown and Langer at West Care. She visited Defendant for a full check-up, and Defendant examined her accordingly. Prior to this visit, she underwent two prenatal examinations with Brown at West Care, one in June and one in July. Her next pre-

natal examination with Brown was scheduled for August 25, 2005.

In September of 2005, Langer examined Plaintiff at West Care and noted a mass in her abdomen. Langer ordered a sonogram, which was performed on October 12, 2005. The next day, a radiology report was faxed to Defendant, who noted its reference to a mass consistent with benign fibrolipoma. She did not discuss the report with Plaintiff or any other doctors at West Care. The West Care doctors concluded it was best to wait and observe Plaintiff's condition, rather than incur the risks of surgery.

Plaintiff's second visit to Defendant took place in January of 2006. Plaintiff sought a referral from Defendant to a physical therapist for treatment of her sprained ankle.

Plaintiff gave birth in February of 2006. In June of 2006, she visited a different primary care physician regarding a tick bite on her abdomen. She had seen this second primary care physician before, in February of 2005. In October of 2006, Plaintiff visited a plastic surgeon, who noted two abdominal masses, and performed an excision and biopsy in December of 2006. Plaintiff was diagnosed with "atypical lipoma," suggesting malignancy. She subsequently underwent a "wide radical excision of th[e] area."

After discovery, the Court denied Defendant's motion for summary judgment. The court found questions of fact as to whether Defendant carried out thorough abdominal examinations on August 4, 2005 and January of 2006. The court based its finding on the testimony of Plaintiff's expert, who characterized the abdominal mass as a "medical issue" rather than a "gynecological" problem, something within the scope of a primary care physician's duty.

The Appellate Division reversed, noting that the lower court, without reference to law and relying erroneously on Plaintiff's expert, "imposed on the [D]efendant a duty of overseeing a course of treatment commenced by another treating physician who specifically referred the plaintiff to a different specialist to follow up on her condition."

First, the Court established that whether a doctor owes a duty of care is a question of law; accordingly, "it is generally not an appropriate subject for expert opinion." Consequently, "when no duty is found to exist, the opinion of plaintiff's medical expert that defendant deviated from the standard of accepted medical practice is irrelevant."

Second, the Court held that the existence of this duty is dependent on "the circumstances of the particular scenario." Under these circumstances, the fact that Brown faxed Defendant the radiology results did not serve to involve Defendant in the setting or monitoring of Plaintiff's treatment for the mass such that it imposed a duty on her to take further action with regard to these results.

Appellate Division Holds That a Hospital Is Not Liable for the Alleged Medical Malpractice of Medical Resident Who Did Not Exercise Medical Judgment Independent of Supervising Physicians

Wulbrecht v. Jehle, 92 A.D.3d 1213, 938 N.Y.S.2d 707 (4th Dep't 2012). Plaintiff, the administratrix of her husband's estate, brought a medical malpractice and wrongful death action against Erie County Medical Center Corporation (the "Hospital"), seeking damages for the death of her husband, a psychiatric patient who committed suicide. The trial court granted the Defendants' motion for summary judgment, and the Appellate Division, Fourth Department affirmed.

In support of its decision the Court held that the Hospital was not liable for the alleged malpractice of its resident, Dr. Denise Giessert. Dr. Giessert, who first met with the decedent prior to his admission to the Hospital, was acting under the supervision of two attending physicians who were required to approve any orders Dr. Giessert signed. Accordingly, the Court held that the Hospital was not liable for the alleged malpractice of Dr. Giessert because she did not exercise any independent medical judgment, and the directions to her from her attending physicians did not so greatly deviate from normal practice that the she should be held liable for failing to intervene.

Additionally, in accordance with the well-established rule, the Court held that the Hospital was not concurrently liable for the alleged malpractice of its private attending physicians, because the attending physicians' orders did not contradict normal practice such that ordinary prudence required inquiry into the correctness of the attending physicians' orders.

Court Holds That an Individual's Height Is Not a "Predisposing Genetic Characteristic" Within the Meaning of Executive Law § 296

Peterson v. City of New York, 2012 NY Slip Op 51472(U) (Sup. Ct. Queens County, August 7, 2012). Plaintiff commenced an action against her former employer for terminating her from her position in a transitional employment program. Plaintiff alleged that she was terminated on the basis of her height, a "predisposing genetic characteristic," in violation of the New York State and City Human Rights Law.

Executive Law § 296(1)(a) provides, among other things, that it is unlawful to take an adverse employment action against an individual on the basis of a "predisposing genetic characteristic." The court ruled that based on the plain language of the statute, and its legislative history, the plaintiff's height is outside the scope of the phrase "predisposing genetic characteristics." Recognizing that the legislature defined "predisposing genetic characteristics" as meaning only a genetic predisposition to developing a disease or disability, the Court concluded that the phrase has

no application to a person's height. The court further concluded that such application would contradict the legislature's express intent in promulgating the statute as the legislature explicitly stated it included "predisposing genetic characteristics" as a prohibited basis for discrimination to "preven[t] employers and insurance companies from requiring otherwise healthy individuals, as a condition for employment or insurance coverage, to undergo genetic testing to determine whether they are predisposed to developing a disease or disability in the future and denying employment or coverage because of such predisposition."

The court rejected the plaintiff's reliance on a publication regarding dwarfism, which the plaintiff offered as evidence that her height is genetic, concluding that the plaintiff misinterpreted the plain meaning of the statute. The court determined that the issue is not whether the plaintiff's height is genetic, but whether the plaintiff was fired as a result of genetic testing which determined that she might develop a disease or disability in the future. Accordingly, because the plaintiff failed to allege that her employer told her that "because of her shortness she might develop a medical condition in the future and for that reason her employer did not want to be exposed to the risk of paying for her healthcare," the court granted the defendants' motion to dismiss for failure to state a cause of action.

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

In the New York State Legislature

By James W. Lytle

Introduction and Overview

The 2012 legislative session adjourned on June 21st with the New York State Legislature having passed a total of 571 bills, one of the smallest totals since 1914. Barring any significant action by the Legislature during the balance of the year, the following summarizes the key health laws passed by the Legislature during 2012.

Not every significant health policy is embodied in legislation in New York: many significant policies are enacted as part of the State Budget and a number of additional significant initiatives, such as the Health Benefit Exchange required by the ACA and executive compensation limitations, were promulgated by Executive Order. Nevertheless, the bills described briefly below include a number of key new laws that will affect health care entities and patients for years to come.

Managed Care/Insurance-related Legislation

Insurance Coverage for Cancer Chemotherapy Treatments (Chapter 12 of the Laws of 2012; S.6055 Lanza/A.8906 V. Lopez): Requires that any health insurance policy that provides coverage for prescription drugs and cancer chemotherapy treatments must also provide coverage for orally administered anticancer medications, with co-pays, coinsurance or deductibles at least as favorable as those for other cancer chemotherapy treatments. Signed by the Governor on February 17, 2012, and took effect on January 1, 2012.

Breast Reconstruction Surgery (Chapter 302 of the Laws of 2012; S.3801-A LaValle/A.7193-A Cook): Provides insurance coverage for reconstruction after partial mastectomies, expanding current Insurance Law provisions that require coverage

of only radical mastectomies. Signed by the Governor and took effect on August 1, 2012.

Denial of Claims based on Timely Notification of Hospital Services (Chapter 297 of the Laws of 2012; S.7071-B Hannon/A.9946-B Morelle): Prevents insurers and health plans from denying payment to a general hospital for a claim for medically necessary inpatient services resulting from an emergency admission solely on the basis that the hospital did not timely notify the insurer or plan that the services had been provided. Signed by the Governor on August 1, 2012 and takes effect on July 1, 2013.

Streamline State ACO Process (S.6228-B Hannon/A.8869-B Gottfried): Would clarify and simplify last year's State ACO law, which was passed before federal officials issued its regulations relating to ACOs, and would provide that Health Department regulations governing ACOs must be largely consistent with federal regulations for Medicare ACOs. A streamlined State ACO license process would apply to ACOs that serve only Medicare patients and a limitation on the number of ACOs would be eliminated. Not yet been delivered to the Governor. The bill would take effect immediately.

Self-Funded Student Health Benefit Plans (Chapter 246 of the Laws of 2012; S.7314-A Seward/A.Rules (Morelle)): Authorizes certain universities (i.e., those that offer baccalaureate or graduate degrees, are governed by the Board of Regents, and maintain an endowment of at least $1 billion) to self-insure their students' health plans. Signed on July 18, 2012 and will take effect on January 1, 2013.

Hospital Regulation

Palliative Care Information and Counseling (Chapter 256 of the Laws of 2012; S.7596 Hannon/A.10373 Goldfeder): Amends the Palliative Care Information Act to require that patients diagnosed with a "terminal illness or condition" be given information regarding other appropriate treatment options if the patient wishes to initiate or continue treatment. In the event the health care practitioner is not willing or qualified to provide such information, another health care practitioner must convey the information. Signed by the Governor on July 18, 2012 and will take effect on January 14, 2013.

Whooping Cough Vaccines (Chapter 215 of the Laws of 2012; S.6500 Hannon/A.9381Englebright): This law requires general hospitals that have a newborn nursery or provide obstetric services to offer vaccination against Bordetella pertussis (whooping cough) to parents of hospitalized newborns. Signed by the Governor on July 18, 2012, and will take effect on January 14, 2013.

Dense Breast Tissue Mammography (Chapter 265 of the Laws of 2012; S.6769-B Flanagan/A.9586-D Jaffee): Requires specific written notification to the patient after a finding of dense breast tissue on a mammogram, an explanation of what that means and a recommendation to consult with the patient's physician about an additional screening. Signed by the Governor on July 23, 2012 and will take effect on January 19, 2013.

Healthcare Audit, Fraud and Abuse

"Mini-Stark" Self-referral Law Conforming Amendments (S.4660 Hannon/A.3551-A Gottfried): Would clarify that referrals that are allowed under the federal Stark law (42 U.S.C. 1395nn), or its safe harbor regulations, would be allowed under the

New York State Mini-Stark Law, unless the Public Health and Health Planning Council declares the type of arrangement to pose a substantial risk of payor or patient abuse. The bill, proposed by the Health Law Section, has not yet been delivered to the Governor and would take effect immediately.

Interest on Home Care Recoupments (A.9664-B Brindisi/S.6493-B Hannon): Would prohibit the assessment of interest on Medicaid recoupments from certified home health agencies, licensed home care services agencies and consumer-directed personal assistance program providers on and after April 1, 2009, on the grounds that the assessment of such interest unfairly penalizes such providers for delays in Medicaid rate change approvals. Not yet delivered to the Governor, the bill would take effect immediately and would expire on March 31, 2014.

HCRA Surcharge Amnesty (Veto No. 135; S.7083 Hannon/A.10103 Gottfried): Would have revived for calendar year 2012 an amnesty period for delinquent Health Care Reform Act (HCRA) surcharges that applied in calendar year 2011. Vetoed on August 1.

Behavioral Health Care and Developmental Disability Services

Protection of People with Special Needs Act (S.7749 McDonald/A.10721 Rules (Ortiz)): Would establish a new Justice Center for the Protection of People with Special Needs, which will have primary responsibility for tracking, investigating and pursuing allegations of abuse and neglect at facilities and agencies that are operated, certified, or licensed by the Department of Health, the Office of Mental Health, the Office for People With Developmental Disabilities, the Office of Children and Family Services, the Office of Alcoholism and Substance Abuse Services, and the State Education Department. Would absorb all the functions and responsibilities of the Commission on Quality of Care and Advocacy for Persons with Disabilities, with the exception of the oversight and administration of the Federal Protection and Advocacy and Client Assistance Programs, which it must delegate to an independent public or private agency. The Justice Center would also be responsible for establishing a Statewide Vulnerable Persons' Central Register, consolidating background check procedure, and performing a variety of other functions related to the treatment of people with special needs. Would also increase criminal penalties for endangering the welfare of people with disabilities and special needs and strengthen a prosecutor's ability to prove that any of these individuals in a facility operated, licensed, or certified by the State were the victims of sexual abuse. Not yet delivered to the Governor, where, since it was a high priority within his legislative program, it is certain to be signed. The bill would take effect on June 30, 2013.

Jonathan's Law Extender (S.7475-A McDonald/A.9777-A Ortiz): Would remove the deadline for parents and/or qualified persons to obtain records and documents pertaining to investigations. Not been delivered to the Governor. The bill would take effect immediately.

Abuse Prevention Notification System (Chapter 6 of the Laws of 2012, S.6107-A McDonald /A.8693 Weisenberg): Would provide OPWDD 180 days to create a system whereby OPWDD providers will be able to obtain the prior abuse history of prospective employees or volunteers. Signed by the Governor, and took effect, on February 1, 2012.

Long-Term Care

Increases the Availability of Assisted Living Beds (Chapter 397 of the Laws of 2012; A.10304 Goodell/S.6948 Young): Makes permanent prior enactments that allowed a single assisted living program (ALP) in Chautauqua County to temporarily expand its number of ALP beds. Signed by the Governor, and took effect, on August 17, 2012.

Extension of Residential Care Off-site Facility Demonstration Project (Chapter 159 of the Laws of 2012; S.7062 Robach/A.9948 Morelle): Extends the residential care off-site facility demonstration project until June 2015. The demonstration project allows for the provision of physical, occupational and speech therapy by a residential health care facility at an off-site location. Signed by the Governor, and took effect on July 18, 2012.

Healthcare Professional Licensing and Regulation

Central Service Technicians (S.5155-D Grisanti/A.8620-C Bronson): Would require the certification of central service technicians. Not yet delivered to the Governor. This bill would take effect 180 days day after becoming a law.

Perfusionist Temporary Permits (S.4640-C DeFrancisco/A.4153-C Magnarelli): Would allow perfusionists to directly perform laboratory tests necessary to their job of supporting certain procedures, usually open heart surgery and organ transplants. Not yet delivered to the Governor. The bill would take effect immediately and will expire on July 1, 2014.

Surgical Technology (S.6511-A Savino/A.9303-A Cahill): Would establish requirements for surgical technologists working in health care facilities and would require hospitals to hire only certified or exempt personnel to provide these services. A more wide-reaching bill was vetoed in 2011 (Veto #75). Not yet delivered to the Governor, the bill would take effect eighteen months after enactment.

Sexual Offenses by Health Care or Mental Health Care Providers (Chapter 365 of the Laws of 2012; S.7456-B Saland/A.10336-B Paulin): Requires the office of professional discipline to notify law enforcement of a complaint regarding professional misconduct of a licensed health care or mental health care provider if there is a reasonable belief that an act that constitutes a sex offense has been committed. Signed by the Governor and took effect on August 1, 2012.

Physical Therapist Faculty Practice Corporations (Chapter 323 of the Laws of 2012; S.6980 Ranzenhofer/A.10002 Brennan): Allows physical therapists at academic medical centers and other teaching facilities to form faculty practice corporations, like physicians, dentists, chiropractors and optometrists have been previously authorized. Signed by the Governor and took effect on August 1, 2012.

Optometrists to Certify Vision Disability for Handicapped Parking (Chapter 277 of the Laws of 2012; S.1340-A Dilan/A.7574-A Gantt): Authorizes optometrists to certify a person's vision-related disability for purposes of obtaining handicapped automobile registrations and license plates from the State Department of Motor Vehicles. Signed by the Governor on August 1, 2012, and took effect on August 31, 2012.

Podiatrist Scope of Practice (Chapter 438 of the Laws of 2012; S.7800 Libous/ A.9293-A Pretlow): Authorizes podiatrists to diagnose, treat, operate and prescribe for any disease, injury, deformity or other condition of the ankle and soft tissue of the leg below the knee if they have obtained special privileges. Signed by the Governor on August 17, 2012, and will take effect on February 17, 2014.

Occupational Therapy Assistant Authorization (Chapter 329 of the Laws of 2012; S.7175 LaValle/A.10118 Canestrari): Allows an occupational therapy assistant who has graduated from an accredited occupational therapy assistant program to receive a limited permit to practice under the direction and supervision of an occupational therapist or a physician. Signed on August 1, 2012 and will take effect on October 30, 2012.

Occupational Therapists and Occupational Therapy Assistants Continuing Education Requirement (Chapter 444 of the Laws of 2012; S.2935-B LaValle/A.4519-B Canestrari): Requires an occupational therapy assistant to complete 36 hours of mandatory continuing competency in each triennial registration period. Signed by the Governor on August 17, 2012, and will take effect on February 13, 2013.

Certification of Certified Registered Nurse Anesthetists (S.5356-D Young/A.8392-C Paulin): Would establish the criteria for certification as a certified registered nurse anesthetist and would prohibit any individual other than a certified person from using the title "certified registered nurse anesthetist," subject to a "grandfathering" provision for current practitioners. Not yet been delivered to the Governor, the bill would take effect 180 days after becoming a law and the certification requirements would become effective 3 years thereafter.

Public Health/Patient Rights

Prohibit Use by Children of Indoor Tanning Facilities (Chapter 105 of the Laws of 2012, S.2917-A Fuschillo/A.1074-B Weisenberg): Prohibits the use of indoor tanning facilities by anyone under the age of 16. Prior law had allowed the use of indoor tanning facilities by anyone between the ages of 14 and 18, but had required parental consent prior to use. Signed by the Governor on July 16, 2012, and became law on August 15, 2012.

Authority of Health Care Agents (S.5014 DeFrancisco/A.8389 Lavine): Authorizes a health care agent to act outside a hospital setting, mental hygiene facility or residential health care facility regarding decisions to transport an unconscious or unresponsive patient to a particular medical setting. Not yet delivered to the Governor, the bill would take effect 120 days after becoming a law.

Update Organ and Tissue Donation Registry (Chapter 158 of the Laws of 2012; S.6972 Hannon/A.9901 Titone): Athorizes the use of the New York State Donate Life Registry website to provide notice confirming registration and to amend or revoke registration. Signed by the Governor and took effect, on July 18, 2012.

Death Certificate to Sibling of Deceased (Chapter 130 of the Laws of 2012; S.6314 Golden/A.9107 Gunther): Authorizes the Commissioner of Health to issue a death certificate to the sibling of the deceased. Signed by the Governor and took effect on July 18, 2012.

Pharmacy

Prescription Drug Reform (S.7637 Lanza/A.10623 Cusick) at request of the Governor: Established the Internet System for Tracking Over-Prescribing (ISTOP) Act—a real-time monitoring registry for controlled substances that practitioners must consult before prescribing or dispensing. The Medicaid Fraud Control Unit, local health departments (for specified research purposes), medical examiners or coroners, and law enforcement agencies would have access to ISTOP. Within two years, requires most prescriptions to be issued electronically, except for prescriptions: issued by veterinarians; dispensed by out-of-state pharmacies; issued in circumstances where electronic prescribing is not available due to temporary failure; issued by practitioners who have received a waiver for a specified period or where it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner. Directed the Prescription Pain Medication Awareness Program workgroup to make recommendations relating to pain medication and palliative care. Rescheduled hydrocodone from Schedule III to Schedule II and added Tramadol to Schedule IV and established a safe disposal program to allow for the voluntary and secure surrender of controlled substances. Signed August 27, the bill took effect immediately.

Standard Prior Authorization Form (S.7384-A Hannon/A.10248-B P. Rivera): Requires the Department of Health to develop a standard prior authorization form to be used by Medicaid managed care providers to determine coverage of prescription drug benefits. Not yet delivered to the Governor, the bill would take effect immediately.

Prescription Fertility Drugs (Chapter 10 of the Laws of 2012; S.6126 Skelos/A.8900 Silver): Requires coverage for prescription fertility drugs purchased through a participating non-mail order retail pharmacy on same terms as covers participating mail order or non-retail specialty pharmacy. Signed and took effect on February 17, 2012.

Access to Drugs at Retail Pharmacies (Chapter 11 of the Laws of 2012; S.6054 Maziarz /A.8904 Heastie): Mandates coverage of drugs purchased at a participating non-mail order retail pharmacy on same terms established with the participating mail order and non-retail specialty pharmacies. Also signed and effective on February 17, 2012.

Authorizes Pharmacists to Administer Immunizations (Chapter 116 of the Laws of 2012; S.3808-B Fuschillo/A.6301-D Paulin): Extends existing authority of pharmacists to administer immunizations, allows nurse practitioners to write patient specific orders for such actions and permits pharmacists to administer the vaccine for Herpes Zoster (Shingles) for adults. Signed by the Governor on July 18, 2012, it takes effect on October 13, 2013 and expires on July 1, 2015.

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In the New York State Agencies

By Francis J. Serbaroli

Establishment of Certified Home Health Agencies (CHHAs)

Notice of Emergency Rulemaking. The Department of Health amended section 760.5 of Title 10 NYCRR to establish new or expand existing CHHAs to promote cost effectiveness and integration of health care coordination of services. Filing date: April 3, 2012. Effective date: April 3. *See* N.Y. Register April 18, 2012.

Minimum Standards for the New York State Partnership for Long-Term Care Program

Notice of Adoption. The Department of Financial Services amended Part 39 (Regulation 144) of Title 11 NYCRR to amend minimum standards for inflation protection, to add a new plan and add disclosure requirements relating to reciprocity. Filing date: April 26, 2012. Effective date: June 1, 2012. *See* N.Y. Register May 16, 2012.

Claims for Personal Injury Protection Benefits

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Subpart 65-3 of Title 11 NYCRR to combat no-fault fraud while also accelerating the resolution of no-fault claims. *See* N.Y. Register May 16, 2012.

Reduction to Statewide Base Price

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.16 of Title 10 NYCRR to continue a reduction to the statewide base price for inpatient services. Filing date: May 1, 2012. Effective date: May 1, 2012. *See* N.Y. Register May 16, 2012.

Rights of Patients

Notice of Proposed Rulemaking. The Office of Mental Health proposed

amending Part 527 of Title 14 NYCRR to extend rights in Part 527 to inmates receiving services at DOCCS regional medical units/ residential crisis treatment programs. *See* N.Y. Register May 16, 2012.

Limits on Executive Compensation and Administrative Expenses in Agency Procurements

Notice of Proposed Rulemaking. The Department of Health proposed adding Part 1002 to Title 10 NYCRR to ensure state funds and state authorized payments are expended in the most efficient manner and appropriate use of funds. *See* N.Y. Register May 30, 2012.

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

Notice of Emergency Rulemaking. The Department of Financial Services added section 362-2.9 (Regulation 171) to Title 11 NYCRR to place limitations on new enrollment to the Healthy NY high deductible plan pursuant to section 4326(g) of the Insurance Law. Filing date: June 4, 2012. Effective date: June 4, 2012. *See* N.Y. Register June 20, 2012.

Unauthorized Providers of Health Services

Notice of Emergency Rulemaking. The Department of Financial Services added Subpart 65-5 (Regulation 68-E) to Title 11 NYCRR to establish standards and procedures for the investigation and suspension or removal of a health service provider's authorization. Filing date: June 6, 2012. Effective date: June 12, 2012. *See* N.Y. Register June 27, 2012.

NYS Medical Indemnity Fund

Notice of Emergency Rulemaking. The Department of Health amended Part 69 of Title 10 NYCRR to provide the structure within which the NYS Medical Indemnity Fund will operate. Filing date: June 11, 2012. Effective date: June 11, 2012. *See* N.Y. Register June 27, 2012.

Home Care Services Worker Registry

Notice of Adoption. The Department of Health added Part 403 and amended sections 700.2, 763.13 and 766.11 of Title 10 NYCRR; and amended sections 505.14 and 505.23 of Title 18 NYCRR to provide guidance for workers, providers, etc. regarding the rights, duties and responsibilities for the Home Care Services Worker Registry. Filing date: June 7, 2012. Effective date: June 27, 2012. *See* N.Y. Register June 27, 2012.

Prior Approval Review (PAR) for Quality and Appropriateness

Notice of Adoption. The Office of Mental Health amended Part 551 of Title 14 NYCRR to add provisions for electronic submission of PAR applications. Filing date: June 11, 2012. Effective date: June 27, 2012. *See* N.Y. Register June 27, 2012.

Personalized Recovery Oriented Services (PROS)

Notice of Adoption. The Office of Mental Health amended Part 512 of Title 14 NYCRR to add provisions regarding Behavioral Health Organization (BHO) implementation. Filing date: June 12, 2012. Effective date: June 27, 2012. *See* N.Y. Register June 27, 2012.

Pharmacy and Durable Medical Equipment Fee Schedules and Requirements for Designated Pharmacies

Notice of Emergency Rulemaking. The Workers' Compensation Board added Parts 440 and 442 to Title 12 NYCRR to adopt pharmacy and durable medical equipment fee schedules, payment process and requirements for use of designated pharmacies. Filing date: June 11, 2012. Effective date: June 11, 2012. *See* N.Y. Register June 27, 2012.

Child Care Personnel Tuberculosis Testing

Notice of Proposed Rulemaking. The Office of Children and Family Services proposed amending section 180.8 of Title 9 NYCRR; and sections 414.11, 416.11, 417.11, 418-1.11, 418-2.11, 442.18 and 448.3 of Title 18 NYCRR to amend the regulations that reflect the current means by which child care personnel are tested for Tuberculosis. *See* N.Y. Register July 3, 2012.

Hospital Temporary Rate Adjustments

Notice of Adoption. The Department of Health amended section 86-1.31 of Title 10 NYCRR to no longer require that a merger, acquisition or consolidation needs to occur on or after the year the rate is based upon. Filing date: June 13, 2012. Effective date: July 3, 2012. *See* N.Y. Register July 3, 2012.

Temporary Rate Adjustment (TRA)—Residential Health Care Facilities (RHCF) (Nursing Homes)

Notice of Adoption. The Department of Health added section 86-2.39 to Title 10 NYCRR to provide a TRA to eligible RHCFs subject to or impacted by closure, merger, acquisition, consolidation, or restructuring. Filing date: June 13, 2012. Effective date: July 3, 2012. *See* N.Y. Register July 3, 2012.

Temporary Rate Adjustment (TRA)—Licensed Ambulatory Care Facilities (LACF)

Notice of Adoption. The Department of Health added section 86-8.15 to Title 10 NYCRR to expand TRA to include Article 28 LACFs subject to or affected by closure, merger, acquisition, consolidation, or restructuring. Filing date: June 13, 2012. Effective date: July 3, 2012. *See* N.Y. Register July 3, 2012.

Patient Rights, Inpatient Rehabilitation Services, Residential Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Parts 815, 818 and 819 of Title 14 NYCRR to improve quality of service by clarifying regulations to eliminate frequent waiver requests and reduce administrative burdens. Filing date: June 20, 2012. Effective date: July 11, 2012. *See* N.Y. Register July 11, 2012.

AIDS Scatter Beds

Notice of Emergency Rulemaking. The Department of Health amended section 86-2.40 of Title 10 NYCRR to provide a rate adjustment to eligible nursing homes that are not eligible for payment rates as AIDS facilities/discrete AIDS units. Filing date: June 20, 2012. Effective date: June 20, 2012. *See* N.Y. Register July 11, 2012.

Municipal Public Health Services Plan—Radioactive Material and Radiation Equipment

Notice of Emergency Rulemaking. The Department of Health amended Part 40 of Title 10 NYCRR to establish funding for certified counties to inspect radiation equipment and the NYCDOHMH to conduct licensing and inspections. Filing date: June 25, 2012. Effective date: June 25, 2012. *See* N.Y. Register July 11, 2012.

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

Notice of Emergency Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the provision of continuous PC and continuous CDPA services. Filing date: June 27, 2012. Effective date: June 27, 2012. *See* N.Y. Register July 18, 2012.

Audits of Institutional Cost Reports (ICR)

Notice of Emergency Rulemaking. The Department of Health amended Subpart 86-1 of Title 10 NYCRR to impose a fee schedule on general hospitals related to the filing of ICRs sufficient to cover the costs of auditing the ICRs. Filing date: June 27, 2012. Effective date: June 27, 2012. *See* N.Y. Register July 18, 2012.

Medical Assistance Rates of Payment for Assertive Community Treatment Services

Notice of Adoption. The Office of Mental Health repealed Part 508 and added Part 508 to Title 14 NYCRR to repeal a Part and replace with a new Part that clarifies reimbursement standards and methodologies for ACT providers. Filing date: June 27, 2012. Effective date: July 18, 2012. *See* N.Y. Register July 18, 2012.

Plan of Care Support Services Requirements

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending section 635-10.5(a) of Title 14 NYCRR to revise qualifications for service coordinators, eligibility for services, and reimbursement eligibility and methodology. *See* N.Y. Register July 18, 2012.

Changes to HCBS Waiver Hourly Community Habilitation Services

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending section 635-10.5 of Title 14 NYCRR to modify the fee schedule for the clinical oversight component of funding and to provide expectations for clinical oversight. *See* N.Y. Register July 18, 2012.

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

Notice of Adoption. The Office of Mental Health amended Part 578 of Title 14 NYCRR to freeze rates paid to residential treatment facilities consistent with the enacted 2012-2013 State Budget. Filing date: July 10, 2012. Effective date: July 25, 2012. *See* N.Y. Register July 25, 2012.

Authority to Collect Pharmacy Acquisition Cost

Notice of Emergency Rulemaking. The Department of Health amended section 505.3 of Title 18 NYCRR to establish a requirement that each enrolled pharmacy report actual acquisition cost of a prescription drug to the Department. Filing date: July 23, 2012. Effective date: July 23, 2012. *See* N.Y. Register August 8, 2012.

Orthodontic Screening

Notice of Emergency Rulemaking. The Department of Health repealed section 85.45 of Title 10 NYCRR; and amended section 506.4 of Title 18 NYCRR to clarify Orthodontic Screening Provider Qualifications and Recipient Eligibility Criteria. Filing date: July 24, 2012. Effective date: July 24, 2012. *See* N.Y. Register August 8, 2012.

Adult Homes

Notice of Proposed Rulemaking. The Department of Health proposed amending Parts 486 and 487 of Title 18 NYCRR to limit the number of residents with serious mental illness in large adult homes. *See* N.Y. Register August 8, 2012.

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

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Parts 580 and 582 of Title 14 NYCRR to establish provisions prohibiting the discharging of patients to transitional adult homes. *See* N.Y. Register August 8, 2012.

General Facility Requirements

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 814; and adding a new Part 814 to Title 14 NYCRR to add updates to reflect standards that are currently enforced as well as new provisions required by changes in other regulations. *See* N.Y. Register August 15, 2012.

Statewide Pricing Methodology for Nursing Homes

Notice of Emergency Rulemaking. The Department of Health added section 86-2.40 to Title 10 NYCRR to establish a new Medicaid reimbursement methodology for Nursing Homes. Filing date: July 30, 2012. Effective date: July 30, 2012. *See* N.Y. Register August 15, 2012.

Reduction to Statewide Base Price

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.16 of Title 10 NYCRR to continue a reduction to the statewide base price for inpatient services. Filing date: July 30, 2012. Effective date: July 30, 2012. *See* N.Y. Register August 15, 2012.

Episodic Pricing for Certified Home Health Agencies (CHHAs)

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.44 of Title 10 NYCRR to exempt services to a special needs population from the episodic payment system for CHHAs. Filing date: July 31, 2012. Effective date: July 31, 2012. *See* N.Y. Register August 15, 2012.

Rates of Reimbursement—Hospitals Licensed by OMH

Notice of Emergency/Proposed Rulemaking. The Office of Mental Health amended Part 577 of Title 14 NYCRR to amend the audit protocol for hospitals licensed by OMH pursuant to Article 31 of the Mental Hygiene Law. Filing date: July 27, 2012. Effective date: July 27, 2012. *See* N.Y. Register August 15, 2012.

Synthetic Phenethylamines and Synthetic Cannabinoids (SP & SC) Prohibited

Notice of Emergency Rulemaking. The Department of Health added Part 9 to Title 10 NYCRR to prohibit possession, manufacture, distribution, sale or offer of sale of some substances and products containing SP & SC. Filing date: August 7, 2012. Effective date: August 7, 2012. *See* N.Y. Register August 22, 2012.

Withholding of Payments; Incorporation by Reference

Notice of Adoption. The Office of the Medicaid Inspector General amended sections 518.7 and 518.9 of Title 18 NYCRR to amend regulations governing the withholding of Medicaid payments in accordance with federal requirements. Filing date: August 6, 2012. Effective date: August 22, 2012. *See* N.Y. Register August 22, 2012.

Medical Assistance Payments for Comprehensive Psychiatric Emergency Programs (CPEP)

Notice of Emergency/Proposed Rulemaking. The Office of Mental Health amended Part 591 of Title 14 NYCRR to increase Medicaid fees paid to CPEPs effective July 1, 2012. Filing date: August 6, 2012. Effective date: August 6, 2012. *See* N.Y. Register August 22, 2012.

Smoker/Nonsmoker Mortality Tables and Underwriting Classifications

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Part 57

(Regulation 113) of Title 11 NYCRR to provide that juveniles will be treated as non-smokers unless an insurer has evidence to the contrary. *See* N.Y. Register August 29, 2012.

Operation of Hospitals for Persons with Mental Illness

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending section 582.8 of Title 14 NYCRR to add provisions regarding fire safety and smoking within buildings. *See* N.Y. Register August 29, 2012.

Medicaid Managed Care Programs

Notice of Emergency Rulemaking. The Department of Health repealed Subparts 360-10 and 360-11 and sections 300.12 and 360-6.7; and added Subpart 360-10 to Title 18 NYCRR to repeal old and outdated regulations and to consolidate all managed care regulations to make them consistent with statute. Filing date: August 21, 2012. Effective date: August 21, 2012. *See* N.Y. Register September 5, 2012.

Nursing Home Sprinklers

Notice of Proposed Rulemaking. The Department of Health proposed adding section 86-2.41 to Title 10 NYCRR to assist eligible nursing homes with accessing credit markets to finance the costs of installing automatic sprinkler systems. *See* N.Y. Register September 5, 2012.

Early Intervention Program

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 69-4 of Title 10 NYCRR to eliminate conflicts of interest by evaluators, service coordinators, and service providers in the Early Intervention Program. *See* N.Y. Register September 5, 2012.

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 NYCRR to continue the 2011 rates paid to freestanding psychiatric hospitals for the 2013 rate year, effective January 1, 2013. Filing date: August 20, 2012. Effective date: September 5, 2012. *See* N.Y. Register September 5, 2012.

Prior Approval Review for Quality and Appropriateness

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Part 551 of Title 14 NYCRR to repeal an outdated reference and establish consistency with Federal requirements regarding accessibility standards. *See* N.Y. Register September 5, 2012.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a shareholder in the Health & FDA Business Group of Greenberg Traurig's New York office. He is the former Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and is a former Chair of the Health Law Section. The assistance of Whitney M. Phelps, Of Counsel, and Caroline B. Brancatella, Associate, of Greenberg Traurig's Health and FDA Business Group in compiling this summary is gratefully acknowledged.

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions

Compiled by Eugene M. Laks

New York Service Network, Inc. (DOH administrative hearing decision dated April 24, 2012, David A. Lenihan, Administrative Law Judge). In a decision of significance to the OMIG audit process, the Department of Health Administrative Law Judge denied the provider's motion to dismiss the extrapolation of OMIG disallowances in the audited sample of chemical dependence outpatient services provided by New York Service Network, Inc. during the period May 1, 2003 through December 31, 2007. For the selection of an audit sample, each claim in the universe is assigned a number. A computer program, a Random Number Generator, selects numbers which represent the claims to be audited. For extrapolation to the universe of claims in the audit period to be a statistically valid process, the audit sample must be random.

The issue was that the OMIG does not record and retain the random seed that is used by the computer program to generate the samples to be audited from the universe of all claims of a provider for the audit period. The random seed is selected by the computer. The motion to dismiss the extrapolation was based in part on the argument that without the random seed, it is not possible to replicate the generation of the particular audit sample and the provider is deprived of due process. Granting the motion would have jeopardized every extrapolation audit conducted by the OMIG. The ALJ held that the random seed is not necessary to statistically test whether the audit samples used by the OMIG in this audit were random representatives of the universe of claims. The ALJ held

therefore that the provider had not established that the process was arbitrary, capricious or in any way unfair.

Lawrence L. Rezkalla, M.D. (DOH administrative hearing decision dated April 23, 2012, John Harris Terepka, Administrative Law Judge). The Department of Health Administrative Law Judge sustained Medicaid audit adjustments for the difference between what was paid to the physician by the Medicaid program and the amount, based on Medicare payment records, that should have been paid by the Medicaid program as a secondary payor to Medicare for services provided to dual-eligible persons and adjustments for failure of the physician to bill Medicare for some dual-eligible persons.

Vito Frank Taverna, M.D. (DOH administrative hearing decision dated April 6, 2012, Christine C. Traskos, Administrative Law Judge). The Department of Health Administrative Law Judge sustained audit adjustments for the difference between what was paid to the physician by the Medicaid program and the amount, based on Medicare payment records, that should have been paid by the Medicaid program as a secondary payor to Medicare for services provided to dual eligible persons.

Concourse Rehabilitation & Nursing Center, Inc. (DOH administrative hearing decision dated March 13, 2012, John Harris Terepka, Administrative Law Judge). This was an audit of the facility's 1983 through 1985 Medicaid reimbursement in which the OMIG corrected a Department of Health rate sheet error that included employee fringe benefit costs twice in the rate calculation. The Department of Health Administrative Law Judge held that this had not been an error of judgment by the Department, which would not be subject to audit adjustment, but simply a mistake in the reimbursement calculation that was subject to audit adjustment. That the audit was timely under the regulations had been resolved in an earlier interim decision by ALJ Frederick Zimmer.

New York State Attorney General Press Releases

Compiled by Charles Z. Feldman

Falsification of Controlled Substance Prescriptions Leads to the Arrests of Two Plattsburgh Area Nurses—August 16, 2012—Two Plattsburgh area nurses were arrested for forging prescriptions. One nurse took blank prescriptions she accessed through her RN position to write Hydrocodone and Xanax prescriptions to herself. The other nurse admitted to creating forged computer accounts under the name of hospital patients, which she used to steal Oxycodone pills prescribed for the patient for her personal use.

Medicaid Beneficiaries Arrested for Engaging in "Doctor Shopping" to Fill Oxycodone Scripts and then Selling the Pills for Profit—August 15, 2012—The Attorney General's Office announced the arrests of five people in connection with a scheme where Medicaid beneficiaries illegally obtained Oxycodone through Medicaid, Social Security Disability Insurance (SSDI) benefits and Medicare, and then sold the drugs for profit. The investigation revealed that the scheme began five years ago when one of the individuals made a

no-fault automobile insurance claim and then "shopped" for doctors who would prescribe him Oxycodone. Over the next five years, he continued to use the same doctors to prescribe narcotics, and submitted the claims to Medicaid, SSDI, and Medicare and then sold the drugs for profit. The individuals face prison sentences ranging from 1 1/2 to 20 years.

Dentist Who Paid Kickbacks to Patient Recruiters to Pay Over $550K in Restitution—August 13, 2012—A Brooklyn Dentist pled guilty to submitting hundreds of false Medicaid claims. The Dentist paid kickbacks to patient recruiters to supply him with patients. The patients were often recruited from soup kitchens and homeless shelters. The recruiters netted about $25-$30 per patient, and the Dental Clinic regularly gave the recruiters an additional $15-$20 to pay the recipient after his or her appointment. The Dentist will pay $559,424 in restitution.

Drug Distributor That Allegedly Manipulated the "Average Wholesale Price" Benchmark That New York Uses to Set Pharmaceutical Payment Rates Settles with MFCU for $64 Million—July 27, 2012—McKesson Corp., a large drug distributor, settled a Medicaid Fraud Control Unit investigation alleging that McKesson inflated drug prices and overcharged Medicaid by improperly setting rates for reimbursement. The charges relate to allegations that McKesson inflated the "Average Wholesale Price" (AWP) benchmark by reporting false prices to the First Data Bank, a publisher of drug prices used by New York to set the AWP. New York will receive $64 million from McKesson.

GlaxoSmithKline Agrees to Pay New York $146 Million, Abbott Laboratories $54 Million and Merck $61 Million to Resolve Multistate Investigations Into Their Marketing Practices—July 2, 2012, May 7, 2012, April 20, 2012—Separate multistate investigations into pharmaceutical giants GlaxoSmithKline, Abbott Laboratories and Merck revealed widespread violations relating to the pharmaceutical companies' marketing practices. The investigation revealed that all three of the companies marketed certain of their drugs for unapproved purposes and made false representations about the safety of certain drugs. In addition, GlaxoSmithKline and Abbott were charged with paying kickbacks to medical professionals. The charges against GlaxoSmithKline relate to the marketing of drugs including Paxil, Welbutrin, Advair, Lamictal, Zofran, Avandia, Lotronex, Flovant and Valtrex. The charges against Abbott relate to the marketing of the anti-seizure drug Depakote. The charges against Merck relate to the marketing of Vioxx. GlaxoSmithKline paid $3 billion to settle the multistate investigation and four ***qui tam*** lawsuits. Abbott agreed to pay $1.5 billion to settle the multistate investigation and Merck paid $615 million.

Insurer and Large Provider Agree to Refund Overcharges to Patients / Insureds—July 12, 2012—Responding to complaints lodged through the Attorney General's Health Care Bureau, the AG's Office launched an investigation into complaints that both Group Health Inc., a medical insurer, and NYMDC, a twenty-provider group in New York City, overcharged patients. In the GHI case, its health insurance policy was required to cover certain key medical providers, who might be out-of-network, with no member cost-share. But despite this requirement, GHI processed claims at its standard out-of-network rate which led to patients being billed for covered physician services. In the case of NYMDC, the multi-specialty health care provider was billing patients the difference between NYMDC's charge and the payment by the patient's health plan, despite the fact that NYMDC, as a participating provider with the health plan, was required to accept the plan's payment as payment in full. Both entities will reimburse their customers, pay a penalty, and assist consumers with resolving any debt collection activity.

Two Are Arrested for Practicing Medicine Without a License After Injecting Patients With Unknown Substances and Administering Unidentified Pills—May 22, 2012—Two individuals claiming to be physicians were arrested in Chinatown because they did not have licenses to practice medicine in New York. The two face up to four years in jail and both were forced to surrender their passports. They injected patients with unknown substances and administered unidentified pills to patients.

Improper "J Code Claim" Billing Leads to $2.3 Million Penalty Paid by Sound Shore Health System—April 18, 2012—As part of a project to investigate improper billing practices of hospitals and physicians related to injectable drugs ("J code claims"), the Sound Shore Health System paid $2.3 million to MFCU. Under New York Medicaid law, hospitals and doctors are not allowed to make a profit on the drugs they administer. Accordingly, the hospitals and physicians are required to bill Medicaid only for the price they pay for the drugs. Since Sound Shore Health System billed in excess of the cost of the drugs, it agreed to pay New York State double its profit, plus interest.

CEO of Marcus Garvey Nursing Home Ordered to Repay Executive Compensation Deemed to Be Excessive—April 4, 2012—The Charities Bureau settled charges with Marcus Garvey Nursing Home relating to claims that the former CEO collected excessive compensation and engaged in self-dealing. The CEO self-approved her salary, which grew to $500,000 annually, and steered IT work for the Nursing Home to her son without a competitive bidding process. Also, the CEO designated a close personal friend to serve on the board of the Nursing Home. The settlement includes restitution of $871,000, plus an agreement that the Nursing Home's board will improve its oversight function.

MFCU Busts Black Market HIV Medication Distribution Ring—April 4, 2012—MFCU arrested four individuals in connection with a black market HIV drug operation. The supervising pharmacist for MOMS Pharmacy, a high-volume pharmacy in Brooklyn and Suffolk County, allegedly accepted bribes to purchase black market HIV medications and then distributed the medications to MOMS' patients, many of whom were Medicaid recipients. MOMS allegedly then billed Medicaid for the drugs that it knew were purchased illegally. MOMS is also alleged to have created various shell distributors to disguise the sale of the black market pills.

New York State Office of the Medicaid Inspector General Update

Compiled by the Editor

OMIG Releases New Self-Disclosure Guidance—August 2012—OMIG updated its March 12, 2009 Self-Disclosure Guidance with this new document, which discusses the advantages, requirements, process and mechanisms involved in self-disclosures, introducing a new web-based OMIG\HMS online "PORTal"; information available at http://www.omig.state.ny.us/data/images/stories/self_disclosure/omig_provider_self_disclosure_guidance.pdf; http://www.omig.ny.gov/data/content/blogsection/25/208/.

Erie County to Hire Three Workers to Probe Medical Fraud—July 11, 2012—Erie County will investigate potential Medicaid fraud by local pharmacists, transportation agencies and other providers under a new agreement with New York State that would add three state-funded positions to the County workforce to focus solely on examining whether Medicaid providers are properly billing.

OMIG/TLC Sweeps Unlicensed Drivers Off the Street—July 10, 2012—15 investigators from OMIG and TLC conducted a coordinated review of ambulette service providers in Brooklyn, covering the areas on and around Coney Island Avenue and Coney Island Hospital.

OMIG Compliance Alert 2012-01: Medicaid Provider Certification of Its Compliance Program—July 5, 2012—Discusses certification requirements and processes.

Brighton Beach Proctologist Convicted of $3.5 Million in Fraud: OMIG New York City Staff Assisted in Investigation—June 13, 2012—A proctologist was convicted by a Federal jury in Brooklyn of one count of health care fraud and seven counts of making false health care statements. The proctologist had claimed to treat a number of conditions and perform surgeries but did not actually perform the procedures.

OMIG 2012-2013 Work Plan Released—The Work Plan provides brief descriptions of activities that OMIG plans to initiate or continue during New York State fiscal year 2012-13. This document describes the primary objectives and goals for each of OMIG's new business line teams outlined in the Plan through March 31, 2013; available at http://www.omig.ny.gov/data/images/stories/work_plan/1213work_plan.pdf.

OMIG Releases Hospital Compliance Guidance—This Guidance is intended to assist hospitals in creating and maintaining effective compliance programs. While hospitals are not required to adopt the particular Recommendations contained in the Guidance, hospitals are required to take appropriate measures to create effective compliance programs that meet all delineated Elements and Requirements; available at http://www.omig.ny.gov/data/images/stories/compliance/compliance_program_guidance-general_hospitals.pdf.

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For Your Information

By Claudia O. Torrey

Items of interest:

- By the time this column is read, the North Shore-Long Island Jewish Health System ("Health System") will have been awarded a Sepsis Heroes Award in September 2012, from the Sepsis Alliance, for its leadership role in improving care for patients across all of their hospitals; the Health System serves as a model both domestically and internationally.[1]

  For those who do not know, sepsis is rooted in the Greek language for "decay" or "to putrefy." The word is defined as either "the presence of pathogenic organisms or their toxins in the blood and tissues, or "the poisoned condition resulting from the presence of pathogens or their toxins as in septicemia."[2] Sepsis is akin to blood poisoning—the body's deadly response to infection or injury.

- July 16, 2012 was the effective date for the final rule entitled *Reform of Hospital and Critical Access Hospital Conditions of Participation* ("CoP") published by the Centers for Medicare & Medicaid Services ("CMS").[3] The goal of the CoP requirements is to have high quality patient care, and the requirements must be met in order to participate in both the Medicare and the Medicaid programs. Thus, this July final rule is to ease the perceived burdens on hospital-oriented providers.

  A summary of some of the CoP contained in Part 482 of the Code of Federal Regulations:

  i. Expanding medical staff leadership to include podiatrists;

  ii. Requiring eligible candidates, including PAs and APRNs, to be considered for medical staff appointments with the potential grant of all rights, privileges, and responsibilities accorded to appointed medical staff members;

  iii. Increased flexibility for hospitals by allowing one entitiy to oversee multiple hospitals in a single health system;

  iv. Verbal orders do not have to be authenticated within forty-eight hours; and

  v. Hospitals can opt to have a stand-alone nursing care plan for a patient or a single interdisciplinary care plan that addresses nursing and other disciplines.

- On July 1, 2012, 89 new Accountable Care Organizations ("ACOs") in 40 States plus the District of Columbia were positioned to serve over a million Medicare beneficiaries. The ACO designation means the entity has entered into an agreement with CMS to be held to certain care standards in return for the opportunity to "share in savings" realized via high quality coordinated care.[4] Some of the New York State ACOs are:

  i. the Accountable Care Coalition of Syracuse, LLC;

  ii. the Asian American Accountable Care Organization located in NYC;

  iii. the Beacon Health Partners, LLP located in Manhasset, NY;

  iv. the Mount Sinai Care, LLC located in NYC; and the

  v. WESTMED Medical Group, PC located in Purchase, NY serving Medicare beneficiaries in the States of Connecticut and New York.

  While ACO provider participation is voluntary, the shared savings opportunity is one of the many initiatives within the Affordable Care Act.

Endnotes

1. www.sepsisalliance.org.
2. www.sepsisalliance.org.
3. www.cms.gov.
4. www.hhs.gov.

Claudia O. Torrey, Esq. is a Charter Member of the Health Law Section, and also serves in the NYSBA House of Delegates representing Non-Resident Members of the Association (NYSBA members who primarily live and work outside of the State).

Board Fiduciary Duty to Oversee Quality: New Challenges, Rising Expectations

By Tracy E. Miller

The United States Supreme Court decision in *National Federation of Independent Business v. Sebelius* upheld the constitutionality of the individual mandate to purchase health insurance, thereby allowing continued implementation of hundreds of other provisions of the Patient Protection and Affordable Care Act (the "PPACA").[1] Although the subject of much less public attention than the individual mandate, innumerable provisions in the PPACA focus on health care quality and the redesign of health care services. These provisions have already begun to reshape the nation's health care delivery system.

Certain key initiatives to advance quality of care predated national health reform legislation. Development of new quality measures, transparency of quality reporting, and pay for performance were emerging policies at the federal and state levels a decade before enactment of the PPACA. However, the PPACA accelerated these trends, extended their reach across the continuum of care, and embedded these practices in the operation and evaluation of new care delivery models, such as accountable care organizations ("ACOs"), bundled payment arrangements, and health homes.

These fundamental changes in quality reporting, pay for performance and care delivery models have significant implications for board oversight of health care providers. In addition to its importance to mission, health care quality will have an increasing impact on financial performance, as well as strategic opportunities and risks for health care providers. While the unfolding changes in health policy and reimbursement have generated new tools for governing boards, such as comparative measures of health care quality, they have also posed new challenges and raised expectations for board oversight.

Background

Studies about the exceptionally high rate of medical errors leading to substantial injury and poor outcomes first emerged in the 1990s, culminating in a series of landmark public reports that brought patient safety to national attention.[2] Major barriers impeded quality improvement and patient safety initiatives, including the absence of comparative quality measures, the lack of transparency about quality, immature information technology systems, and notably, the absence of a compelling business case to invest in quality in a fee-for-service system.[3]

These same barriers limited the role that governing boards could play in overseeing quality. Without publicly available comparable measures of quality, boards could respond to serious events or poor survey findings, but often had little access to data that would inform a more proactive role. Moreover, the medical staff structure and regulatory oversight standards vested primary responsibility for overseeing quality in a largely independent medical staff. While boards had the authority and responsibility to grant final approval for medical credentialing, in practice, substantive evaluation of physicians occurred at the medical staff level, often with pro forma approval by boards of credentialing decisions.

"Although the subject of much less public attention than the individual mandate, innumerable provisions in the PPACA focus on health care quality and the redesign of health care services. These provisions have already begun to reshape the nation's health care delivery system."

Making Quality Transparent

Beginning in 2002 with publicly reported measures of nursing home quality and subsequent establishment of Hospital Compare on the United States Department of Health and Human Services website, the Centers for Medicare and Medicaid Services ("CMS") launched a series of initiatives to promote public reporting of quality measures. The PPACA vastly expanded these initiatives, moving from voluntary reporting to financial penalties for failure to report and mandated public measures for providers across the continuum of care. Hospitals now face financial penalties for failing to report specific quality measures. Under the PPACA, financial penalties for failure to report quality measures will be phased in for hospice programs, long-term care hospitals, and physicians, among other providers, over the next three years.[4]

In addition to increasing the types of providers that report standardized public measures, the PPACA broadened the domains of quality of care that will be reported. Initial quality measures adopted by CMS focused on processes or outcomes of care for specific conditions such as acute myocardial infarction, heart failure and pneumonia. The PPACA extended public reporting and accompanying financial incentives for quality of care to serious errors captured by "never events" and measures of patient satisfaction.[5] While less standardized, programs to promote patient-centered care must also be reported to CMS as part of initiatives such as ACOs.[6]

The PPACA also seeks to strengthen the foundation for quality improvement, authorizing $75 million in funding annually through 2014 to improve the scope and reliability of quality measures, targeting specific priorities, such as measures of care management for high cost, chronically ill patients, meaningful use of information technology, and patients' experience of care.[7] Section 10322 of the PPACA will further promote public availability and analysis of quality data by making information extracted from Medicare claims data available to private entities that have the capacity to combine Medicare claims data with data from other sources to assess quality. As a result, data mining and analysis by private organizations may generate substantial additional information about quality of care related to a potentially broad spectrum of providers. Under provisions generally referred to as the Payment Sunshine Act, the PPACA also requires transparency and public reporting of payments by pharmaceutical, device, biotech, and medical supply companies to physicians and teaching hospitals for a wide array of purposes.[8] In addition to the potential impact on reputation, this data may be a powerful tool for quality and compliance oversight, enabling enforcement agencies to target investigation of unnecessary services as well as patient safety concerns.[9]

Pay for Performance

The expansion in public reporting of quality measures set the stage for federal and state initiatives to implement pay for performance in health care delivery. Since CMS launched a nationwide hospital demonstration program in 2003, it has steadily increased financial incentives tied to quality, through both penalties for poor quality and rewards for high performance. State government and private payers have followed suit, magnifying the impact of the financial incentives.

Never Events

In 2008, CMS instituted a policy of nonpayment for so-called "never events" in hospitals, serious incidents deemed preventable such as surgical site infections, falls, and stage III and IV pressure ulcers. In October 2008, New York State's Medicaid program also implemented a non-payment policy for 14 never events in hospitals. The PPACA mandated the non-payment policy for Medicaid programs nationally, barring state governments from paying for "health care-acquired conditions" identified by CMS.[10] The implementing regulations issued by CMS granted states the discretion to expand the list of health care acquired conditions as well as the provider settings where the non-payment policy would apply.[11] Under the PPACA, CMS must also study and report on applying the never events policy to long-term care, home care, and other settings.[12]

Further penalties for preventable conditions that occur in hospitals will take effect in fiscal year 2015, in accordance with Section 3008 of the PPACA. At that time, hospitals in the top quarter nationally for the number of health care-acquired conditions will face a one percent reduction in Medicare reimbursement.

Hospital Readmissions

Focusing on the high costs of hospital readmissions, the PPACA included provisions to penalize "excess" admissions at hospitals, beginning with readmissions in October 2012.[13] The Final Rule to implement the readmissions incentive, released by CMS on August 2, 2012, sets forth the methodology and payment adjustment factors that will apply.[14] Long-term care providers also have an incentive to reduce preventable hospital admissions; the United States Office of Inspector General ("OIG") identified such admissions as an enforcement priority in its 2012 Work plan.[15] In addition, it is likely that avoidable hospitalizations for short- and long-stay residents in nursing homes will be included in pay for performance incentives at both the federal and state levels, starting as early as January 1, 2013, in New York State.

Value-Based Purchasing

The PPACA made significant strides towards pay for performance based on an identified set of quality measures, or in the nomenclature of CMS, "value-based purchasing ("VBP"). First initiated on a voluntary basis for hospitals in 2003, VBP will be implemented in October 2012 for all hospitals nationally as required by Section 3001 of the PPACA. Under the VBP program, hospitals will be assessed against their performance on a baseline set of measures of clinical processes of care and patient satisfaction.[16] As structured by CMS, VBP for hospitals will be a zero sum game—CMS will generate funds for the incentive pool by reducing hospitals' base operating Diagnosis-Related Group payments by 1% in year one, increasing to 2% in year five of the incentive program. In recent reports to Congress, CMS signaled its intention to take a similar approach to VBP for long-term care providers. Specifically, in reports issued pursuant to PPACA Section 3006, CMS indicated that the VBP program for nursing homes and home care providers would redistribute funds available for reimbursement in accordance with measures of quality, hospital readmission, and patient satisfaction, starting in 2014.[17] As of 2015, CMS will reimburse physicians based on measures of quality as well as resource utilization.[18]

New Models of Care Delivery

The most ambitious provisions of the PPACA that seek to affect quality promote improved quality, reduced cost, and enhanced care coordination through new models of care delivery. Those models, encompassing ACOs, bundled care delivery initiatives, health homes, and medical homes, among others, seek to redesign the care delivery system, fostering reimbursement alterna-

tives to fee-for-service and providing financial incentives to improve quality and care coordination. Notably, the PPACA established the Center for Medicare and Medicaid Innovation ("CMMI") to fund and evaluate innovative methods of payment and care delivery, with $10 billion of funding for activities initiated from 2011 through 2019.[19]

The first shared savings model to emerge as part of federal health reform ACOs are organizations comprised of health care providers that share responsibility for the cost and quality of care for a specified group of patients in the Medicare fee-for-service program. Hospitals, physician groups, rural health centers, and federally qualified health centers are authorized to form an ACO, but providers across the continuum of care can participate in an ACO and potentially share in savings and losses.[20] While providers can chose the "one-sided" ACO model for the first three years and share savings without assuming the risk of losses, CMS has indicated that after the initial three-year term, all ACOs will be expected to assume the risk of shared losses with Medicare.[21] Many providers responded negatively to ACOs as initially conceived under proposed regulations issued by CMS. However, the final rule prompted far more support from providers and activity to form ACOs. In July 2012, CMS announced that 154 ACOs had been established. Here too, private payers have followed suit, contributing to ACOs' ability to generate enrollment and the economies of scale that may prove essential to successful implementation and cost savings.

CMS has also advanced bundled payment arrangements as a significant new approach to cost savings and quality. The PPACA requires CMS to establish a five-year pilot program by January 2013 to integrate care by hospitals, physicians, skilled nursing facilities, and other care providers immediately prior to, during, and following hospitalization.[22] In advance of the pilot program, the CMMI rolled out the Bundled Payment Initiative, offering providers four alternative models. The request for proposals for the Initiative required providers to define the conditions that would be covered, develop quality improvement projects, and propose a target for the cost of care. CMS also permitted providers to submit proposals for gain sharing to incentivize improved quality and efficiency. Studies of early bundled payment programs suggest both the long-term potential of the programs as well as the challenges and risks providers face in assigning accountability for outcomes across different providers, generating actionable data, and building programs large enough to realize savings.[23]

Seeking to improve care coordination for complex, high-cost patients with multiple chronic conditions, the PPACA provided federal funding for up to 90% of the cost for care coordination to states for Medicaid programs that develop a health home program.[24] CMS guidance to the states in establishing the program required health homes to develop extensive policies and processes to manage care, use information technology and data to improve quality, and deliver person-centered care.[25] New York State has launched its health home program, implementing the program in phases, starting with patients with multiple chronic conditions and/or a mental health condition.[26] The Department of Health has announced that the next wave of enrollment will focus on long-term care residents followed by individuals with developmental disabilities.

Heightened Focus on Poor Quality as a Compliance Risk

Federal and state regulators overseeing fraud and abuse enforcement have also raised the stakes for quality of care, pursuing poor quality as a violation of the False Claims Act ("FCA"), and requiring providers to address patient safety as part of their compliance oversight programs. Armed with data publicly reported or mined from the Medicare or Medicaid databases, the OIG and the New York State Office of Medicaid Inspector General have asserted that poor quality violates the FCA on several grounds: (i) the treatment billed for was medically unnecessary, (ii) the quality of care was so poor that the services were essentially not delivered or worthless, or (iii) the care delivered violated other federal standards related to quality such as the use of restraints. In New York State, providers with more than $500,000 annual revenue from the Medicaid program must encompass quality and credentialing in the elements of their compliance program and oversight.[27]

The 2012 OIG Work Plan also includes quality as a compliance priority for federal enforcement. The Work Plan lists specific aspects of quality among the priorities identified, including preventable hospital readmissions and quality of care delivered by post-acute care providers.[28]

Legal and Regulatory Standards for Board Oversight of Quality

In accordance with long-standing legal precedents, governing boards of non-profit organizations must meet three basic fiduciary duties: the duty of care, loyalty, and obedience to mission.[29] The duty of care requires board members to carry out their obligations to the corporation in good faith, and with the degree of care, attention, and skill that a person in a like position would reasonably believe appropriate under the circumstances. The duty of care is shaped by the business judgment rule, which affords board members broad protection.[30] In accordance with the business judgment rule, board members are not liable for decisions they make, even if the decisions later prove wrong and harmful to the corporation, if the directors acted in good faith, with the required degree of care

and a reasonable belief that the decision would serve the best interests of the organization.

As established by judicial decisions, board members can be found liable for breach of fiduciary duty for: (i) a board decision that is negligent or self-dealing, and (ii) an unconsidered failure to act in circumstances when "due attention" would have prevented the loss.[31] *In re Caremark International Inc. Derivative Litigation* enunciated the now well-accepted principle that while board members have no duty to conduct an investigation to uncover wrongdoing, they are responsible for ensuring that an adequate system exists to gather and report information to the board so that it can fulfill its fiduciary duty.[32] Hence, governing boards of health care providers have no duty to investigate in order to identify quality of care problems; board members can rely on the Chief Executive Officer and other senior executives to bring problems, including poor quality of care, to their attention. However, once notified of a concern, board members have a duty to inquire and seek corrective action, as needed.

For hospitals, the Joint Commission leadership standards and Medicare Conditions of Participation provide additional guidance about board duties relating to quality of care.[33] Under both sets of standards, the governing body is responsible for overseeing the medical staff, through approval of medical staff bylaws and structure, and credentialing standards and decisions. Joint Commission standards stress the importance of communication between the governing body, executive management and leaders of the medical staff regarding key elements of quality oversight such as performance activities, quality measures, and reports.[34]

In 2004, the OIG and the American Health Lawyers Association jointly issued a detailed statement about board duties to oversee quality (the "Joint Statement").[35] At the outset, the Joint Statement underscored the mounting focus on health care quality and concomitant heightened expectations for boards in carrying out the duty to oversee quality.[36] The core of the Joint Statement sets forth key lines of inquiry for governing boards to pursue in overseeing quality, advising boards to focus on: (i) quality goals and measures to assess those goals; (ii) accountability among key management personnel and staff to oversee quality; (iii) mechanisms to foster internal reporting on quality; (iv) coordination between the quality and compliance programs; (v) the sufficiency of information reported to the board to assess the quality improvement program; (vi) the allocation of resources for patient safety and quality improvement; (vii) the process for internal reporting of quality concerns or serious errors; and (viii) the process to identify, analyze and respond to serious adverse events. The Joint Statement also highlights the importance of board training about quality of care and assessment by the board of its own competence and activity to oversee quality.

Recent events in New York State also reflect a heightened focus on the duty of governing boards to oversee quality of care. The report of the Workgroup established by the Medicaid Redesign Team to evaluate Brooklyn's hospitals addressed the role of governing boards in overseeing quality, casting a harsh light on the boards' performance at several Brooklyn hospitals. As stated in the report,

> The boards at some of these hospitals have failed to satisfy fully their responsibilities to the organization and their communities. They have not evaluated financial and clinical performance, set strategic goals to address them, and held management accountable for achieving them.[37]

Among other recommendations, the report proposed that legislation should grant the Commissioner of Health the authority to appoint temporary operators for health care facilities that present a danger to the health or safety of their patients, and replace board members who are not fulfilling their duties to the organizations they oversee.[38] These recommendations were proposed by Governor Cuomo as part of the Executive Budget, but were not ultimately adopted.

Implications of Delivery System Change for Board Oversight

While quality has always been core to the mission of health care institutions, financial incentives from public and private payers, transparency, and the shift in care delivery models centered on care coordination have raised the stakes for governing boards and the institutions they oversee. Heightened focus on poor quality as a compliance violation and increasing use of data mining by enforcement bodies create other significant incentives for boards to oversee patient safety.

Transparency of public quality measures has direct implications for board duties to oversee quality. As discussed earlier, while governing boards have no duty to investigate to identify quality of care problems, boards must implement procedures to ensure the flow of information, and once put on notice of a quality concern, have an obligation to inquire further. In this regard, public measures of quality are an important development for board oversight, creating a public record that may trigger a board's duty to seek additional information and corrective action. Comparative, public quality measures also enable boards to assess quality in relation to peer institutions and competitors, and set affirmative goals.

Financial incentives tied to specific measures of quality or never events will have a growing impact in the wake of the PPACA. New models of care delivery—ACOs, bundled payment arrangements and health homes—also

require an effective quality program to manage patients with complex, multiple medical needs to improve coordination and drive down cost. Providers' ability to execute these models will determine the financial risks and rewards of participation, and will in turn depend on strong management skills and quality competence. In particular, providers will need the capacity to determine or participate in shared quality goals, identify measures of those goals, assign accountability for outcomes, and collect and analyze quality data in real time to change clinical behavior. As boards evaluate whether an organization should make the substantial financial investment required by these new delivery models, they will have to understand the challenges presented and the organization's capacity to adopt systems of quality improvement that can effectively change patient outcomes and reduce cost.

Qualilty performance will also shape the opportunities providers can pursue in the strategic alliances emerging in a consolidating health care marketplace. The concentration of public measures and financial incentives on certain key outcomes, including reducing hospital readmission and coordinating of care for chronically ill patients, means that providers will seek partners who can contribute to their own success. For this reason, in addition to regulators and public and private payers, other providers are a key audience for public quality measures and performance.

Meeting the Challenge: Roadmap for Board Oversight

As a result of changes in quality measurement, reporting, and incentives, a passive role for governing boards in reviewing credentialing decisions has been replaced by an emerging paradigm of a board that is more informed, more proactive, and more accountable for the quality of care. Boards can also be expected to take a data-driven approach to quality, evaluating quality based on public as well as internal performance measures.

Boards should assess their own readiness, competence, and activities to oversee quality in light of the changes under way in the health care delivery system, starting with board training to understand public measures of quality, existing and anticipated financial incentives, and the infrastructure needed for quality improvement. Significantly, studies have found that certain board actions are associated with higher performing institutions, including frequent use of quality dashboards, board training about health care quality, and a higher percentage of time at meetings devoted to quality.[39] According to one study, boards that have a committee devoted to quality are more likely to use quality dashboards, rely on quality measures to evaluate executive performance, and establish strategic goals for quality.[40]

In consultation with executive and clinical leadership, boards should consider an array of tasks to oversee quality of care in the face of mounting financial incentives and the unfolding transformation in the care delivery system, including:

- Review and evaluate a strategic plan for quality;
- Review existing and anticipated financial incentives for quality, emerging models of care delivery relevant to the organization, and regulatory priorities for quality and compliance oversight;
- Evaluate the organization's weaknesses and strengths in relation to all dimensions of quality and the organization's public profile from the perspective of regulators, payers, potential strategic partners and consumers;
- Develop priorities and goals for improvement, and establish benchmarks based on the organization's past performance, peer groups, and strategic goals;
- Require and review a concise dashboard of actionable measures of performance in relation to identified goals, including financial incentives and publicly reported measures;
- Review the organization's process to identify and address serious adverse events, develop corrective action, and report to the board of directors and to outside entities, as required;
- Seek coordination between the organization's oversight of patient safety, compliance, and conflicts of interest among executives and physicians that could give rise to patient safety or compliance concerns;
- Consider financial incentive arrangements to align physician and organizational goals for quality of care, and seek analysis of the corresponding compliance concerns that such arrangements may pose; and
- Seek review of the organization's legal infrastructure for quality (medical staff bylaws, medical director and physician contracts, and credentialing standards and procedures) to determine if these documents support a data-driven, systemic approach to quality of care.

Federal and state governments, as policymakers, payers, and regulators, have created an array of powerful new incentives for health care facilities to focus on quality of care. As a result, governing boards must now oversee quality of care not only as core to mission, but as key to the financial and strategic success of their organizations.

Endnotes

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4. PPACA §§ 3002, 3004.
5. *See, e.g.*, PPACA §§ 2702, 3001, 3008.
6. *See, e.g.*, 42 C.F.R. § 425.112.
7. PPACA § 3013.
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21. 42 C.F.R. § 425.600.
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Opening the Hospital Door: Medicare and New York Set Standards for Non-Discrimination in Visitation Policies

By Paul Knag and Christina Hage

New Conditions of Participation ("CoPs") issued by the Centers for Medicare and Medicaid Services ("CMS") require hospitals to revise visitation policies. The CoPs are the federal health and safety standards that all Medicaid and Medicare participating hospitals and critical access hospitals ("CAHs") must meet in order to participate in federal health care programs. The additions to the CoPs address the scope and inclusiveness of hospital visitation policies. The Joint Commission has revised its standards to conform to the new CoPs.

This article will provide guidance for hospitals reviewing visitation policies to ensure compliance with the CoPs. Additionally, it will provide an overview of New York laws and regulations enacted to protect hospital visitation rights.

"A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation."

I. Federal Hospital Visitation Conditions of Participation

On April 15, 2010, President Obama issued a Presidential Memorandum on hospital visitation that discussed patients who had been denied visitation with a loved one as a result of a hospital visitation policy.[1] In response, CMS published: "Changes to the Hospital and Critical Access Hospital Conditions of Participation to Ensure Visitation Rights for All Patients" (the "Final Rule").[2]

In the Final Rule, CMS amended the CoPs to require hospitals to have written policies and procedures regarding patients' visitation rights, including those setting forth any clinically necessary restrictions that may be imposed by the hospital. In the Commentary to the Final Rule,[3] CMS expressed its support for clinically necessary restrictions: (i) if the patient is undergoing care interventions; (ii) for infection control; (iii) to avoid interfering with the care of other patients; (iv) where a court order restricts contact; (v) to control disruptive, threatening or violent behavior; (vi) when the patient needs privacy or rest; (vii) to limit the number of visitors; (viii) to set a minimum age requirement; and (ix) where inpatient substance abuse treatment program protocols limit visitation.[4] The Final Rule, which applies to all patients regardless of payment source,[5] is set forth at 42 C.F.R. § 482.13:[6]

> (h) *Standard: Patient visitation rights*. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must:
>
> (1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation.
>
> (2) Inform each patient (or support person, where appropriate) of the right subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.
>
> (3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.
>
> (4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.[7]

In the preamble to the Final Rule, CMS concluded that some existing hospital visitation policies can effectively eliminate advocates for many patients, potentially to the detriment of the patient's health and safety.[8] In the commentary to the Final Rule, CMS identified grievance procedures for patients[9]: (1) the patient may file a griev-

ance through the hospital's internal grievance resolution process; (2) a Medicare beneficiary may file a complaint with the appropriate Quality Improvement Organization (QIO) in that state;[10] (3) the patient or visitor may file a complaint with the State Survey Agency responsible for oversight of the facility[11] or the facility accrediting body. Noncompliance with the visitation provisions of the CoPs "could result in the provider's termination from the Medicare program."[12]

II. New York Laws Regarding Visitation in Hospitals

In 2003, New York State enacted the Sexual Orientation Non-Discrimination Act (SONDA). SONDA prohibits discrimination on the basis of actual or perceived sexual orientation at any place of public accommodation.[13] Hospitals cannot directly or indirectly refuse, withhold or deny accommodations, advantages, facilities or privileges because of a person's actual or perceived sexual orientation.[14]

New York also has specific enumerated rights regarding hospital visitation. All hospitals licensed in New York are required to abide by the requirements set forth in New York Public Health Law 2805-q, which states: "no domestic partner or surrogate may be denied any rights of visitation of his or her domestic partner or the patient for whom he or she is the surrogate, when such rights are accorded to spouses and next-of-kin at any hospital, nursing home, or health care facility." Same-sex spouses and domestic partners have the same rights as other married couples or next-of-kin.

Hospitals risk civil liability if they violate state laws prohibiting discrimination.[15] Additionally, hospitals can potentially be held liable by patients or other interested parties for failing to comply with hospital visitation requirements.[16]

III. Conclusion

Any New York hospital participating in the Medicare and/or Medicaid program(s) must comply with the requirements of the CoPs, SONDA and the Public Health Law. The hospital must specifically inform the patient or the patient's representative of the right to receive designated visitors, including same-sex domestic partners and non-family members. Additionally, hospitals must have policies and procedures on patient visitation rights that address clinically necessary restrictions or limitations that the hospital may place on visitation. Hospitals may not restrict patient visitation rights based on race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. Finally, hospitals must ensure that all visitors have the same visitation privileges consistent with patient preferences.

Endnotes

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2. See U.S. Dep't of Health and Human Serv., Centers for Medicare & Medicaid Serv., Medicare and Medicaid Programs: Changes to the Hospital and Critical Access Hospital Conditions of Participation to Ensure Visitation Rights for All Patients, 75 Fed. Reg. 70831 (Nov. 19, 2010) (Final Rule).
3. *Id.* at 70838, 70839.
4. This is not a complete list and other conditions meriting reasonable restrictions may be applicable.
5. 75 Fed. Reg. 70831, 70835.
6. The visitation rights provisions of the Conditions of Participation for CAHs (which are identical to the visitation rights provisions for hospitals) are found at 42 C.F.R. § 485.635(f) (2011).
7. 42 C.F.R. § 482.13(h). In the commentary to the Final Rule, CMS emphasized that hospitals and CAHs must ensure "that patient rights information is provided in a language and manner the patient understands." 75 Fed. Reg. at 70834 (citing Guidance Related to Title VI of the Civil Rights Act of 1964).
8. 75 Fed. Reg. 70831, 70832.
9. *Id.* at 70835.
10. In the preamble to the Final Rule CMS noted that "information regarding the Medicare beneficiary patient's right to file a grievance or complaint with a QIO may be found at the HHS Centers for Medicare & Medicaid Services Web site: http://www.cms.gov/QualityImprovementOrgs/." *Id.* at 70832.
11. Additional information regarding the right to file a complaint with the state surgey agency may be found at: http://www.cms.gov/Medicare/Provider-Enrollment-andCertification/SurveyCertificationGenInfo/ContactInformation.html.
12. 75 Fed. Reg. at 70833.
13. N.Y. Exec. Law § 296(2)(a).
14. *Id.*
15. N.Y. Exec. Law § 298.
16. The New York Code of Public Health does not regulate hospitals discriminating against patients on the basis of sexual orientation. The Code states: "[Hospital] shall not discriminate because of race, color, creed, national origin or sponsor in admission or retention of patients." NY Pub. Health § 2801-a(9)(b).

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The U.S. Supreme Court's *Marmet* Decision and Its Potential Impact Upon Personal Injury Claims Against New York Nursing Homes

By Keith L. Kaplan

On February 21, 2012, in *Marmet Health Care Ctr., Inc. v. Brown*,[1] the U.S. Supreme Court invalidated West Virginia's "public policy" prohibition against predispute arbitration agreements as to personal injury and wrongful death claims against nursing homes. The Court held that such prohibition is inconsistent with, and preempted by, the Federal Arbitration Act ("FAA"),[2] and thus contrary to the FAA's "terms and coverage."[3]

This article examines the *Marmet* decision and its potential impact upon the resolution of bodily injury and wrongful death claims against nursing homes in New York, concluding that the state's statutory prohibition against the arbitration of Public Health Law §2801-d claims, as set forth in Sub-section (8) of the statute, is preempted and invalidated by *Marmet*. This article also concludes that notwithstanding *Marmet*'s repudiation of state law "public policy" prohibitions against pre-litigation agreements to arbitrate, such agreements will be deemed unenforceable by New York courts in *certain* instances, based upon principles of contract and agency law.

The *Marmet* Decision

Marmet stemmed from three personal injury/wrongful death suits against nursing homes in West Virginia. All three cases involved admission agreements containing identical clauses requiring the parties to arbitrate all disputes, except claims as to collecting late payments owed by the patient. Two of the three cases were dismissed at the trial court level, and the third case, involving other issues, was consolidated with those cases before the Supreme Court of Appeals of West Virginia. The West Virginia court held that as a matter of public policy, arbitration clauses in nursing home admission agreements "adopted prior to an occurrence of negligence or wrongful death shall not be enforced to compel arbitration of a dispute concerning the negligence."[4] The West Virginia court also determined that Congress did not intend the FAA to apply to personal injury or wrongful death lawsuits that "only collaterally derive from a written agreement affecting interstate commerce, particularly where the agreement involves a service that is a practical necessity for members of the public."[5]

In reversing, the Supreme Court held the West Virginia court's interpretation of the FAA to be "both incorrect and inconsistent"[6] with precedent. Citing the FAA's text declaring arbitration agreements to be "valid, irrevocable, and enforceable,"[7] the Court noted that "[t]he statute's text includes no exception for personal-injury or wrongful-death claims,"[8] requires "courts to enforce the bargain of the parties to arbitrate,"[9] and "reflects an emphatic federal policy in favor of arbitral dispute resolution."[10]

Additionally, the *Marmet* decision also addressed the West Virginia court's "alternative" holding that the arbitration clauses were "unconscionable."[11] In that regard, the Supreme Court noted it was unclear as to what degree the West Virginia court based its "unconscionability" determination upon its incorrect conclusion the arbitration agreement ran afoul of public policy in requiring bodily injury and wrongful death claims to be submitted to arbitration.[12] Accordingly, the Court remanded the cases to permit the West Virginia court to consider whether the arbitration clauses are unenforceable under state common law principles that are not specific to arbitration and preempted by the FAA.[13]

Marmet's Potential Impact Upon New York Law

Marmet's preemption of state law prohibitions against predispute arbitration agreements of personal injury and wrongful death claims against nursing homes will likely alter New York law significantly. The decision eliminates all substantive restrictions against the arbitration of such claims, including those derived by statute or deemed to exist by state common law.

In New York nursing home litigation, plaintiffs have increasingly sought recovery for bodily injury and wrongful death by asserting causes of action for violations of PHL §2801-d, in addition to common law negligence and medical malpractice claims. The PHL §2801-d cause of action permits recovery for "deprivations"[14] of resident "rights or benefits"[15] conferred by any applicable state or federal statute, code, rule, regulation or contract provision.[16] If a nursing home resident is determined to have sustained injury secondary to a PHL §2801-d violation, the statute calls for the awarding of compensatory damages of no less than 25% of the daily per patient rate of payment established under PHL §2807, or if no such rate exists, the average daily total charges per patient for the facility.[17] Furthermore, if an alleged deprivation is determined to be "willful,"[18] or committed with "reckless disregard"[19] of the rights and benefits conferred upon the resident, punitive damages may be imposed.[20]

Critically, Sub-section (8) of PHL §2801-d prohibits the enforceability of predispute arbitration agreements, as it states that "[a]ny party to an action brought under this section shall be entitled to a trial by jury and any waiver of the right to a trial by jury, whether oral or in writing, prior to the commencement of an action, shall be null and void, and without legal force or effect."[21] In light of this statutory prohibition against the arbitration of PHL §2801-d claims, New York nursing homes have generally not included predispute arbitration clauses in their admission agreements, as such clauses would not be deemed enforceable as to PHL §2801-d claims pursuant to the statute's very text.

The *Marmet* decision, however, seemingly preempts and invalidates PHL §2801-d(8), as the High Court determined that the FAA preempts state law "public policy"-based prohibitions against arbitration in situations in which the FAA does not prohibit such claims, or similar claims, from being resolved by arbitration. New York courts have heeded *Marmet*, as the Appellate Division, First Department very recently held, in *Ayzenberg v. Bronx House Emanuel Campus, Inc.*,[22] that General Business Law §399-c(2)(a)'s prohibition against arbitration clauses in contracts for the sale of consumer goods is pre-empted by federal law with respect to transactions "involving commerce" within the meaning of the FAA. Accordingly, New York courts should similarly hold that the FAA likewise preempts and invalidates PHL §2801-d(8)'s prohibition against arbitration of PHL §2801-d claims.

New York's common law prohibition against the awarding of punitive damages in arbitration proceedings, as espoused in *Garrity v. Lyle Stuart, Inc.*, [23] will not likely invalidate an enforceable agreement to arbitrate PHL §2801-d claims, notwithstanding the potential availability of punitive damages under Sub-section (2) of the statute. In *Mastrobuono v. Shearson Lehman Hutton, Inc.*,[24] the U.S. Supreme Court held that if contracting parties to an arbitration agreement agree to be bound by New York law, without any provision excluding the arbitration of punitive damages claims, the FAA preempts and invalidates the Garrity rule and permits the awarding of punitive damages award at arbitration.[25] Accordingly, assuming an arbitration provision contains no restriction on the arbitrator's authority to award punitive damages, all claims against a nursing home, including claims for punitive damages, can be resolved at arbitration.

Obstacles to the Enforceability of Arbitration Clauses under New York Contract and Agency Law

Notwithstanding the removal of blanket state law prohibitions against pre-suit arbitration agreements, New York nursing homes will still need to establish that a valid, enforceable agreement to arbitrate was effectuated under New York law to compel arbitration, as the question of whether parties are bound to proceed to arbitration is governed by state law.[26] The determination as to whether the parties entered into an enforceable agreement to arbitrate is largely fact sensitive and involves the application of state contract law and agency principles. The question of whether the parties entered into enforceable arbitration agreements will be the "battleground" issue before New York courts, as has been the case in other states.

Under New York law, parties will not be compelled to arbitrate absent a "clear, explicit, and unequivocal agreement to do so."[27] In the wake of *Marmet*, agreements to arbitrate between a nursing home and a mentally competent resident will likely be deemed enforceable, assuming the substantive requirements governing contract formation have been met. Furthermore, if a mentally competent resident assents to an arbitration provision, but subsequently dies, the arbitration provision will nevertheless be binding upon and enforceable against his/her estate representative pursuant to CPLR 7512.[28]

In many instances, however, nursing home admission agreements are signed by individuals other than the actual resident, such as family members, due to the resident's lack of mental capacity/legal competency to enter into an enforceable agreement. Occasionally, the individual who signed the nursing home admission agreement is the resident's legal guardian or attorney in fact, with broad legal authority to act on the resident's behalf. Very often, however, the person signing the admission agreement is not empowered by a legal document executed by the resident, or by court order, to act on the resident's behalf. Under such circumstances, New York courts may nevertheless enforce arbitration provisions, upon concluding that the resident was a third-party beneficiary of the agreement, or upon principles of agency, waiver and estoppel,[29] among others.

In other instances, nursing home residents of questionable legal competence will sign the admission agreement, thus raising the question of whether an arbitration clause is binding against them and/or their personal/estate representative(s) in future litigation.

Courts in other states have grappled with the abovementioned factual scenarios and legal issues in deciding upon the enforceability of agreements to arbitrate bodily injury and wrongful death claims against nursing homes, deriving varying results.[30] New York courts will likewise need to address these and other fact-sensitive situations in determining whether the parties entered into a valid and enforceable arbitration agreement. Such enforceability issues can only be decided by the courts, not the arbitrators, under New York law.[31] Since arbitration clauses have generally not been used in New York nursing home admission agreements, and have been statutorily prohibited as to the resolution of PHL §2801-d claims, there are no reported cases to date as to their enforceability.

Conclusion

Although arbitration appears to offer many advantages to nursing homes, such as the potential for lower damages awards from arbitrators, as compared to juries, as well as streamlined discovery and reduced defense costs, the issue as to the enforceability of arbitration agreements will likely be vigorously contested, requiring litigation in the traditional court system to resolve such issues. Although *Marmet* removes blanket state statutory and public policy prohibitions against the arbitration of bodily injury and wrongful death claims against nursing homes, New York courts will nevertheless have to decide whether enforceable agreements to arbitrate were effectuated under the specific facts before them, in conformity with principles of contract and agency law. This will likely result in differing results, with the courts directing the parties to arbitration in some instances, while invalidating the contractual arbitration provisions in others.

Endnotes

1. 565 U.S. __, 132 S.Ct. 1201, 182 L.Ed.2d 42 (2012).
2. 9 U.S.C. §1
3. *Marmet*, 132 S.Ct. at 1204.
4. *Id*. at 1203, *citing Brown v. Genesis Healthcare Corp.*, 228 S.E.2d 646, 724 S.E.2d 250 (W. Va. 2011).
5. *Id.*
6. *Id.*
7. 9 U.S.C. §2
8. *Marmet*, 132 S.Ct. at 1203.
9. *Id., citing*, *Dean Witter Reynolds Inc. v. Byrd*, 470 U.S.213, 217 (1985).
10. *Marmet*, 132 S.Ct. at 1203, *citing*, *KPMG LLP v. Cocchi*, 565 U.S.__, 132 S.Ct. 23, 181 L.Ed. 323 (2011).
11. *Marmet*, 132 S.Ct. at 1204.
12. *Id.*
13. *Id*.
14. PHL §2801-d(1).
15. *Id.*
16. *Id*.
17. PHL §2801-d(2).
18. *Id.*
19. *Id.*
20. *Id.*
21. PHL §2801-d(8).
22. 93 A.D.3d 607, 608, 941 N.Y.S.2d 106, 108 (1st Dep't 2012); *see also, Triad Health Mgmt of Georgia III, LLC v. Johnson*, 298 Ga. App. 204, 679 S.E.2d 785 (Ct. App. Ga. 2009), *cert. den.*, Nov. 9, 2009. In this case, the court invalidated a Georgia statute, OCGA §9-9-62, which prohibited pre-arbitration agreements for medical malpractice claims, as preempted by the FAA.
23. 40 N.Y.2d 354, 386 N.Y.S.2d 831, 353 N.E.2d 793 (1976).
24. 514 U.S. 52, 115 S.Ct. 1212, 131 L.Ed. 76 (1995).
25. *Id.*; *see also*, *Martin v. SCI Mgmt L.P.*, 296 F.Supp.2d (S.D.N.Y. 2003); *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Adler*, 234 A.D.2d 139, 651 N.Y.S.2d 38 (1st Dep't 1996).
26. *See*, 9 U.S.C. §2; *see also, Perry v. Thomas*, 482 U.S. 483, 492, 107 S.Ct. 2520, 96 L.Ed. 426 (1987).
27. *Dean v. Harvestime Tabernacle United Pentecostal Church Int'l*, 79 A.D.3d 793, 794, 913 N.Y.S.2d 707, 708 (2d Dep't 2010), *citing, Matter of Waldron [Goddess]*, 61 N.Y.2d 181, 183, 473 N.Y.S.2d 136, 461 N.E.2d 273 (1984).
28. *See, In re Kalikow*, 58 A.D.3d 846, 848, 872 N.Y.S.2d 511 (2d Dep't 2009), *quoting* CPLR §7512.
29. *See, e.g., Bernstein v. Wysoki*, 77 A.D.3d 241, 252, 907 N.Y.S.2d 49, 56 (2d Dep't 2011).
30. *Tenn. Health Mgmt, Inc. v. Johnson*, 49 So.3d 175 (Ala. 2010) (personal representative of patient's estate was bound by the arbitration agreement she signed on her mother's behalf based upon principles of apparent authority); *Compare, Adams Comm. Ctr., LLC v. Reed*, 37 So.3d 1155 (Miss. 2010) (failure of nursing home to establish that the resident-principal conferred authority to her sons to bind her to the admission agreement precluded the enforcement of the arbitration clause); *Cook v. GGNC Ripley, LLC*, 786 F. Supp.2d 1166 (N.D. Miss. 2011) (resident, although not a party to the admission agreement, is an intended third-party beneficiary of it, and therefore bound by its terms, including the arbitration agreement); *Compare, Drury v. Assisted Living Concepts, Inc.*, 245 Or. App. 217, 262 P.3d 1162 (Ct. App. Or. 2011); *see also*, *Buhler v. French Woods Festival of Performing Arts*, 154 A.D.2d 303, 546 N.Y.S.2d 591 (1st Dep't 1989); *Public Adm'r Bronx Co. v. Montefiore Med. Ctr.*, 93 A.D.3d 620, 941 N.Y.S.2d 104 (1st Dep't 2012)
31. *See, Jalas v. Halperin*, 85 A.D.3d 1178, 1181, 927 N.Y.S.2d 659, 662 (2d Dep't 2011) ["The issue of whether there is a clear, unequivocal agreement to arbitrate is for the court and not the arbitrator to determine" (citations omitted).].

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The Home Care Worker Wage Parity Law, Dissected

By Emina Poricanin

Home health providers in New York City and Nassau, Westchester and Suffolk Counties must comply with the new Home Care Worker Wage Parity Law. Codified in New York Public Health Law § 3614-c, the Wage Parity Law establishes a "minimum wage rate" for home care aides providing Medicaid-reimbursed services on behalf of certified home health agencies, long-term home health care programs, and managed care plans. In addition to the minimum wage rate requirements, the Wage Parity Law obligates covered entities to provide home care aides with "health benefits" or a wage supplement in lieu of benefits.

The Wage Parity Law will, in most cases, increase the hourly wages that must be paid to home care aides, though no corresponding increase in Medicaid reimbursement rates for the covered providers has been approved. The end result is that the Wage Parity Law will increase the cost of doing business for covered providers.

This article summarizes the critical aspects of the Wage Parity Law to ensure that covered entities understand their compliance requirements.

Overview

The Wage Parity Law was the result of Governor Cuomo's Medicaid Redesign initiative and was enacted as part of the 2011-12 New York State budget. According to the proponents of the law, it is designed to address "inconsistency in wages among home care workers" and improve recruitment and retention of home care aides, thereby improving the quality of care for Medicaid service recipients. It is anticipated that 60,000 home care aides will be affected by the Wage Parity Law.

To Whom Does the Law Apply?

The Wage Parity Law applies to "home care aides" employed by home care agencies operating in New York City and, beginning on March 1, 2013, aides working in covered entities in Nassau, Suffolk, and Westchester counties. The law defines "home care aides" as home health aides, personal care aides, home attendants, or other licensed or unlicensed workers whose primary duties include the provision of in-home assistance with activities of daily living. Excluded from the definition of "home care aides" are any aides working on a casual basis or those who are "relatives" of the employer or the person for whom the worker is delivering services under a program funded or administered by the federal, state, or local government.

Additionally, the Wage Parity Law only applies to home care aides working for certified home health agencies (CHHAs), long-term home health care programs (LTHHCPs), managed care plans (MCPs), and any subcontractors of a CHHA, LTHHCP, or MCP. So, for example, aides providing Medicaid reimbursed hospice, nursing home transition and diversion or traumatic brain injury services are protected by the Wage Parity Law if the services are provided pursuant to a contract with a CHHA, LTHHCP, or MCP. Assisted living programs, however, are not affected by the Wage Parity Law.

Lastly, the Wage Parity Law applies to home care aides rendering episodes of care reimbursed in whole or in part by Medicaid.

What Are the Requirements of the Wage Parity Law?

The Wage Parity Law establishes a "minimum wage rate" for home care aides and requires covered entities to provide aides with a health benefit, or pay aides a wage supplement in lieu of a health benefit. Thus, to ensure compliance, covered entities must pay a specific minimum hourly wage and provide a health benefit valued in accordance with the Wage Parity Law, or a higher hourly wage to account for lack of health benefits.

The Wage Parity Law will be implemented in phases over the next several years, with each year bringing an increase in the hourly rate that must be paid to home care aides. The minimum hourly wage rates are based upon the living wage law of New York City, which establishes the minimum hourly wages for different industries. From March 1, 2012 through February 28, 2013, home care aides in New York City must be paid 90% of "total compensation" mandated by the living wage law of New York City, which equates to a $9.00 minimum hourly wage rate. Starting on March 1, 2014, home care aides in New York City must be paid no less than the prevailing rate of compensation, or the total compensation, mandated by the living wage law of New York City, whichever is greater.

The Wage Parity Law will take effect on March 1, 2013 in Nassau, Suffolk, and Westchester counties. Just as in New York City, the minimum hourly wage rates for home care aide services will be based upon the rates established by the New York City living wage law.

The "minimum hourly rate" established by the Wage Parity Law must be paid to aides for all hours worked. Aides working on a part-time basis are covered by the

law. New employees, who may be in their probationary period, are likewise immediately entitled to the benefits of the Wage Parity Law. Aides working on a "casual basis," however, are not covered by the Wage Parity Law. The Department of Health has noted that an aide works on a "casual basis" if he or she works on an incidental, irregular, and/or intermittent basis.

The Wage Parity Law also requires covered entities to provide home care aides with health benefits, or a wage supplement in lieu of a health benefit. Specifically, by reference to the New York City living wage law, which states that covered employers must pay covered employees "no less than the living wage and must either provide employees with health benefits or supplement their hourly wage rate by an amount no less than the health benefits supplement rate," the Wage Parity Law establishes the requirement for provision of health benefits or a wage supplement in lieu of those benefits.

The value of the health benefit that covered entities must provide under the Wage Parity Law is also derived from the living wage law of New York City. While the New York City living wage law presently requires covered employers to provide health benefits, or a wage supplement in lieu of a benefit, that is equivalent to $1.50 per hour, entities affected by the Wage Parity Law must provide a benefit that is valued at $1.35 per hour, or 90% of the benefit under the New York City living wage law.

Covered entities that choose to provide health benefits to aides instead of wage supplements must ensure that the health benefits are valued in accordance with the Wage Parity Law. If the benefit supplement rate is $1.35 per hour, for example, covered entities must ensure that they provide health benefits to aides that are valued at $1.35 per hour, for each hour the aide actually works. If the value of the health benefits that are provided to aides is less than $1.35 per hour, the covered entity must pay to the aide, in cash, any difference between the actual value of the benefit and the benefit supplement rate established by the Wage Parity Law. Ultimately, the covered entity must expend at least $1.35 for benefits, or pay a wage supplement in lieu of a benefit, for each hour the employee works.

To illustrate, if a covered entity in New York City, in 2012, contributes $1.00 towards qualifying health benefits for every hour that a covered aide works, and the entity is required to provide a health benefit valued at $1.35 per hour, the covered entity will be required to pay to the employee 35 cents for each hour worked, which is the difference between the value of the health benefit actually provided and the health benefit value required to be provided. Ultimately, the aide should be paid $9.35 per hour, and provided with a health benefit.

Covered entities that provide home care aides with health benefits pursuant to a collective bargaining agreement must also comply with the Wage Parity Law. A collective bargaining agreement does not obviate the covered entity's obligation to provide a "minimum hourly rate" in accordance with the Wage Parity Law. Thus, regardless of the value of benefits provided to aides covered by a collective bargaining agreement, the entity must pay the aides the applicable minimum hourly wage rate.

Compliance Requirements

The New York State Department of Health will provide all covered CHHAs, LTHHCPs, MCPs, and their subcontractors with an official notice of minimum hourly wages and benefit supplement rates by November 1 of each year. In order to receive payment from government agencies, the covered entities must submit written certification to the Department of Health that all services provided under each episode of care are in compliance with the terms of the Wage Parity Law. Providers must remit the certifications to the Department of Health on an annual basis. The Wage Parity Law prohibits "government agencies" from paying any CHHA, LTHHCP, or MCP for any episode of care furnished, in whole or in part, by any home care aide that is not compensated in accordance with the Wage Parity Law. Thus, to ensure receipt of payment for services, covered entities must implement the Wage Parity Law requirements and comply with the annual certification requirements.

Subcontractors of covered entities that provide Medicaid-reimbursable home care services are also subject to the certification requirements of the Wage Parity Law. As such, the subcontractor providers are also required to comply with the legal requirements of the law. The subcontractor providers must submit to the covered entity with which it contracts certification affirming that the subcontractor has compensated its aides in accordance with the Wage Parity Law. The subcontractor certifications must be submitted to the covered entity on a quarterly basis.

Covered entities must maintain records of compliance for at least ten years, since they are subject to review by the Department of Health upon request.

Conclusion

The Wage Parity Law creates new wage and benefit provision requirements for covered providers rendering services reimbursed by Medicaid. To receive payment for services, providers must ensure that they comply with all requirements of the law. And, since there has been no corresponding increase in Medicaid reimbursement rates, receiving payment for all services will become increasingly important for the covered entities.

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The Complex History of Medicaid Reimbursement in New York State

By Eugene M. Laks

The 2011-2012 enacted state budget for the first time places fixed dollar caps on Medicaid expenditures for this and the 2012-2013 state fiscal years. The Commissioner of Health is authorized to adjust Medicaid rates and fees to assure that expenditures remain within the authorized caps. The N.Y. Constitution Article VII Medicaid budget legislation imposes numerous cost-containment provisions on reimbursement methodologies to achieve billions in savings over projected growth. While the magnitude of the reductions to be borne by the Medicaid program is high, Medicaid has since its inception been subject to tension between program costs and state revenues. Costs of the Medicaid program have been a continuing concern of every budget session, with cost containment provisions periodically added to the various reimbursement methodologies in N.Y. Constitution Article VII bills accompanying and implementing the budget. State Medicaid cost-containment initiatives to restrain the rate of growth in Medicaid expenditures have been balanced against the needs of urban safety net institutions that rely on government funding and the needs of rural communities to maintain viable local health care services.

Balancing the state budget through Medicaid cost-containment initiatives has the multiplier effect on health care providers of concomitant loss not only of the state share but also of the fifty percent federal share of Medicaid expenditures. An alternative has been the imposition of provider taxes on segments of the health care system, which raises revenue for the state without the loss of federal funds for health care providers. The expansion of Medicaid managed care in the state reduces the fiscal impact of cost control proposals that address fee-for-service reimbursement methodologies, other than nursing home services that generally are not covered by most managed care arrangements.

Governor Cuomo has appointed a Medicaid Redesign Team to develop recommendations for program areas where reduced Medicaid costs and increased quality and efficiencies may be realized.[1] An initial list of 274 areas to be considered and ranking of favored recommendations has been issued.

This article will provide a brief history and overview of the Medicaid program, selected salient reimbursement issues, and a policy concern that should be considered regarding all reimbursement proposals.

I. Program Background

In 1964, prior to the Medicaid program, Governor Nelson Rockefeller appointed the Governor's Committee on Hospital Costs to address concerns over the State's costs of care for public assistance recipients under reimbursement negotiated by the Department of Social Services with health care providers. This led to the vesting of responsibility in the Department of Health under Article 28 of the N.Y. Public Health Law for health facility regulation and establishment of reimbursement rates under the new Medicaid program enacted by Congress in 1965.[2]

Medicaid is a joint federal-state partnership under Title XIX of the federal Social Security Act in which the federal government shares a percentage of a state's expenditures in providing medical assistance to eligible needy individuals.[3] For each state, covered health care items and services, Medicaid eligibility criteria, and state reimbursement methodologies for participating providers, practitioners and suppliers are set forth in a State Medicaid Plan.[4]

Each state must provide certain mandatory services under its State Medicaid Plan and may provide various optional services. New York State provides a broad array of health care services to over four million persons enrolled in Medicaid. Some federal program requirements may be waived and additional services provided upon application of a state for a waiver and federal approval. The Secretary of the Federal Department of Health and Human Services must approve the State Medicaid Plan and proposed plan amendments to assure compliance with federal requirements. State Medicaid payment rates must be consistent with efficiency, economy and quality of care and must be sufficient to enlist enough providers so that Medicaid services are available to recipients at least to the same extent that comparable services are available to the general public.[5]

The Medicaid program oversight by the federal government is administered by the Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration, within the Federal Department of Health and Human Services. A State Medicaid Plan Amendment may be approved by CMS retroactive to the beginning of the quarter in which the proposed amendment is submitted.[6] A state must publish a public notice of a proposed amendment. In New York, such notices are published in the *New York State Register*.

The N.Y. Social Services Law provided for jurisdiction by the Department of Social Services over various aspects of the Medicaid program.[7] The Department of Social Services, however, was reorganized in 1996. General supervision and authority over the Medicaid program was transferred[8] and all references in the law to the state Department of Social Services and to the state Commis-

sioner of Social Services are now deemed to refer to the state Department of Health and to the state Commissioner of Health, respectively.[9] The Department of Health now is the "single State agency" authorized under the Federal Social Security Act to supervise the state's Medicaid program.[10] Under statutes[11] and memoranda of understanding,[12] various functions are transferred from the Department of Health to other state and local governmental agencies.[13]

II. Federal Medical Assistance Percentage

The federal share of Medicaid expenditures by a state for health care services, called the federal medical assistance percentage (FMAP), varies from state to state depending on a complex formula that measures state levels of need and wealth compared to the national average.[14] For New York State, the FMAP has been generally 50 percent.[15]

FMAP enhancements for all states were provided for the twenty-seven month period, October 2008 through December 2010, under the recent federal economic stimulus legislation, based in part on unemployment within the state.[16] New York qualified for FMAPs increasing to over sixty percent.[17] The increase in the FMAP was extended for six months through June 2011, phasing down each quarter over the six-month extension period.

III. Local Share

In New York, medical assistance had been a local county or city of New York responsibility with reimbursement from federal funds and from state funds.[18] The state provided reimbursement for the non-federal component of Medicaid expenditures in varying percentages depending upon the particular item or service.[19]

The escalating cost of the Medicaid program placed an increasing burden on local government revenue. Under 2005 legislation, local governments' shares of Medicaid expenditures are limited to a capped amount. For 2006, each local government's share of Medicaid expenditures is capped at a 3.5% increase over base year 2005 expenditures with additional cumulative non-compounded increases over base year expenditures of: 3.25% for 2007 and a further additional 3.0% per year for 2008 and each year thereafter.[20] Various Medicaid payments for the benefit of county operated facilities or public benefit corporations for which the county is responsible for the non-federal share of the payment are excluded from the cap.

The calculated Medicaid expenditure cap for each county and the city of New York is paid to the Department of Health in equal weekly installments as their maximum responsibility for Medicaid expenditures. The Commissioner of Health maintains an accounting of what would have been each local government's share without the cap, and applies that amount if lower. To encourage innovations, the savings from any local government Medicaid demonstration program approved by the Department of Health will be shared equally by the state and such local government.[21]

For the Family Health Plus program, the state assumed the full county share cost for services provided on and after October 1, 2005. For New York City, the state assumed the full local share on January 1, 2006.[22]

The Commissioner of Health has developed a plan for assumption by the state of the administrative services performed by counties and the city of New York under the Medicaid program.[23] The plan provides a five-year implementation period beginning April 2011.

IV. Rate Methodologies

Formula-based Medicaid rates of payment are established by the Commissioner of Health for hospitals, nursing homes, diagnostic and treatment centers, home health care providers, and hospices. Formula-based rates of payment are established by the Commissioner of Mental Health for inpatient and outpatient mental health services providers, by the Commissioner of Developmental Disabilities for inpatient and outpatient developmental disabilities services providers, and by the Commissioner of Alcoholism and Substance Abuse Services for inpatient chemical abuse services providers. For providers dually licensed by the Department of Health and another agency, the rates are established by the Department of Health except for certain outpatient mental health services. All Medicaid reimbursement rates are subject to approval by the Director of the Budget.

Medicaid cost-based rate-setting begins with a comprehensive cost report submitted by a provider. From the cost report, allowable operating and capital costs for rate setting purposes are determined in accordance with federal Medicare reimbursement principles and specific costs disallowed in state regulations.

The state then applies complex rate-setting methodologies to convert provider allowable costs into Medicaid reimbursement rates. The methodologies vary among different types of service providers and may include such factors as ceilings on certain costs, peer group efficiency comparisons, group average costs, and adjustments to reflect regional or provider differences in wage levels and other costs. Rates are established for a prospective rate period.[24] If a provider fails to file required financial and statistical reports and data, Medicaid payment rates may be reduced.[25] Provider cost reports are subject to audit and rates may be adjusted based on audit findings.[26]

Following an initial rate setting effort and an attempt to freeze hospital rates, cost control legislation was enacted in 1969[27] to require the Department of Health to consider in the reimbursement methodology not only provider incurred costs but to relate such costs to the efficient production of service and the general economy in the area. A prospective rate setting methodology based on histori-

cal costs, subject to peer group ceilings on costs, projected to the rate period to reflect inflation, was adopted and approved by the federal government.

The next major methodology change followed a study by the Council on Health Care Financing and introduced the New York Prospective Hospital Reimbursement Methodology (NYPHRM).[28] NYPHRM initially applied to the period 1983 through 1985 as an "all-payer" system, using 1981 reported hospital operating costs trended to the rate period.[29] For capital costs, including interest on indebtedness and depreciation or amortization, actual rate period data for the provider was used. A state-set *per diem* rate-setting and charge control methodology was applied. NYPHRM instituted a system of percentage surcharges on payer payments for inpatient care, to be paid into state-operated pools and distributed to hospitals under a formula methodology to defray part of the costs of uncompensated care, including care for the uninsured.[30] This NYPHRM system was continued in 1986 and 1987, except for Medicare payments that were no longer subject to the state rate-setting methodology.[31]

In 1988, the system became a comprehensive state-set generally per-case payment methodology applicable to all third-party payers except Medicare, based on assignment of each patient upon discharge to a weighted diagnosis-related group (DRG) for payment purposes, reflecting the intensity of care for each patient.[32] The 1981 hospital cost base for operating costs trended to the rate period and actual provider rate period capital costs were applied to calculate the per discharge rate for a hospital. The state-operated pools were expanded to encompass various other state policy goals, in addition to defraying part of the cost to hospitals of uncompensated care. This system was continued, with various cost containment adjustments and enhancements, through 1996.[33]

Beginning with 1997, under the New York Health Care Reform Act (HCRA) of 1996,[34] reimbursement rates for Blue Cross, commercial insurers, HMOs, and self-insured funds and hospital charges were deregulated. Such payers have since 1997 been permitted to negotiate payment rates with hospitals. For Medicaid, the state-set per case rate-setting system was continued and periodically modified.[35]

The Health Care Improvement Act of 2009[36] provides the statutory structure for a new methodology, the All-Patient-Refined Diagnosis-Related Group (APR DRG) methodology, initiating major revisions in hospital inpatient reimbursement, including: utilizing a more sophisticated DRG taxonomy to account for severity of illness, updating the base year utilized for hospital operating costs from 1981 to 2005, establishing a Medicaid-only cost base, eliminating previous rate add-ons, and providing for a new more sophisticated DRG taxonomy.[37] Hospital 2005 operating costs trended to the rate period and rate period capital costs are applied to establish the per discharge rate. Medicaid rates must be designed to result in a reduction in inpatient hospital reimbursement in the aggregate of $225 million annually.

Budget initiatives over the various methodologies to contain the growth in Medicaid spending have included such factors as: annual limits on case mix increases, elimination or reduction of the annual inflation factors, reductions in funding for graduate medical education, addition of efficiency adjustments, percentage and fixed dollar reductions in various components of the rate structure, applying peer group averages for reimbursement of common services, selective contracting for certain services, and elimination of payments for preventable hospital readmissions or hospital-acquired conditions (referred to as "never events").

Hospital emergency room and outpatient services, freestanding clinic services and ambulatory surgical services have been reimbursed under various fee methodologies. Reflecting a shift in Medicaid reimbursement resources from hospital inpatient services to ambulatory care services, Medicaid payment rates for such services were implemented in 2008 and 2009 to reflect the utilization of an ambulatory patient groups classification system reimbursement methodology (APG), rather than the per-threshold-visit fixed-rate methodologies.[38] Under the new payment methodology, ambulatory care reimbursement is based on the complexity of the case and intensity of services provided for a patient visit. This is intended to foster the delivery of comprehensive outpatient care and promote the migration of inpatient services to less costly outpatient venues.

For clinic services licensed by the Office of Mental Health, transition to an APG methodology begins retroactive to October 2010; for Office of Alcoholism and Substance Abuse Services clinics and Office for Persons with Developmental Disabilities clinics, transition begins retroactive to July 2011. Implementation of APGs for such clinics is contingent on federal approval.

Nursing homes, home health care, and inpatient and outpatient providers under the Mental Hygiene Law also have complex histories under diverse Medicaid rate and fee setting methodologies. These programs were also subject to numerous methodology revisions to reflect state Medicaid cost control initiatives.[39]

From 1986 through 2006, nursing home reimbursement was based on 1983 reported nursing home costs with costs containment features periodically added during the budget processes, including base price reductions, elimination of or reductions in the annual inflation factors, applying administrative and fiscal costs limits, adding a productivity adjustment, and applying adjustments to encourage providers to pursue Medicare reimbursement for dual-eligible patients. Transition to a new methodology rebased to 2002 reported costs was adopted and deferred and then instituted with specific limits on the overall growth in nursing home reimbursement.

For home health care services, rates are calculated based upon rolling base year reported costs, with cost containment features including administrative and general costs limits, factors to promote Medicare utilization for dual-eligible patients and elimination of or reductions in annual trend factor adjustments. For providers regulated under the N.Y. Mental Hygiene Law reimbursement methodologies, cost containment initiatives have included cost limits on various rate components, productivity adjustments and elimination of or reductions in annual trend factor adjustments.

V. Fee Schedules

Reimbursement for services provided by health care practitioners and suppliers enrolled in the Medicaid program are made by the state in accordance with state fee schedules. Billing instructions are published in the New York State Department of Health MMIS (Medicaid Management Information Systems) *Provider Manuals*. *Provider Manuals* are issued by Computer Sciences Corporation, the state's contracted fiscal agent[40] and are available online.[41] State fee schedules, policies and billing instructions are updated and revised in *Medicaid Update*, a monthly publication of the New York State Department of Health, Office of Medicaid Management, available online.[42] Provider fee schedules are established by the Department of Health and approved by the Director of the Budget. Fee schedules for certain services provided by facilities licensed by their respective agencies also may be established by the Commissioner of Health, Commissioner of Mental Health, Commissioner of Developmental Disabilities, and Commissioner of Alcoholism and Substance Abuse Services, subject to approval by the Director of the Budget.

VI. Provider Taxes

A provider-specific tax is defined under federal law and regulations as a tax or assessment imposed by a state on a class of health care providers, or on the payment for health care services, or the tax is related to health care items or services and at least eighty-five percent of the burden of the tax falls on health care providers. States may raise funds through provider-specific taxes if such taxes are either broad-based and uniform, as defined in the federal regulations, or the state receives a federal waiver for its tax program. Waivers may only be granted under very narrow parameters in which a tax, under a statistical analysis, must be "generally redistributive" in its effect on health care providers. A statistical regression analysis is applied to measure whether the burden of the assessment falls disproportionately on providers with higher Medicaid revenue. State revenue from taxes that do not meet these tests and do not receive a waiver would be offset against state Medicaid expenditures, thus reducing federal financial participation under the Medicaid program.[43]

In addition, a state may not provide, directly or indirectly, for any payment, offset or waiver that guarantees to hold the provider harmless for any portion of the costs of the tax.[44] The "indirect" guarantee test has not applied to a provider-specific tax that was not more than six percent of the revenues received by the provider for periods through 2007, reduced to 5.5% beginning January 2008.

New York's assessments on hospital services did not qualify as broad-based and uniform in part because under the federal rules the assessment had to be applied equally to acute care hospitals and to psychiatric hospitals and had to include all revenue. New York's program did not apply to psychiatric hospitals. In addition, various provider-specific taxes did not apply to all revenue. Federal waivers therefore would have been required. There was a dispute, however, between the state and the federal government over the proper methodology to calculate whether New York was eligible for a waiver.

To resolve the waiver issues, Congress passed legislation in 1997 as part of the federal budget process that allowed New York's then existing provider-specific tax programs.[45] However, a new law had given to the President the authority to exercise a line-item veto over Congressional additions to the federal budget. This provision for New York's provider-specific tax programs was subject to a line-item veto by President William Clinton. The authority of the President to exercise a line-item veto was subsequently declared unconstitutional by the U.S. Supreme Court in a suit relating in part to the provider-specific tax legislation.[46]

VII. Partnership Plan and Federal-State Health Reform Partnership

New York's application under Section 1115 of the Social Security Act for a waiver of State Medicaid Plan requirements to implement a statewide comprehensive Medicaid managed care program, called the Partnership Plan, was approved by the Health Care Financing Administration (now CMS) for the five-year period July 15, 1997 through March 31, 2003, renewed through March 31, 2006, and further renewed through September 30, 2011. The program provides for the mandatory enrollment of various categories of Medicaid beneficiaries at various times. In 2006, an additional Section 1115 waiver program was approved for five years as the Federal-State Health Reform Partnership (F-SHRP) through September 30, 2011.[47]

Under a budget neutrality condition of the approval of the Partnership Plan, federal financial participation in payments by the state for Medicaid services covered by the Partnership Plan is subject to an overall expenditure limit. The cap is calculated on an aggregate basis over the term of the waiver. The overall payment limit is based upon an estimate of what aggregate Medicaid expenditures would have been for the period under the fee-for-service system on a *per capita* cost basis. Thus, the state is

not at risk for increased program costs that result from a negative change in the overall economy resulting in more persons becoming eligible for the Medicaid program.

The Partnership Plan established a Community Health Care Conversion Demonstration Project, a $1.25 billion fund ($250 million per year for five years in federal funds) out of federal savings under the original 1997 waiver. Distributions were made to assist voluntary and public hospitals that serve a large number of Medicaid and uninsured persons in the transition to a managed care environment. The funds also assisted in restructuring the hospital delivery systems to promote primary care and retraining the hospital workforce.

The F-SHRP waiver provides for federal reinvestment in New York of $1.5 billion over five years ($300 million per year) of federal funds limited to fifty percent of the federal savings (anticipated to be over three billion dollars) during this period from Medicaid managed care Partnership Program and F-SHRP savings under the waivers, and savings from implementation of health care system reforms. The F-SHRP waiver funds are available as a federal Medicaid match to state expenditures for certain designated state health programs that would not otherwise be Medicaid eligible programs. The federal funds free up state funds for New York to invest in the reform initiatives. As a condition of receiving the additional funds under the waiver, the state must expend at least $600 million each year in various Medicaid reform initiatives. The state also must meet performance milestones, including: increasing Medicaid fraud and abuse recoveries to meet annual targets reaching $644 million in 2011.

VIII. State Medicaid Inspector General

During the summer of 2005, a series of articles in *The New York Times* focused on an exposé of Medicaid fraud and abuse that had gone undetected by regulators.[48] In response to these disclosures, Governor Pataki appointed, by Executive Order,[49] a Medicaid Inspector General of the State of New York to coordinate the investigation of waste, fraud and abuse in the Medicaid program. In 2006, an independent Medicaid Inspector General and Office of Medicaid Inspector General (OMIG) were established by law in the Department of Health, and their authority, duties and responsibilities delineated.[50] The responsibilities of the various state agencies regarding fraud and abuse were consolidated in the new Office, including the audit functions. Under federal regulations[51] and a Memorandum of Understanding, where the OMIG suspects fraud or abuse the case must be referred to the Attorney General's Medicaid Fraud Control Unit for criminal or civil prosecution.

IX. On Our Own Petard

New York State health care regulatory agencies have adopted complex detailed regulatory structures governing the program operation of health care providers within their respective jurisdictions. The regulatory strictures, however, may not have been intended as absolute compliance requirements as a prerequisite to entitle a provider to Medicaid reimbursement. Furthermore, overly zealous auditors from the Federal Office of Inspector General and from the State Office of Medicaid Inspector General have been applying such regulations as absolute requirements. The Federal Office of Inspector General, for example, in two audits of the personal care program and an audit of rehabilitative services by community residence providers has demanded repayment by New York of Federal Medicaid funds exceeding $500 million.[52]

The New York State Department of Health stated in response, for example, to the community residence rehabilitative services audit that the audit findings are "punitive," based upon "technical violation of New York State program regulations," that there were "no findings or allegations that the services provided were not medically necessary, were not in fact provided" and were "for alleged violations having nothing to do with the quality or appropriateness of care, recipient eligibility or provider fraud or abuse."[53]

X. Conclusion

Medicaid reimbursement methodologies are complex and regulatory compliance requirements are very broad. In considering Medicaid cost containment initiatives to maintain a balanced state budget, program regulations should be revised to afford greater flexibility to health care providers to allow them to reduce their operating costs. Standards that exceed minimum federal requirements, and for which adequate Medicaid reimbursement may not be provided under state cost containment initiatives, should not be a basis for future audit adjustments.

Endnotes

1. N.Y. Exec. Order No. 5, 9 NYCRR 8.5 (Jan. 5, 2011) (establishing the New York Medicaid Redesign Team).
2. For additional information, see N.Y. State Council on Health Care Financing, Recommendations for Financing Hospital Inpatient Care (1980) [hereinafter Recommendations for Financing Hospital Inpatient Care].
3. *See* Social Security Act of 1965, Pub. L. No. 89–97, §§ 1901–36, 79 Stat. 366, *amended by* 42 U.S.C. §§ 1396–96v (2010). The new amendments to the Social Security Act were recently held unconstitutional as not severable by a Florida federal court. *See* Florida ex rel. Bondi v. U.S. Dep't of Health & Human Servs., 2011 WL 285683 (N.D. Fla. Jan 31, 2011).
4. *See* New York State Medicaid Plan, http://www.health.state.ny.us/nysdoh/phforum/foil/foil.htm (last visited March 30, 2011).
5. *See* Social Security Act, Pub. L. No. 89–97, § 1902(a)(30)(A), 79 Stat. 366, *amended by* 42 U.S.C. § 1396a(a)(30)(A) (2010).
6. *See* 42 C.F.R. § 447.205 (1983).
7. *See* N.Y. Soc. Serv. Law §§ 363–69 (McKinney 2010).
8. *See* 1996 N.Y. Laws Ch. 474 §§ 233–48.
9. *See* N.Y. Soc. Serv. Law §§ 2(1), (6) (McKinney 2009).
10. *See* N.Y. Pub. Health Law § 201(1)(v) (McKinney 2010).

11. *See, e.g.*, N.Y. Soc. Serv. Law § 364, *amended by* 2010 N.Y. Laws Ch. 58; N.Y. Mental Hyg. Law § 43.02 (McKinney 2010).
12. *See* N.Y. Soc. Serv. Law § 364-a (McKinney 1996).
13. *See* Medicaid Inst., United Hosp. Fund, Administration of Medicaid in New York State: Key Players and Their Roles (2006), *available at* http://www.medicaidinstitute.org/publications/434595 (last visited Mar. 30, 2011).
14. *See* Social Security Act of 1965, Pub. L. No. 89–97, § 1905(b), 79 Stat. 366, *amended by* 42 U.S.C. § 1396d(b) (2010).
15. *See, e.g.*, 74 Fed. Reg. 227, 62315–17 (2009), *available at* http://aspe.hhs.gov/health/fmap11.htm.
16. *See* The American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 5001, 123 Stat. 115, 496.
17. *See* Daniel R. Levinson, Review of New York State's Compliance With the Prompt Pay Requirements for the Increased Federal Medical Assistance Percentage Under the American Recovery and Reinvestment Act of 2009 (A-02-09-01037) (2010), *available at* http://docs.google.com/viewer?a=v&q=cache:CDmcDrf4A4J:oig.hhs.gov/oas/reports/region2/20901037.pdf.
18. *See* Toia v. Regan, 387 N.Y.S.2d 309 (App. Div. 1976).
19. *See, e.g.*, N.Y. Soc. Serv. Law § 365 (McKinney 1996).
20. *See* 2005 N.Y. Laws Ch. 58, Part C, §§ 1–4, 6 (the several amendments to this legislation are scattered through the Consolidated Laws of New York as well as the Session Laws of New York).
21. *See* 2005 N.Y. Laws Ch. 58, Part C, § 5.
22. *See* N.Y. Soc. Serv. Law § 368-a(1)(t) (McKinney 2010).
23. *See* 2010 N.Y. Laws Ch. 58, Part B, § 47-b; N.Y. State Dep't of Health, New York State Medicaid Administration November 2010 Report (2010), *available at* www.health.state.ny.us/health_care/docs/ 2010-11_medicaid_admin_report.pdf.
24. *See* N.Y. Pub. Health Law §§ 2807(7), (7-a) (McKinney 2010), *amended by* 2010 N.Y. Laws Ch. 58; Anthony L. Jordan Health Corp. v. Axelrod, 493 N.E.2d 941 (N.Y. 1986).
25. *See* N.Y. Pub. Health Law § 12-d (McKinney 2010); N.Y. Comp. Codes R. & Regs. tit. 14, §§ 578.5, 635-4.4, 841.5 (1992–2006).
26. *See* N.Y. Comp. Codes R. & Regs. tit. 18, § 517 (1988).
27. *See* 1969 N.Y. Laws Ch. 957.
28. *See* Recommendations for Financing Hospital Inpatient Care, *supra* note 2.
29. *See* N.Y. Pub. Health Law § 2808-c (McKinney 1985).
30. *See id.* §§ 2808-c(4), (9).
31. *See* N.Y. Pub. Health Law § 2807-a (McKinney 1988); 1985 N.Y. Laws Ch. 807.
32. *See* N.Y. Pub. Health Law § 2807-c (McKinney 2010), *amended by* 2010 N.Y. Laws Ch. 58. This law was preempted by two federal decisions. *See* Travelers Ins. Co. v. Cuomo, 14 F.3d 708, 710 (2nd Cir. 1993); U.S. v. West Virginia, 238 F.Supp.2d 751, 753 (S.D.W.Va. 2002).
33. *See* 1990 N.Y. Laws Ch. 922; 1993 N.Y. Laws Ch. 731.
34. *See* 1996 N.Y. Laws Ch. 639, *amended by* 2009 N.Y. Laws Ch. 58, Part B, § 21.
35. *See* 1996 N.Y. Laws Ch. 639, § 168(5); 1999 N.Y. Laws Ch. 1, § 138(1), *amended by* 2008 N.Y. Laws Ch. 58, Part B, §§ 1, 1-a.
36. *See* 2009 N.Y. Laws Ch. 58, Part C, § 1-a.
37. *See* N.Y. Pub. Health Law § 2807-c(35)(h) (McKinney 2010).
38. *See id.* § 2807(2-a)(a), *amended by* 2010 N.Y. Laws Ch. 58.
39. For additional information concerning Medicaid rate and fee setting methodologies, see Eugene M. Laks, 2011–2012 New York Medicaid Reimbursement Guide (2010).
40. *See* N.Y. Soc. Serv. Law § 367-b(8) (McKinney 2008).
41. *See* eMedNY, http://www.emedny.org.
42. *See* N.Y. State Dep't of Health, *Medicaid Update*, http://www.health.state.ny.us/nysdoh/mancare/ omm/main.htm (last visited Mar. 30, 2011).
43. *See* Social Security Act of 1965, Pub. L. No. 89–97, § 1903(w), 79 Stat. 366, *amended by* 42 U.S.C. § 1396b(w) (2010).
44. *See* Social Security Act of 1965, Pub. L. No. 89–97, § 1903(w), 79 Stat. 366 *amended by* 42 U.S.C. § 1395b(w)(4)(C).
45. *See* Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4722(c), 111 Stat. 251, 515 (1997).
46. *See* Clinton v. City of New York, 524 U.S. 417 (1998).
47. *See* Mark R. Ustin, *F-SHRP: A Strong Note for Reform*, 12 N.Y. St. B.A. Health L.J. 23 (2007); N.Y. State Dep't of Health, Ctrs. for Medicare & Medicaid Servs., Federal-State Health Reform Partnership Medicaid Section 1115 Demonstration, Number 11-W-00234/2 (2006–2011), *available at* http://www.health.state.ny.us/health_care/managed_care/appextension/health_reform_partnership/docs /special_terms_and_conditions.pdf.
48. *See* Michael Luo & Clifford J. Levy, *New York Medicaid Fraud May Reach Into Billions*, N.Y. Times, July 18, 2005, at A1; Michael Luo & Clifford J. Levy, *As Medicaid Balloons, Watchdog Force Shrinks*, N.Y. Times, July 19, 2005, at A1.
49. *See* N.Y. Exec. Order No. 140-1 (Feb. 2, 2006), *available at* http://www.omig.state.ny.us/data/content/ view/38/36/ (last visited Mar. 30, 2011) (establishing the Office of the Medicaid Inspector General and revoking N.Y Exec. Order No. 140 (Aug. 5, 2005)); N.Y. Comp. Codes R. & Regs. tit. 9, §§ 140.0, 140.1 (1969).
50. *See* N.Y. Pub. Health Law §§ 30–36 (McKinney 2006–2007).
51. *See* 42 C.F.R. 455.15 (1986).
52. *See* Daniel R. Levinson, Review of Medicaid Personal Care Services Claims Made by Providers in New York City (A-02-07-01054) (2009); Daniel R. Levinson, Review of Medicaid Personal Care Services Claims Made by Providers in New York State (A-02-08-01005) (2010); Daniel R. Levinson, Review of New York's Medicaid Rehabilitative Services Claims Submitted by Community Residence Providers (A-02-08-01006) (2011).
53. *See* N.Y. Dep't. of Health, *comments,* August 23, 2010, *to* Report of the Office of Inspector General, Review of New York's Medicaid Rehabilitative Services Claims Submitted by Community Residence Providers, A-02-08-01006, (2011).

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Why Are You Calling Me?: The Importance of the Do-Not-Call Registry in Protecting the Elderly from Financial Abuse

By Matthea Ross

Introduction

Financial abuse affects many groups of people, especially the elderly, and the problem grows as the elderly population increases. The elderly are more vulnerable to financial abuse because they are more likely to be at home and therefore more accessible to telephone solicitations.[1] The problem is worsened by the mental afflictions which are suffered primarily by the elderly, such as dementia and Alzheimer's.[2] Because the elderly are living longer, it is becoming more likely that they will develop dementia.[3]

The national Do-Not-Call Registry protects the elderly to some extent by preventing commercial telemarketers from contacting them. However, requiring the elderly to opt into the Do-Not-Call Registry is not enough to protect them from financial abuse. The elderly may not realize the dangers of financial abuse and need extra protections. One possible protection would be to shift the current default rule from a "'call list' to a 'do-not-call list.'"[4] Under this new default rule, a person aged sixty-five and older would automatically be placed on the Do-Not-Call Registry and would therefore need to opt-out of the registry to receive solicitations rather than having to opt-in to prevent commercial calls.[5] However changing the default rule may not be possible, so an alternative would be education. People should be educated about the financial dangers they could face as an elderly person, how the danger is increased if they suffer from dementia, and how to prevent financial abuse.

This article will discuss how the elderly population is growing in the United States. As the elderly population continues to increase, there will be a greater number of people who are vulnerable to financial abuse. The second section will examine the most common diseases that affect the mental capacity of the elderly. These diseases place an already vulnerable group in an even more vulnerable position when it comes to financial abuse. The third section will examine why the elderly are so often targets of financial abuse. This includes not only dementia, but also the aspects of elderly people's lifestyle that make them particularly susceptible. The fourth section will examine the use of telemarketing and how it facilitates the financial abuse of the elderly. Telemarketers also take advantage of the elderly lifestyle, increasing the likelihood of abuse. The fifth section will examine the Do-Not-Call Registry and its importance in preventing financial abuse of the elderly. The sixth section will examine possible solutions to protect the elderly from financial abuse.

I. The Growing Elderly Population

The percentage of elderly people in the United States is increasing at a rapid rate.[6] With continuing advances in science, technology, and medicine, people in the United States are living longer,[7] and can lead healthier and more productive lives.[8] In 2003, twelve percent of the country's total population, or 35.9 million people, were age sixty-five or older.[9] Of these 35.9 million people, 18.3 million were between the ages of sixty-five and seventy-four, 12.9 million were between the ages of seventy-five and eighty-four, and 4.7 million were age eighty-five and older.[10] In 2005, there were over one million people in the United States over one hundred years old.[11] In 2009, it was estimated that the sixty-five or older population in the United States consisted of thirty-nine million people.[12] Between the years 1980 and 1990, the fastest growing age group was eighty-five to ninety years old, and between the years 1990 and 2000 the fastest growing age group was ninety to ninety-five.[13]

It is predicted that, by the year 2030, the number of elderly will reach seventy-two million, or twenty percent of the population of the United States.[14] Another estimate for the same year is that the number of elderly will reach eighty-nine million, or twenty-five percent of the United States population.[15] Of the eighty-five million, nine million will be over the age of eighty-five.[16] By 2050, the population of people sixty-five and older may increase to eighty-nine million,[17] and the population over eighty-five may increase to ten percent of the total population in the United States.[18]

As the population of the United States grows older, the elderly will begin to control a significant portion of the nation's wealth. In 2007, "people over fifty control[led] seventy percent of the nation's wealth"[19] and ninety-one percent of the nation's net worth was in the hands of families whose heads of household were over forty.[20] It is estimated that over the next twenty years, seventy-five million people in the United States will turn sixty, which averages to "more than 10,000 people retiring every day."[21] The majority of the nation's net worth will eventually be controlled by newly retired baby boomers.[22] Since the elderly hold such wealth, and are considered a vulnerable group, they have become targets for people who try to take that wealth. This situation is worsened by diseases that make the elderly vulnerable to potential financial abuse.

II. The Diseases of the Elderly: Dementia and Alzheimer's

a. Dementia

As people live longer, the number of patients with dementia continues to rise.[23] Dementia refers to many diseases of the brain where there is a "slow progressive deterioration of cognitive ability and personality traits and severe behavior changes."[24] More and more people are developing dementia, and live with the condition for a long time because of increased life expectancy and the slow progression of the disease.[25]

"[T]he number of individuals with dementia is increasing rapidly, and individuals diagnosed with dementia can expect to live for many years with gradually decreasing cognitive functioning including diminishing ability to respond to their environment."[26] Dementia can cause the elderly to have impaired memories and judgment, and difficulty communicating.[27] The ability of the elderly to make decisions that are well informed and rational is significantly limited.[28]

b. Alzheimer's

Of the more than sixty causes of dementia, Alzheimer's disease is the most common.[29] Alzheimer's accounts for somewhere between fifty and seventy percent of dementia cases,[30] and mainly affects people over seventy.[31] Alzheimer's disease "results in an irreversible, progressive mental decline due to nerve cell degeneration in the brain,"[32] leading to "loss of cognitive functions as well as behavioral disturbances."[33] Those with Alzheimer's experience memory impairment, but the disease will also eventually destroy the person's ability to reason, make sound judgments, and communicate.[34] These individuals degenerate over the course of months or years.[35] While the disease decreases life expectancy significantly, a person with Alzheimer's can live on average "five to eight years after diagnosis, and the length of survival varies from about three to twenty years."[36] In the United States there are about four million people who suffer from Alzheimer's[37] and, "due to the aging of the baby boomers and increased life expectancy in general, this number is projected to increase to fourteen million by 2050."[38]

There is a period of time prior to diagnosis where the elderly, and the people around them, may not be aware that they are suffering from the disease. At this point in time, when the family may not know for certain that their elderly family member needs help, the elderly person is especially vulnerable to financial abuse.

III. Why the Elderly Are Targets for Financial Abuse

The financial exploitation of the elderly includes "[t]heft, fraud…and use of undue influence as a lever to gain control over an older person's money or property."[39] It has been estimated by the National Center on Elder Abuse "that there are five million cases of financial elder exploitation annually."[40] With their growing population and increased life expectancy, the elderly have become appealing targets for scam artists and con men.[41] The elderly also tend to be easily accessible.[42] They are easy to reach by phone or mail since they are often home for most of the day. [43] Some elderly are homebound because of a disability, creating a "captive audience" for telemarketers.[44] They also have more time to listen and welcome visitors.[45]

The isolation of the elderly also contributes to the risk of elder abuse, including financial abuse.[46] The elderly tend to be lonelier, which can make them more willing to talk with strangers, even appreciating their company.[47] The elderly are also generally more courteous and will not hang up on telemarketers.[48] There is also the perception that the elderly are more trusting.[49] "Because the elderly are members of a more trusting generation…they are more likely to rely on the representations made by the telemarketer, making it difficult for seniors to recognize when they are being swindled."[50] Additionally, "many older people do not see the danger in giving out personal information, such as social security numbers, credit card numbers, and even bank account numbers, over the phone."[51]

Dementia also contributes to the perception that the elderly are less aware of their surroundings and easier to handle.[52] This perception has some merit. The gradual decrease in cognitive functioning caused by dementia limits the elderly person's ability to make informed and rational decisions.[53] Elderly persons with dementia tend to be even more susceptible to financial abuse during the early stages of dementia, prior to diagnosis,[54] where they and the people around them may not be aware of the disease.

There are several other reasons why scam artists choose the elderly as targets.[55] Businesses are very aware of the increasing population of elderly and their desire to grow their retirement investments and will "frequently participate in the financial fleecing of the elderly."[56] The elderly "are [more] likely to have a 'nest egg,' own their homes, and/or have excellent credit."[57] They are less likely to report the fraud because they "fear losing control of their money if they appear unable to care for themselves,"[58] "do not know to whom to report it, are too ashamed at having been defrauded, or do not know they have been defrauded."[59] Most of these cases are unreported due to embarrassment by the elderly or their inability to recognize that the theft has happened or is happening.[60] When the fraud is reported, the elderly "often make poor witnesses, due to the effects of age on memory."[61]

While some states have criminalized financial abuse of the elderly specifically, or rely on the general application of statutes to proscribe the abuse,[62] "the perpetrators are seldom prosecuted due to problems of proof and court delays," or there are few incentives for prosecutors

to pursue financial abuse cases.[63] Additionally, "only a small number of civil cases are brought in connection with financial abuse."[64] The problem with bringing civil cases is that the victims themselves must bring the suit.[65] However, victims do not receive the necessary guidance to bring the suit, may be overwhelmed or embarrassed, lack financial resources, or cannot face a long court battle.[66]

The current environment is particularly dangerous due to technological advances and deregulation of consumer protection.[67] For example, "[c]omputer, high-tech databases, and other information systems make personal data much more accessible to legitimate as well as illegitimate businesses."[68]

For the same reasons that the elderly are targets for scam artists, they also tend to be attractive targets for abuse by institutions that are considered reputable and the professionals they employ.[69] Institutions may try to take advantage of the elderly because of the perception that they are more trusting, easier to handle, and have assets.[70] When financial elder abuse is done by an organized business it is known as "commercial elder abuse."[71] In those situations, the commercial abuser gains access to assets by acting as a business, not by outright theft.[72]

Most scams on the elderly by commercial abusers are actually legal. [73] "They are just poor financial deals."[74] An example of a poor financial deal is a credit card offer.[75] Many who take these offers see the credit card as easy money.[76] However, credit cards also have high interest rates and fees that prevent the elderly from getting out of debt.[77] Credit card companies conduct studies to determine how best to exploit their customers' cognitive biases and errors.[78] They design their products so that consumers will take on credit that exceeds their ability to pay it back.[79]

The elderly tend to suffer more than other groups from these poor financial deals since "many have no capacity to rebound from financial setbacks" because they are frequently retired, and may find it difficult to find a job in order to recoup what they lost, or cannot work for reasons such as a disability.[80] Elderly victims then face a future without any savings to rely upon.[81] This often pushes the victims who have lost their savings to rely on public programs for their housing and health care needs.[82] "Many elderly victims have had to cut back their monthly expenditures as a result of fraud, and some have had to take low-paying jobs to survive."[83]

Not only are the elderly hurt financially, but their dignity may be negatively impacted should their family begin to take away freedoms.[84] Little can be done to protect the elderly from financial harm, except to educate them or remove some freedoms.[85] Family members may be reluctant to protect the elderly from financial abuse because of the need to limit their elderly family member's independence to stop or prevent exploitation.[86] It is important to find a way to protect the elderly from these financial deals while preserving their dignity.

IV. Telemarketing

Poor financial deals are frequently made over the telephone between the elderly and telemarketers.[87] Telemarketing is conducted to exchange payment for goods or services by telephone and "involves more than one telephone call by a telemarketer."[88] While telemarketing may have its benefits, it has been reported that over ninety percent of adults in the United States have received fraudulent offers from telemarketers.[89] Telemarketing is a very large industry with a significant number of businesses engaging in the practice.[90] An average household receives more than nineteen calls annually.[91]

The telemarketing business has grown significantly over the years. Between 1994 and 1999, the telemarketing industry grew from a $400 billion a year industry to over $540 billion a year.[92] During those same years, employment in the telemarketing industry grew by approximately two million people, from 3.5 million to nearly 5.5 million people.[93] Between 1991 and 2002, the number of calls increased from eighteen million calls per day to 104 million per day.[94] By 2002, the telemarketing industry generated approximately $668 billion and created 6 million jobs.[95] "[S]tudies [in 2004 showed] that on any given day there [were] more than 300,000 solicitors working on behalf of telemarketing companies to contact over eighteen million people."[96]

a. Telemarketing Fraud

The cost of telemarketing fraud to consumers in the United States is "between $15 and $40 billion annually."[97] This impacts all groups of people, making it a "national problem."[98] The IRS also loses millions of dollars every year in unreported illegal income.[99] Additionally, the economy suffers because there is less investment capital to "finance legitimate business opportunities."[100]

b. Telemarketer Practices

It has been estimated by the American Association of Retired Persons (AARP) that about ten percent of "telemarketing firms use fraudulent or deceptive sales tactics."[101] Telemarketers prey on the weaknesses of people, including the elderly, by winning their confidence.[102] "A sophisticated telemarketer can use his powers of persuasion to paint a 'word picture' in the mind of his client" thereby increasing the "salesperson's ability to convince a purchaser to spend money on the fraudulent scam."[103] A word picture is used to lead the consumer into making an assumption about a product that is not true.[104] These tactics "play upon the client's fears and emotions in ways that would be difficult or impossible in a face-to-face meeting."[105] Over the phone, the person being called can only rely on the telemarketer's voice, tone, and what he or she is saying.[106] At a face-to-face meeting a person can look to facial expression and body language.[107]

c. Telemarketer Practices on the Elderly

Telemarketers are particularly dangerous for the elderly and their tactics can have devastating effects.[108] This is not the only case "for those seeking to commit fraud and identity theft" but also "for sellers of goods and services and solicitors of charitable contributions."[109] It has been reported by the AARP that more than half of victims of telemarketing fraud are fifty years or older.[110] "While Americans over fifty account for more than one half of the telemarketing fraud victims, they only comprise twenty-two percent of the total population."[111] This group of consumers loses an estimated $14.8 billion yearly to telemarketers. [112]

V. The Do-Not-Call Registry

One way both state and federal governments have fought telemarketing fraud and financial abuse is by creating do-not-call registries. Before the implementation of the national Do-Not-Call Registry, fourteen states had set up their own do-not-call lists, and "at least ten more states [were] considering establishing state lists."[113] While the state registries are similar to the federal registry, each state is different. The "do-not-call protection typically establishes a list of consumer names telemarketers must obtain before doing business in a state."[114] The telemarketers cannot call the people who have placed themselves on the list.[115] Some states required consumers to pay a fee to register and telemarketers to pay larger fee to obtain the list, which is maintained and updated by a state agency.[116] A significant number of state residents took advantage of the "state no-call lists" to avoid the hassle of adding themselves to individual telemarketer no-call lists.[117] Under the company specific do-not-call list system, consumers could request that they be removed from that company's telemarketing list after the initial call.[118]

The national Do-Not-Call Registry was a culmination of "efforts to alleviate consumer frustration with unwanted sales calls."[119] Frustration was shown by the significant increase in complaints over telemarketing calls between 1998 and 2002.[120]

Other reasons for creating the Do-Not-Call Registry included protecting consumer privacy and reducing abusive and deceptive telemarketing practices.[121] Congress "spoke of protecting the peace and quiet of the home and preventing family dinners from being interrupted by unwanted calls."[122] It was also believed that the original company specific do-not-call lists "placed too heavy a burden on consumers, who [were] forced to repeat their request to be removed from a calling list to each individual caller."[123] Telemarketers would also ignore "consumer requests, and consumers had no way of verifying their removal from the list."[124] It was believed that a "national registry would provide a more convenient one-stop method for reducing unwanted calls.…"[125]

In January 2003, the Federal Trade Commission (FTC) "promulgated its final, amended Telemarketing Sales Rule [that] established[ed] the nationwide do-not-call registry and prohibit[ed] telemarketers from calling phone numbers consumers listed on the registry."[126] The original Telemarketing Sales Rule (TSR) was adopted August 16, 1995 and was created to help combat fraudulent telemarketing practices.[127] The original rule required telemarketers to tell consumers "(1) the identity of the seller; (2) the fact that the purpose of the call [was] to sell goods or services; (3) the nature of the goods or services being offered; and (4) in the case of prize promotions, that no purchase or payment [was] necessary to win."[128] In 2002, several revisions to the TSR were proposed, including the creation of the national Do-Not-Call Registry,[129] which later become one of the amendments to the TSR.[130]

The Do-Not-Call Registry was likely the most significant amendment to the TSR.[131] Consumers could add their phone numbers via telephone or the internet.[132] The registry became very popular very quickly with more than fifty million telephone numbers placed on the registry within the first three months.[133] Once a phone number is placed on the registry, telemarketers are required to remove it from their phone lists.[134] For the elderly specifically, the Do-Not-Call Registry serves the purpose of protecting registered elderly persons from telemarketers who are exploitative or promoting fraudulent schemes.[135] Since the only information that telemarketers receive is the telephone numbers of the people registered[136] the elderly cannot be specifically targeted. Additionally, the TSR gives the FTC the authority to "identify and prohibit…abusive telemarketing practices beyond the specified practices that implicate privacy concerns."[137] Such practices would include threats, intimidation, or the intent to harass or oppress the called party.[138]

a. The Shortcomings

While the Do-Not-Call Registry does prevent a significant number of telemarketing calls, which helps limit abuse, it does have some shortcomings. For example, charities seeking donations are exempt from the protections of the Do-Not-Call Registry.[139] The Do-Not-Call Registry was originally intended to regulate charitable solicitations; however, it was decided that they would be regulated using the company-specific approach.[140] Under the company-specific approach, consumers must make a "'do-not-call' request with every telemarketer that calls."[141] There were a couple of reasons for this exemption for charities. First, it was feared that the Do-Not-Call Registry would hinder "the ability of charities to continue their philanthropic mission."[142] Second, it was assumed that charities did not need regulation to the same extent as commercial callers.[143]

While it is important not to hinder a charity's ability to raise money, there should be some changes in how

the Do-Not-Call Registry is implemented so the elderly can be better protected. The company-specific approach is burdensome to the average consumer since there is no way to verify that their names have been placed on the list, and their requests to be placed on the list could simply be ignored.[144] Additionally, the consumer must keep track of which charities contacted them and when they called.[145] This would be extremely burdensome for the average consumer, but for an elderly person and especially one suffering from dementia, requesting each individual charity not to contact them, and keeping track of who contacted them and when, would be nearly impossible.

VI. A Possible Solution: Opting-Out Rather Than Opting-In

Currently the default rule is that telemarketers can call people as long as they have not placed their number on the Do-Not-Call Registry.[146] It has been suggested that the Do-Not-Call Registry would better protect the elderly if "the default rule [was shifted] from a 'call list' to a do-not-call list for people over the age of sixty-five."[147] Under this rule, once a person turns sixty-five, he cannot be solicited by phone or mail unless he opts-in to be solicited.[148] This "ban would switch the [current] presumption that people want to be called unless they [have] asked to be placed on a do-not-call list."[149]

The default rule matters a great deal when determining what a person's choices will be.[150] In an online study on default rules and organ donation, it was found that when the subjects had to opt-out, they were significantly more likely to be donors.[151] When a person has to opt into a program, he is less likely join the program.[152] Thus, if the default is that the person is already in the program and has to opt-out, people are much more likely to remain in the program.[153] Additionally, in the case of elderly with dementia, it is very unlikely that they will opt-out of the Do-Not-Call Registry. Since dementia impairs the memories of those who suffer from the disease,[154] it is unlikely that a person suffering from dementia would remember that he or she has been placed on the Do-Not-Call Registry and therefore, would not think to remove himself or herself from it.

There are likely significantly fewer elderly people registered with the Do-Not-Call Registry because of its opt-in nature. [155] If the default was that persons aged sixty-five and older were automatically placed on the list, more elderly would be registered.[156] Other countries have also developed their own versions of the Do-Not-Call Registry. However, in those counties, as in the United States, a person has to register to be placed on the list, making them opt-in programs rather than opt-out programs.[157] Were any of these lists opt-out lists there would likely be a decrease in financial abuse, especially if charitable solicitations were included.

a. Presumed Consent: Shifting Presumption

There have already been laws developed where a person has to opt-out of a program rather than opt-in, such as presumed consent laws with regard to organ donation.[158] In this type of law, known as a "shifting presumption law,"[159] instead of presuming no consent to organ donation there would be a presumption of consent.[160]

Under the 2006 Uniform Anatomical Gift Act, coroners or medical examiners have the authority to make anatomical gifts, usually of corneal tissues and pituitary glands, when the deceased individual or authorized person did not make a gift and there is no known objection by the family.[161] This presumption, that the gift is acceptable, can be rebutted by the donor, prior to death, or the family of the donor after death.[162] Family members can rebut by simply objecting to the donation.[163] These laws reduce the likelihood that a potential donor will be a "passive bystander" as is the case when individuals need to opt-in.[164] By making consent to organ donation the presumption, the belief is that there will be an increase in organ donations.[165]

It is possible that a presumed consent law for the Do-Not-Call Registry may have less impact than other opt-out laws because there may be religious and other concerns regarding one's remains, and donors and family members have an opportunity to refuse to donate.[166] The opportunity to refuse to donate would be similar to giving the elderly placed on the Do-Not-Call Registry at sixty-five the ability to opt-out.

Shifting the presumption of consent with regard to a person's placement on the Do-Not-Call Registry after the age of sixty-five is not likely to bring out the same emotional response as presumed consent for organ donation. Therefore, people are less likely to protest being placed on the Do-Not-Call Registry automatically after age sixty-five.

b. Concerns Regarding Shifting Presumption and the Do-Not-Call Registry

There may be *First Amendment* concerns to the automatic placement of person over age sixty-five on the Do-Not-Call Registry. In *Mainstream Marketing Services, Inc. v. Federal Communications Commission*[167] the court found that one of the reasons the Do-Not-Call Registry did not violate the *First Amendment* was because it was "an opt-in program that [placed] the choice of whether or not to restrict commercial calls entirely in the hands of the consumer."[168] The primary issue in the case was "whether the *First Amendment* prevent[ed] the government from establishing an opt-in telemarketing regulation that provide[d] a mechanism for consumers to restrict commercial sales calls but does not provide a similar mechanism to limit charitable or political calls."[169] The court held that the

opt-in provision made the law narrowly tailored by not "inhibit[ing] any speech directed at the home of a willing listener."[170] It is possible that if the default rule was shifted to an opt-out rule, even for a limited group of people, the court may find that it violates the *First Amendment*. However, because it is important to protect vulnerable groups like the elderly who are particularly susceptible to financial abuse, the court should not find that an opt-out program limited to a particular group violates the *First Amendment*.

The court in *Mainstream* used the three-part *Central Hudson* test for *First Amendment* challenges to commercial speech.[171] First, a substantial interest must be asserted by the government, which the proposed regulation is intended to achieve.[172] Second, the regulation must directly advance the government's interest.[173] Third, the regulation must be narrowly tailored to restrict as little speech as necessary.[174]

An opt-out program for persons sixty-five and older would achieve the government interest of protecting the elderly from financial abuse. This would directly advance the interest because it would be created expressly for elderly persons. The regulation would be narrowly tailored in that it would focus on specific groups of people and anyone in that group can opt-out if he or she chooses to. For these reasons, opt-out programs should be found to pass the test for commercial speech and not violate the *First Amendment*.[175]

c. Other Solutions

Since the court does not place a great deal of value on the opt-in nature of the Do-Not-Call Registry, other solutions must be considered. The current methods being used to protect the elderly from financial abuse only come into effect after the abuse has taken place and rely on the abuse being reported by the elderly person, family members, or friends. Signs family members or friends should look for are suspicious changes in finances and accounts, bank withdrawals that are unusual, or loss of property.[176] The suspected financial abuse can be reported to an adult protective services agency or law enforcement by family members, friends, or elderly people themselves.[177]

Another way to prevent or stop financial abuse is for family and friends to keep in contact with the elderly person.[178] By maintaining communication, there is a decreased likelihood that there will be mistreatment and the elderly person has a chance to express any problems he may be experiencing.[179] Additionally, family and friends should be aware of the possibility of financial abuse, and they should "take note of what may be happening with [their] older neighbors and acquaintances."[180]

The AARP suggests that if an elderly person or a family member believes that they or their elderly family member is a victim of financial abuse they should contact the Eldercare Locator.[181] The Eldercare Locator helps victims to identify "local programs and sources of support" in their community.[182] It was created with the goal of "provid[ing] users with the information and resources that will help older persons live independently and safely in their homes and communities for as long as possible."[183] This organization achieves this goal by helping older adults, families and caregivers navigate the "maze of services" and identify the trustworthy resources in the older person's geographic area.[184] Such programs provide a defense against abuse by maintaining health, well-being, and independence.[185]

New York State helps the elderly maintain as much of their independence as possible through Article 81 of the Mental Hygiene Law (MHL).[186] Under the MHL it is recognized that the "needs of the persons with incapacities are diverse and complex as they are unique to the individual."[187] This law allows for the "least restrictive form of intervention which assists [elderly persons] in meeting their needs but…permits them to exercise the independence and self-determination of which they are capable."[188] This allows for the protection of the individual while preserving their rights.[189] Personal or property management is tailored to the needs of each individual.[190] "By limiting the determination of incompetency to the area where the individual cannot function—[e.g.,] financial transactions—the court maximizes the patient's autonomy by allowing him to maintain control over other aspects of his life.…"[191] The intended result is a "least restrictive form of intervention consistent with the person's functional level"[192] and providing the guardian with only the powers necessary to protect the incapacitated person in the area of his life in which he needs protecting.[193] With help, the financial well-being of the elderly can be protected while also protecing their dignity.

The FTC has also been combating telemarketing fraud through their telemarketing sweeps. Operation Tele-PHONEY[194] was the "largest telemarketing sweep… by the [FTC]."[195] Under this operation, the FTC coordinated with more than thirty law enforcement agencies at the international, federal, state, and local levels to stop consumers from being defrauded by unscrupulous telemarketers.[196] Additionally, under Operation False Charity, the FTC worked with forty-nine states to bring actions against organizations and people who participated in charitable solicitation fraud.[197]

The FTC has also developed an education campaign called "Who's Calling?"[198] This campaign educates consumers on how to recognize phone fraud, and report it, and encourages consumers to place their phone numbers on the Do-Not-Call Registry.[199] The FTC disseminates the "Who's Calling?" information through the internet and provides people and organizations with brochures to distribute.[200]

d. An Alternative Solution to Shifting Presumption

The educational information is not always received by the elderly. Making sure that the elderly receive the information is very important to preventing financial elder abuse. In 1999, a bill was proposed in the Senate called the "Telemarketing Fraud and Seniors Protection Act."[201] The purpose of this bill was to protect senior citizens from telemarketing fraud through the use of education.[202] The education program included informing senior citizens of how often their demographic was the target of telemarketing fraud, how telemarketing fraud works, how to identify and report it, and how seniors can protect themselves.[203] The information would be disseminated through public service announcements, a manual or pamphlet, the internet, and telephone.[204] While this program would be a step in the right direction this form of dissemination is easy for people to ignore or they may never receive the information.

One way to be sure that seniors receive the information and read it is to send it with a statement important to financial planning. From October 1999, every year, after workers and former workers turned twenty-five, the Social Security Administration (SSA) used to send out a Social Security statement in an automatic mailing.[205] One of the reasons the SSA did this was to aid in financial planning.[206] However, due to budget cuts the SSA discontinued this practice in 2011.[207] In early 2012, the SSA resumed sending statements to people age sixty and older.[208] Additionally, the SSA has developed a way for everyone aged eighteen and older to check their statements online.[209] Included in these statements is a person's earnings record, an estimate of how much he will receive after retiring, how much he would receive should he become disabled, and how much the person's family would receive should he die in the coming year.[210]

In order to educate people about the financial abuse they could face as elderly persons, the SSA should also provide information about the dangers of financial abuse and how much more susceptible people can become to such abuse in the years after retirement. This information would help people avoid becoming targets of financial abuse.

In addition to the information about the dangers elderly people face, a form should be provided giving people the option to be automatically placed on the Do-Not-Call Registry once they reach the age of sixty-five. This form should be provided with the automatic SSA mailing. For persons age fifty-nine and under, who will not be receiving the SSA mailing, the form should be included with the online statement the SSA provides for persons in this age group. By giving the option, the opt-in nature of the Do-Not-Call Registry would be maintained because people would still be choosing to be placed on the registry, rather than placement being automatic at a certain age. People would also have the ability to plan and protect themselves against the fraudulent and abusive solicitations they may receive while they are younger and in less danger of suffering from dementia.[211] People should also be provided with the additional option of including charities on the list of organizations that cannot call, so the person would not receive any telephone solicitations after the age of sixty-five.[212]

VII. Conclusion

The elderly are living longer and so are more likely to develop some form of dementia, putting them at risk for financial abuse. Shifting the default rule from an opt-in to an opt-out for the elderly with regard to the Do-Not-Call Registry would help to decrease financial abuse. Financial abuse is especially harmful to the elderly. They are at risk of losing their life savings, and also their autonomy.

As an alternative, the population should be educated prior to age sixty-five about the Do-Not-Call Registry and the dangers the elderly face from telemarketers. Then people not already registered would be able to decide whether they want to be placed on the Do-Not-Call Registry at age sixty-five. People would be informed in advance that there are financial dangers they could face as elderly persons and the possibility that they could suffer from dementia and the greater danger that poses. People would then be able to plan for these possibilities if they are given the option of whether they would like to be placed on the Do-Not-Call Registry at age sixty-five. This approach would maintain the opt-in aspect while allowing people to plan on how to best protect themselves from financial abuse.

Endnotes

1. Shelby A. D. Moore & Jeanette Schaefer, *Remembering the Forgotten Ones: Protecting the Elderly from Financial Abuse*, 41 San Diego L. Rev. 505, 508 (2004).
2. *See generally* Evelyn M. Tenenbaum, *To Be or to Exist: Standards for Deciding Whether Dementia Patients in Nursing Homes Should Engage in Intimacy, Sex and Adultery*, 42 Ind. L. Rev. 675, 678 (2009).
3. *See id.* at 675.
4. Nathalie Martin, *Consumer Scams and the Elderly: Preserving Independence Through Shifting Default Rules*, 17 Elder L.J. 1, 27 (2009).
5. *Id.*
6. Johnny Parker, *Company Liability for a Life Insurance Agent's Financial Abuse of an Elderly Client*, 2007 Mich. St. L. Rev. 683, 689 (2007).
7. *Id.* at 687; David Brown, *Life Expectancy in the U.S. Varies Widely by Region, in Some Places Decreasing*, The Washington Post, June 15, 2011, *available at* http://www.washingtonpost.com/national/life-expectancy-in-the-us-varies-widely-by-region-and-in-some-places-is-decreasing/2011/06/13/AGdHuZVH_story.html (while overall longevity is increasing in the United States, there are large areas of the country where life expectancy is stagnate or decreasing).
8. Ronald J. Schwartz, Law & Aging: Essentials of Elder Law 1 (2nd ed. 2005).
9. Parker, *supra* note 6, at 684.
10. *Id.* at 684.
11. Schwartz, *supra* note 8, at 1.

12. Press Release, U.S. Census Bureau, Census Bureau Reports World's Older Population Projected to Triple by 2050 (June 23, 2009), *available at* http://www.census.gov/newsroom/releases/archives/international_population/cb09-97.html.
13. Parker, *supra* note 6, at 684.
14. *Id.*
15. Moore & Schaefer, *supra* note 1, at 516.
16. *Id.*
17. Press Release, U.S. Census Bureau, *supra* note 12.
18. Parker, *supra* note 6, at 684.
19. *Id.*
20. *Id*. at 689.
21. *Id*.
22. *Id*.; The Social Security Administration, Full Retirement Age, http://www.ssa.gov/retire2/retirechart.htm (a person can receive retirement benefits as early as age sixty-two. Full retirement age varies depending on date of birth. For persons retiring in 2011, full retirement age is sixty-six. The retirement age increases for people born in later years).
23. Tenenbaum, *supra* note 2, at 677.
24. Schwartz, *supra* note 8, at 9; *see also* Tenenbaum, *supra* note 2, at 678.
25. Tenenbaum, *supra* note 2, at 675, 677, 679 (the progression of Alzheimer's is slow and eventually kills those afflicted).
26. *Id.* at 679.
27. *Id*. at 678; *see also* Schwartz, *supra* note 8, at 9.
28. Tenenbaum, *supra* note 2, at 678.
29. Tenenbaum, *supra* note 2, at 677; Alzheimer's Association, Basics of Alzheimer's disease 8, *available at* http://www.alz.org/national/documents/brochure_basicsofalz_low.pdf.
30. Alzheimer's Association, *supra* note 29, at 8.
31. Schwartz, *supra* note 8, at 9; Alzheimer's Association, *supra* note 29, at 12 (Increasing age is the "greatest known risk factor for Alzheimer's." Every five years after age 65, the risk of developing Alzheimer's doubles and once a person reaches 85 the risk is 50 percent).
32. Tenenbaum, *supra* note 2, at 678.
33. Schwartz, *supra* note 8, at 9.
34. Tenenbaum, *supra* note 2, at 678; *see generally* Alzheimer's Association, *supra* note 29, at 16-21 (stages of Alzheimer's disease).
35. Tenenbaum, *supra* note 2, at 679.
36. *Id.*
37. *Id.* at 677.
38. *Id.*; Alice Park, *Alzheimer's Unlocked: After Years of Disappointing Vaccine and Drug Trials, Researchers are Finding New Ways to Interrupt the Memory-Robbing Disease, Just in Time for an Anticipated Explosion in Cases*, Time, Oct. 25, 2010, at 53-54 ("More than 5 million Americans currently suffer from Alzheimer's disease, a number that will grow to 13.4 million by 2050." Additionally, "[h]ealth experts estimate that a 65-year-old has a 10% risk of developing Alzheimer's and that baby boomers [are] currently approaching [the] peak age for the disease."); Richard Stengel, *Attacking Alzheimer's*, Time, Oct. 25, 2010, at 6 ("More than half of all Americans now know someone with Alzheimer's; for almost 30% of Americans, that person is a family member."); Alzheimer's Association, *supra* note 29, at 8 (the Alzheimer's Association estimates that 5.3 million people in the United States suffer from Alzheimer's. This includes 13 percent of persons over age 65, and 50 percent aged 85 or older. It also estimates that by 2050, "the number of individuals with the disease may reach 16 million.").
39. National Center on Elder Abuse, Why Should I Care About Elder Abuse? 1 (2010), *available at* http://ncea.aoa.gov/NCEAroot/Main_Site/pdf/publication/NCEA_WhatIsAbuse-2010.pdf.
40. Parker, *supra* note 6, at 685.
41. *Id.* at 684-85; Jeffrey L. Bratkiewicz, *"Here's a Quarter, Call Someone Who Cares": Who is Answering the Elderly's Call for Protection from Telemarketing Fraud?*, 45 S.D. L. Rev. 586, 586 (1999/2000) ("Unfortunately, accompanying the growth of the senior population has been a rise in the incidence of consumer fraud perpetrated upon the elderly.").
42. Parker, *supra* note 6, at 690.
43. Moore & Schaefer, *supra* note 1, at 508; Bratkiewicz, *supra* note 41, at 589 ("[S]enior citizens are more likely than those in other age groups to be home in the afternoon, the time that telemarketers typically call.").
44. Bratkiewicz, *supra* note 41, at 589.
45. Parker, *supra* note 6, at 691.
46. National Center on Elder Abuse, *supra* note 39, at 1 (isolation contributes to the risk of elder abuse).
47. Martin, *supra* note 4, at 5; Bratkiewicz, *supra* note 41, at 589 (the elderly may feel lonely and isolated, especially if they live alone. Fraudulent telemarketers prey on these feelings, befriend the elderly victims and then take their money).
48. Patrick E. Michela, *"You May Have Already Won …": Telemarketing and the Need for a Federal Legislative Solution*, 21 Pepp. L. Rev. 553, 558 (1994).
49. Parker, *supra* note 6, at 685.
50. Bratkiewicz, *supra* note 41, at 590.
51. Martin, *supra* note 4, at 6.
52. Parker, *supra* note 6, at 685.
53. Tenenbaum, *supra* note 2, at 678.
54. *See* Bratkiewicz, *supra* note 41, at 589 ("These feelings of loneliness, coupled with a possible deterioration in physical and mental capabilities, make the elderly attractive victims to telemarketers.").
55. *Id.* at 588 ("Telemarketers are thought to prey upon the elderly because of (1) their availability, (2) their frailty, and (3) their financial resources.").
56. Parker, *surpa* note 6, at 686; Michela, *supra* note 48, at 554 ("[T]hey must have taken advantage of my loneliness by constantly calling me on the telephone and talking to me and my need for financial security which they promised they could achieve for me by these hot investments.").
57. Parker, *supra* note 6, at 685.
58. Moore & Schaefer, *supra* note 1, at 519-20; *see also* Martin, *supra* note 4, at 1 (financial abuse as a less obvious threat to the independence of the elderly).
59. Parker, *supra* note 6, at 685; Michela, *supra* note 48, at 574 (discusses how and why boiler room operators focus their efforts on the elderly knowing their desire to increase their income. Describes how the elderly are easy to reach over the phone and are home during the day. The elderly also want to increase their wealth. They are vulnerable due to their poor memory and do not write down phone conversations. Additionally, they become embarrassed once they recognize they have been deceived and will not contact law enforcement).
60. Parker, *supra* note 6, at 685.
61. *Id.*
62. Carolyn L. Dessin, *Elder Law: Should Attorneys Have a Duty to Report Financial Abuse of the Elderly?*, 38 Akron L. Rev. 707, 708 (2005).
63. Moore & Schaefer, *supra* note 1, at 513.

64. *Id.*

65. *Id.* at 524.

66. *Id.*

67. Martin, *supra* note 4, at 1.

68. *Id.* at 2 (the rapidly changing world of "marketing, advertising, and financial product design" makes it particularly difficult for the elderly to cope).

69. Parker, *supra* note 6, at 686.

70. *Id.* at 685.

71. Parker, *supra* note 6, at 686.

72. *Id.* (citing Kurt Eggert, *Lashed to the Mast and Crying for Help: Self-Limitations of Autonomy Can Protect Elders from Predatory Lending*, 36 LOY. L.A. L. REV. 693, 698 (2003)).

73. Martin, *supra* note 4, at 2.

74. *Id.*

75. *Id.* at 8.

76. *Id.* at 8-9.

77. *Id.*

78. *Id.* at 12.

79. *Id.*

80. *See id.* at 16; Bratkiewicz, *supra* note 41, at 589 (the elderly also suffer because, by draining their victims' bank accounts, telemarketers "ultimately rob the senior of her dignity and ability to trust others."); Moore & Schaefer, *supra* note 1, at 513 ("By virtue of age limitations and other disabilities, they are often vulnerable to abuse, whether physical, mental, or financial, and may not be capable of seeking help… .").

81. Michela, *supra* note 48, at 575.

82. *Justice for All: Ending Elder Abuse, Neglect and Financial Exploitation*, *Before the S. Special Comm. on Aging*, 112th Cong. 7 (2011) (statement of Marie-Therese Connolly, Senior Scholar, Woodrow Wilson International Center for Scholars Director, Life Long Justice (an elder justice initiative of Appleseed)), *available at* http://aging.senate.gov/events/hr230mc.pdf.

83. Michela, *supra* note 48, at 575.

84. Martin *supra*, note 4, at 2.

85. *Id.*

86. *Id.*

87. *See id.* at 2-3.

88. N.Y. GEN. BUS. § 399-z(1)(h)(i) (McKinney 2011).

89. Augusta Meacham, *To Call or Not to Call? An Analysis of current Charitable Telemarketing Regulations*, 12 COMMLAW CONSPECTUS 61, 62 (2004).

90. *See* Patricia Pattison & Anthony F. McGann, *State Telemarketing Legislation: A Whole Lotta Law Goin' On!*, 3 WYO. L. REV. 167, 171 (2003).

91. *Id.*; Meacham, *supra* note 89, at 62 ("Telemarketing has become a legitimate form of business in this country because the telephone is one of the most convenient and cost-effective ways for organizations to make contact with potential customers.").

92. Patricia Pattison & Anthony F. McGann, *State Telemarketing Legislation: A Whole Lotta Law Goin' On!*, 3 WYO. L. REV. 167, 171 (2003); Steven R. Probst, *Telemarketing, Commercial Speech, and Central Hudson: Potential First Amendment Problems for Indiana Code Section 24-4.7 and Other "Do-Not-Call" Legislation*, 37 VAL. U.L. REV. 347, 347-48 (2003).

93. Pattison & McGann, *supra* note 92, at 171; Probst, *supra* note 92, at 347-48 (in 2003 it was estimated that "the ten largest telemarketing firms in the country are able to make five hundred and sixty calls per second."); Fred Kaplan, *Demands for Privacy Curb Telemarketers*, BOSTON GLOBE, Dec. 26, 2000, at A1 (in 2000, the telemarketing industry estimated that the "top 10 telemarketing firms [had], together, the capacity to make 560 phone calls per second. That translates to 33,600 calls a minute; 2,016,000 calls per hour; 16,128,000 per eight-hour day; 80,640,000 per five-day week; or enough to call every phone number in the United States, some several times over, each and every month.").

94. Jared Strauss, *The Do-Not-Call List's Big Hang-up*, 10 RICH. J.L. & TECH. 27, 29 (2004), *available at* http://law.richmond.edu/jolt/v10i4/article27.pdf.

95. Pattison & McGann, *supra* note 92, at 171.

96. Meacham, *supra* note 89, at 61.

97. Michela, *supra* note 48, at 573-74.

98. *Id.* at 574.

99. *Id.*

100. *Id.*

101. Bratkiewicz, *supra* note 41, at 587.

102. Michela, *supra* note 48, at 555.

103. *Id.* at 563-64 ("[Telemarketers] can tailor their sales presentations to appeal to the consumers, using different techniques for different types of people. The fraudulent telemarketers' expertise in the use of these powerful tools of deception continues to increase as new scams are developed every day.").

104. *Id.* at 563 n.68.

105. *Id.* at 564.

106. *See generally id.*

107. *See generally id.*

108. *Id.* at 575.

109. Martin, *supra* note 4 at 4-5.

110. Bratkiewicz, *supra* note 41, at 587 ("The American Association of Retired Persons estimates that nearly ten percent of all telemarketing firms use fraudulent or deceptive sales tactics.… The AARP reports that fifty-six percent of the victims of telemarketing fraud are age fifty or older."); Edwin L. Klett & Rochelle L. Brightwell, *Telemarketing: Exercise in Free Speech or Just a Pain in the Neck?*, 24 PENNSYLVANIA LAWYER 38, 39 (Nov./Dec. 2002) ("In one case, the FBI found that fraudulent telemarketers were targeting nearly 80 percent of their calls to older consumers.").

111. Bratkiewicz, *supra* note 41, at 587.

112. *Id.*

113. Pattison & McGann, *supra* note 92, at 188.

114. *Id.*

115. *See generally id.* at 188-189.

116. *Id.*

117. *Id.* at 189.

118. Strauss, *supra* note 94, at 31 (at this time telemarketing was regulated under the Telemarketing and Consumer Fraud Protection Act (TCFAP) which had instructed the Federal Trade Commission (FTC) "to create rules to combat 'abusive telemarketing acts or practices.'" They did so by creating company-specific regulations).

119. *Id.* at 28.

120. *Id.* at 29 (complaints had increased by 1000%).

121. *See id.* at 30.

122. *Id.*

123. *Id.* at 31.

124. *Id.*

125. *Id.*

126. Edward J. Schoen & Joseph S. Falchek, *The Do-Not-Call Registry Trumps Commercial Speech*, 2005 Mich. St. L. Rev. 483, 484 (2005); *see also* Christopher T. Pickens, *Don't Call Us, We'll Call You: Why Telemarketers are Tortfeasors*, 17 Alb. L.J. Sci. & Tech. 615, 617; James Sweet, *Opting-Out of Commercial Telemarketing: The Constitutionality of the National Do-Not-Call Registry*, 70 Tenn. L. Rev. 921, 926, 928-29 ("On March 11, 2003, President George W. Bush signed the Do-Not-Call Implementation Act into law. On June 26, 2003, the FTC began accepting names for the national do-not-call registry, and within two days 735,000 people signed up, and within two weeks that number was up to twenty-three million people.… Enforcement was scheduled to commence October 1, 2003, subjecting telemarketers to $11,000 for each number on the list that they called.").

127. Telemarketing Sales Rule, 68 Fed. Reg. 4580, 4581 (Jan. 29, 2003) (to be codified at 16 C.F.R. pt. 310).

128. *Id.*

129. *Id.* at 4582.

130. Telemarketing Sales Rule 16 C.F.R. § 310.4(b)(1)(iii)(B) (2011).

131. Sweet, *supra* note 126, at 924.

132. Schoen & Falchek, *supra* note 126, at 484.

133. Pickens, *supra* note 126, at 617; Sweet, *supra* note 126, at 929 ("At the height of registration on the first day 158 people signed up every second."); Mainstream Mktg. Servs., Inc. v. Fed. Commc'n Comm'n, 358 F.3d 1228, 1234 (2004) (By 2004, "consumers [had] registered more than 50 million phone numbers on the national do-not-call registry.").

134. Schoen & Falchek, *supra* note 126, at 484 ("They do so by periodically accessing the registry through a secure website to ascertain what numbers, sorted and available by area code have been listed, and then removing those numbers from their calling list."); Meacham, *supra* note 89, at 70-71 ("Telemarketing companies are required to 'scrub' their list of potential callers periodically to remove any names that have been added to the database since the company last updated the list."); *Mainstream*, 358 F.3d at 1234 ("Commercial telemarketers are generally prohibited from calling phone numbers that have been placed on the do-not-call registry, and they must pay an annual fee to access the numbers on the registry so that they can delete those numbers from their telephone solicitations lists."); Nat'l Fed'n of the Blind v. Fed. Trade Comm'n 420 F.3d 331, 334 (2005) ("Specifically, Congress directed the FTC to forbid 'unsolicited telephone calls which the reasonable consumer would consider coercive or abusive of such consumer's right to privacy,' to restrict 'the hours of the day and night when unsolicited telephone calls can be made,' and to require that callers disclose information about the nature and purpose of the call.").

135. Sweet, *supra* note 126, at 926; Telemarketing Sales Rule, 68 Fed. Reg. 4580, 4635 n.669 (Jan. 29, 2003) (to be codified at 16 C.F.R. pt. 310).

136. Telemarketing Sales Rule, 68 Fed. Reg. at 4641.

137. *Id.* at 4614.

138. *Id.* at 4614 n.395.

139. Martin, *supra* note 4, at 5.

140. Strauss, *supra* note 94, at 31-32.

141. Telemarketing Sales Rule, 68 Fed. Reg. at 4629.

142. Strauss, *supra* note 94, at 32.

143. *Id.*

144. Telemarketing Sales Rule, 68 Fed. Reg. at 4629.

145. *Id.*

146. *See* Martin, *supra* note 4, at 26.

147. *Id.* at 27; Pattison & McGann, *supra* note 92, at 197 ("Under the proposal the presumption would be that the people do not want to be called unless they request it.").

148. Martin, *supra* note 4, at 27; Pattison and McGann, *supra* note 92, at 197 (there would be "a ban on all telemarketing calls made without prior knowledge or consent… .").

149. Pattison & McGann, *supra* note 92, at 197.

150. Richard H. Thaler & Cass R. Sunstein, Nudge: Improving Decisions About Health, Wealth, and Happiness 178 (2008).

151. *Id.* ("[W]e know something about how much the choice of the default matters in this domain. Using an online survey, the researchers asked people, in different ways, whether they would be willing to be donors. In the explicit consent condition, participants were told that they had just moved to a new state where the default was not to be an organ donor, and they were given the option of confirming or changing the status. In the presumed consent version, the wording was identical but the default was to be a donor. In the third, neutral, condition, there was no mention of a default—they just had to choose. Under all three conditions, the response was entered literally with one click. As you will not expect, the default mattered—a lot. When participants had to opt in to being an organ donor, only 42 percent did so. But when they had to opt out, 82 percent agreed to be donors. Surprisingly, almost as many people (79 percent) agreed to be donors in the neutral condition.").

152. *Id.*

153. *Id.*

154. Tenenbaum, *supra* note 2, at 678.

155. *See generally* Thaler, *supra* note 150, at 178.

156. *See generally id.*

157. *See* Australian Communications and Media Authority, Do Not Call Register, https://www.donotcall.gov.au/; *see also* Telephone Preference Service, http://www.mpsonline.org.uk/tps/ (in the UK there is no exceptions made for charities); *see also* Canadian Radio-television and Telecommunications Commission, National Do Not Call List, https://www.lnnte-dncl.gc.ca/index-eng.

158. Michele Goodwin, *Empires of the Flesh: Tissue and Organ Taboos*, 60 Ala. L. Rev. 1219, 1236 (2009).

159. Alexandra Powhida, *Forced Organ Donation: The Presumed Consent to Organ Donation Laws of the Various States and the United States Constitution*, 9 Alb. L.J. Sci. & Tech. 349, 359 (1999).

160. *Id.* at 360.

161. Sheldon F. Kurtz et al., *The 2006 Revised Uniform Anatomical Gift Act—A Law to Save Lives*, Health Law Analysis, Feb. 2007, at 48; Erik S. Jaffe, *"She's Got Bette Davis['s] Eyes": Assessing the Nonconsensual Removal of Cadaver Organs Under the Takings and Due Process Clauses*, 90 Colum. L. Rev. 528, 535-36 (1990) (other requirements for the removal of corneal tissues and pituitary glands include "(1) a request for such tissue for the purposes of transplant or therapy is made by an authorized recipient; (2) the removal would not interfere with the course of an autopsy or other investigation [and]; (3) the removal would not alter the deceased's facial appearance."); Uniform Law Commission, Anatomical Gift Act (2006), *available at* http://www.uniformlaws.org/Act.aspx?title=Anatomical%20Gift%20Act%20(2006) (forty-four states and the District of Columbia have enacted the Uniform Anatomical Gift Act and two states have introduced the Act).

162. Powhida, *supra* note 159, at 358 (the author believed that these types of presumed consent statutes are ineffective because the donor and the family can refuse consent, and need to be informed of their right to refuse consent).

163. Jaffe, *supra* note 161, at 535-36.

164. Goodwin, *supra* note 158, at 1236.

165. *Id.*

166. Powhida, *supra* note 159, at 361.

167. Mainstream Mktg. Servs., Inc. v. Fed. Commc'n Comm'n, 358 F.3d 1228, 1232 -1233 n.2 (this case was a consolidation of four cases that challenged the national Do-Not-Call registry. However it did not address "whether the do-not-call registry would be constitutional if it applied to political and charitable callers.").

168. *Id.* at 1232-1233.

169. *Id.*

170. *Id.* at 1237-1238 (the court in this case held that the Do-Not-Call Registry advanced the government's interest because it helped to block a significant number of problem calls. Additionally it was narrowly tailored because of its opt-in character; therefore it would not inhibit speech made to a willing listener).

171. *Id.* (citing *Central Hudson* 447 U.S. 557, 566).

172. *Id.* at 1237.

173. *Id.*

174. *Id.*

175. It may be argued that most people aged sixty-five and over are competent to deal with these types of calls and that an opt-out program is not narrowly tailored. However, this is the best way to prevent financial abuse because there is not a more narrowly tailored option.

176. National Center on Elder Abuse, *supra* note 39, at 2.

177. *Id.* (even if there has been an investigation but there is a belief that the circumstances are continuing to get worse then continue to speak out).

178. *Id.*

179. *Id.*

180. *Id.* ("Do they seem lately to be withdrawn, nervous, fearful, sad, or anxious, especially around certain people, when they have not seemed so in the past?").

181. Lynnette Khalfani-Cox, *Are You a Victim of Financial Abuse?*, AARP, Mar. 7, 2011, http://www.aarp.org/money/scams-fraud/info-03-2011/are-you-being-financially-abused-by-a-family-member.html; Administration on Aging, Eldercare Locator, http://www.eldercare.gov/Eldercare.NET/Public/Index.aspx.

182. National Center on Elder Abuse *supra* note 39, at 2 (this can be done by contacting a local Area Agency on Aging office); Khalfani, *supra* note 181.

183. Administration on Aging, Eldercare Locator, Service, http://www.eldercare.gov/Eldercare.Net/Public/About/Services.aspx.

184. *Id.*

185. National Center on Elder Abuse, *supra* note 39, at 2.

186. *See generally* N.Y. Mental Hyg. Law § 81.01.

187. N.Y. Mental Hyg. Law § 81.01(b); *see also* Hon. Edwin Kassoff, Elder Law And Guardianship in New York § 11:6 (2011).

188. N.Y. Mental Hyg. Law § 81.01.

189. Kassoff, *supra* note 187, at § 11:6.

190. N.Y. Mental Hyg. Law § 81.01.

191. Tenenbaum, *supra* note 2, at 712-713.

192. N.Y. Mental Hyg. Law § 81.09(c)(5)(XII).

193. Kassoff, *supra* note 187, at § 11:10.

194. Press Release, Federal Trade Commission, FTC Announces 'Operation Tele-PHONEY,' Agency's Largest Telemarketing Sweep (May 20, 2008) [hereinafter Operation Tele-PHONEY], *available at* http://www.ftc.gov/opa/2008/05/telephoney.shtm.

195. Press Release, Federal Trade Commission, FTC Stops Two Deceptive Telemarketing Operations (Oct. 9, 2009) [hereinafter Deceptive Telemarketing Operations], *available at* http://www.ftc.gov/opa/2009/10/telephoney.shtm.

196. Operation Tele-PHONEY, *supra* note 194.

197. Press Release, Federal Trade Commission, FTC Announces "Operation False Charity" Law Enforcement Sweep (May 20, 2009) [hereinafter Operation False Charity], *available at* http://www.ftc.gov/opa/2009/05/charityfraud.shtm.

198. Federal Trade Commission, Who's Calling?: Recognize & Report Phone Fraud, *available at* http://www.ftc.gov/bcp/edu/pubs/consumer/telemarketing/tel19.pdf.

199. *Id.*

200. Federal Trade Commission, Who's Calling?: Recognize & Report Phone Fraud, Partner Resources, http://www.ftc.gov/bcp/edu/microsites/phonefraud/partner.shtml.

201. Telemarketing Fraud and Seniors Protection Act, S. 699, 106th Cong. (1999), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-106s699is/pdf/BILLS-106s699is.pdf.

202. *Id.*

203. *Id.*

204. *Id.*

205. Emily Brandon, *Social Security Suspends Annual Statements*, U.S. News Money (Apr. 4, 2011), http://money.usnews.com/money/blogs/planning-to-retire/2011/04/04/social-security-halts-annual-statements-.

206. *See id.*

207. *Id.*; Ann Carrins, *Checking Your Social Security Benefits Online*, N.Y. Times (May 16, 2012), http://bucks.blogs.nytimes.com/2012/05/16/checking-your-social-security-benefits-online/ (in February 2012 the SSA "resumed mailing paper statements to workers who are 60 and older and [are not] yet receiving benefits.").

208. Carrins, *supra* note 207; Brandon, *supra* note 205 (statements were mailed only to people aged sixty and over between 1995-1999).

209. Carrins, *supra* note 207.

210. Brandon, *supra* note 205.

211. Mainstream Mktg. Servs., Inc. v. Fed. Commc'n Comm'n, 358 F.3d 1228, 1237 (the protection of consumers "against the risk of fraudulent and abusive solicitations" was one of the justifications used by the government in the *Mainstream* case).

212. This would replace the charity specific lists once a person reaches age sixty-five for those who choose to opt-in.

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Redefining the Valuation Methods of Modern Day Hospital Care

By Craig B. Garner

Abstract

This article discusses the report published last year by the Joint Commission ("Improving America's Hospitals") that seeks to showcase the achievements of hospitals identified as "Top Performers on Key Quality Measures." The Joint Commission's report also provides a comprehensive analysis on the ways in which those hospitals accredited by the organization fared for all quality measures. This article focuses on specific care measures set forth in the report (heart attack care, pneumonia, and one surgical example), and compares these historical trends with the appropriate Medicare reimbursement data for the same time period.

While it comes as no surprise that hospital reimbursements do not share the same trajectory as Joint Commission quality standards, the contradictory manner in which health care regulations reward annual improvement by reducing reimbursements speaks volumes about a system not just in transition, but in a state of confusion. Mindful of the value based purchasing modifications to the Medicare program in effect as of October 1, 2012, this article suggests that now is an appropriate time to take stock in the collections of data we have amassed as a means to understand and refine the delicate infrastructure of our nation's health care system, with a specific eye toward the ways in which value is assessed and rewarded. As the nation transitions toward a reimbursement policy dictated by performance measures rather than cost, our focus should also be directed toward creating a self-sustaining system that improves the delivery of health care throughout the nation and is fair to both the individuals and institutions that participate therein.

Redefining the Valuation Methods of Modern Day Hospital Care

Due to the sensitive nature of the industry it services, the American hospital must rightfully operate under copious federal and state regulations, in addition to volumes of rules and ordinances established by separate, non-governmental entities. Though policing policies such as accreditation, certification and periodic review come from a variety of both public and private sources, the goal is generally consistent: develop uniform standards to ensure that hospitals in the U.S. operate at an acceptable safety level while delivering quality patient care.

The Many Paths to Accreditation

Though its primary function is without question the delivery of accurate and effective medical treatment, health care is also big business.[1] In an attempt to promote constant vigilance among America's hospitals, any one institution may be subject to accreditation review at any time from private, non-governmental organizations such as the Joint Commission,[2] the Healthcare Facilities Accreditation Program (HFAP),[3] Accreditation Commission for Health Care (ACHC),[4] Community Health Accreditation Program (CHAP),[5] the Compliance Team, Inc.,[6] Healthcare Quality Association on Accreditation (HQAA),[7] or DNV Healthcare, Inc. (DNV),[8] among others.[9]

"While it comes as no surprise that hospital reimbursements do not share the same trajectory as Joint Commission quality standards, the contradictory manner in which health care regulations reward annual improvement by reducing reimbursements speaks volumes about a system not just in transition, but in a state of confusion."

By and large, each private entity governs through its own set of rules. For example, the Joint Commission surveys hospitals by following more than 276 standards and reviewing 1,612 elements of performance. HFAP does largely the same thing pursuant to its 1,100 or more individual standards. Focusing on home medical equipment as well as durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"), HQAA has developed a review process consistent with federal standards.[10]

Hospital Accreditation and the Joint Commission

Should a hospital wish to treat Medicare beneficiaries (with the expectation of payment), it must first enter into a provider agreement with Medicare. As a condition precedent to such participation, hospitals must meet certain requirements established by the Social Security Act[11] or imposed by the Secretary of the Department of Health and Human Services (HHS), more commonly referred to as "conditions of participation" (CoPs).[12] Hospitals can satisfy this statutory requirement by certification through a state agency, or alternatively the provider can seek "accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded."[13] The federal government recognizes the Joint Commission—as well as certain other organizations that have been confirmed as capable of providing appropriate oversight—as a national accreditation program for hospitals participating in Medicare or Medicaid.[14]

Formed December 15, 1951, as an independent, nonprofit entity, the Joint Commission (known until 2007 as the Joint Commission on Accreditation of Healthcare Organizations) began as a collaboration between the American College of Physicians, the American Hospital Association, the American Medical Association, the Canadian Medical Association, and the American College of Surgeons.[15] The Joint Commission started its process of administering hospital accreditations in January 1953, evolving over the years from a one-page set of requirements in 1919 (known as "The Minimum Standard") to a 152-page manual for standards in 1970 (known as the *1970 Accreditation Manual for Hospitals*)[16] to the approximately 500-page manual that exists today.[17]

The Joint Commission provides the following mission statement for the organizations with which it partners: "To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value."[18] As with all acute care hospital accreditation entities,[19] the Joint Commission must confirm that these providers meet specific and extensive criteria set forth by the federal government.[20]

As part of the rigorous set of standards reviewed in any hospital survey, the Joint Commission integrates performance measures in hospital accreditation oversight through its ORYX® initiative (a term unique to the Joint Commission). First deployed by the Joint Commission in 1997, ORYX core measure data are among the key data elements included in the Joint Commission's focus on improvement.[21] In its original form, ORYX had no industry standard detailing the type or amount of data hospitals should collect, and in fact more hospitals initially resisted than participated in this approach. Today, however, this institutionalized method for garnering information based on quality measures is a federal requirement, and the Joint Commission now accumulates data from hospitals for approximately 60 different inpatient measures.[22] Moreover, not only does the federal government penalize hospitals for non-compliance, the 2010 Patient Protection and Affordable Care Act (PPACA)[23] may soon emphasize quality and performance as the core foundation of health care's future reimbursement structure.[24]

In November 2010, the Joint Commission outlined a five-year plan to continue its monitoring of the changing health care climate as the organization addresses areas for improvement:

- Refinement of the process for electronic receipt of high quality standardized performance measure data that cover all aspects of care delivery within and across the various types of health care organizations (e.g., hospitals, long term care, home care, etc.). Approaches to refining this process will include exploration of the potential to expand the capability of the electronic health record to capture measured data as a byproduct of the health care delivery process.
- Expansion of the scope of measure sets available for selection by health care organizations. This includes increasing the complement of measure sets for hospitals to provide a broader menu for measure selection.…
- Creation of sophisticated applications of measurement data use for accreditation, accountability and public reporting purposes.
- Coordination of data demands and prioritization of critical measurement areas by the various public and private sector entities to minimize data collection burden and eliminate redundancies for health care organizations, while maximizing the consistency and usefulness of the data. Coordination activities will focus on the amalgamation of data demands by large national entities including CMS, the QIOs, NQF, AHRQ, IOM and others.
- Continued, proactive support for the leadership role of the National Quality Forum in the identification of national measurement objectives and the establishment of a long-term collaborative relationship.
- Continued proactive support for, and participation in, the work of the Hospital Quality Alliance, the AQA, and their combined efforts to harmonize these activities.[25]

Contemporary Performance Standards in the Context of Modern Health Care

Today, the Joint Commission requires hospitals to collect and submit certain data that falls under its "core measure sets," including but not limited to heart attacks and heart failure, pneumonia, and the Joint Commission's Surgical Care Improvement Project. Last year, the Joint Commission released its Annual Report on Quality and Safety entitled *Improving America's Hospitals* (the "Report") as a means to showcase the commendable achievements of hospitals identified by the Joint Commission as "Top Performers on Key Quality Measures," as well as

to provide a comprehensive analysis on how those hospitals accredited by the Joint Commission fared for all measures.[26]

Joint Commission accountability measures connect evidence-based care with *positive* patient results. The Joint Commission contends that implementation is more effective when it relates to certain programs wherein the public or even an outside regulatory agency holds the provider accountable, similar to the proposed federal regulations for value-based purchasing.[27] The Joint Commission has established four criteria in assessing the success of these evidence-based examples, including:

> **Research:** Strong scientific evidence demonstrates that performing the evidence-based care process improves health outcome (either directly or by reducing risk of adverse outcomes).
>
> **Proximity:** Performing the care process is closely connected to the patient outcome; there are relatively few clinical processes that occur after the one that is measured and before the improved outcome occurs.
>
> **Accuracy:** The measure accurately assesses whether or not the care process has actually been provided. That is, the measure should be capable of indicating whether the process has been delivered with sufficient effectiveness to make improved outcomes likely.
>
> **No Adverse Effects:** Implementing the measure has little or no chance of inducing unintended adverse consequences.[28]

The tables in Appendix A summarize the Report in three areas: (1) heart attack care accountability composite[29]; (2) pneumonia care accountability composite[30]; and (3) joint replacement, just one example contained within the surgical care accountability composite.[31] These tables show a steady increase in the care measure results (the "Care Composite") for each medical condition and surgical procedure.

When taken at face value in relation to the examples set forth in Appendix A, it is difficult to find fault with the Report and the ways in which hospitals have improved the delivery of care in these areas.[32] And yet, while viewing these successes in the context of health care in its totality does not in itself undercut the Report and its significance as a means to gauge the effectiveness of the accreditation process, it does portray somewhat of a different image.

The United States spent an estimated $2.6 trillion on national health in 2010 (17.6 percent of the U.S. GDP).[33] Some estimates expect this figure to be as high as $4.64 trillion by 2020 (nearly 20% of the U.S. GDP).[34] Singling out the nation's biggest spender, trends in California are of special concern as health care expenses continue to grow steadily along with the state's population, even though California lost approximately 10% of its hospital beds between 2002 and 2009.[35]

While few dispute the statistical information proving that we as a nation spend more on health care every year, the nexus between health care spending and actual *revenue* trends calls into question the sustainability of a system that finds itself locked into a self-perpetuating spending binge in its bid for survival.

A Comparison Between the Report and Correlating Medicare DRGs

With respect to tables 1 and 2 in Appendix A (heart attack care measure results), the Joint Commission's Care Composite was compared with the Medicare diagnostic related groups (DRGs) information in 2006 and 2007 for DRG numbers 127 (heart failure and shock) and 140 (angina pectoris), and in 2008 and 2009 for MS-DRG numbers 291 (heart failure and shock with major complication/comorbidity (MCC), 292 (heart failure and shock with complication/comorbidity (CC), 293 (heart failure and shock without CC or MCC), and 311 (angina pectoris).[36]

The Medicare revenue percentage for each respective DRG description was extracted from the DRG data relating to its annual revenue consistent with national data for such acute care, divided by the number of patient days for the same year. This data was taken from the Medicare Provider Analysis and Review (MEDPAR) files, which contain information pertaining to 100% of Medicare beneficiaries using hospital inpatient services national data for short stay, inpatient DRGs. From these figures, Appendix A, Table 1 compares the Medicare revenue percentage for heart failure and shock with the Report's Care Composite in the area of heart attack care for years 2006 through and including 2009.[37] Appendix A, Table 2 compares the Medicare revenue percentage for angina pectoris with the Report's Care Composite in the same area, and for the same time frame (2006 to 2009).

A similar approach was employed to create Appendix A, Table 3, comparing the Joint Commission's Pneumonia Care Composite with the appropriate DRGs. For 2006 and 2007, DRG numbers 89 (simple pneumonia and pleurisy (18 years and older in age)) with CC), 90 (simple pneumonia and pleurisy (18 years and older in age)) without CC, and 91 (simple pneumonia and pleurisy (under 18 years in age)) were used for the study, and for 2008 and 2009

MS-DRG numbers 193 (simple pneumonia and pleurisy with MCC), 194 (simple pneumonia and pleurisy with CC), and 195 (simple pneumonia and pleurisy without CC or MCC). The Medicare revenue percentage for each respective DRG description was extracted from the DRG data relating to its annual revenue consistent with national data for such acute care, divided by the number of patient days for the same year. The source of the data is also the MEDPAR files.[38]

"[F]uture congressional focus should be directed toward creating a self-sustaining system that improves the delivery of health care throughout the nation and is fair to both the individuals and institutions that participate therein."

Appendix A, Table 4 (addressing joint replacement, a single example from the Report's surgical care composite) was created through a compilation of data from within the Report (page 22, Table 6). Using information from three separate line items—(1) "Antibiotics within 1 hour of first cut—For hip joint replacement surgery," (2) "Appropriate Prophylactic Antibiotics—For hip joint replacement surgery," and (3) "Stopping Antibiotics within 24 hours—For hip joint replacement surgery," Appendix A, Table 4 represents the average. The Care Composite for joint replacement was then compared with the appropriate MS-DRGs numbers from 2008 and 2009, including 469 (major joint replacement or reattachment of lower extremity with MCC) and 470 (major joint replacement or reattachment of lower extremity without MCC).[39] The Medicare revenue percentage for each respective MS-DRG description was extracted from the MS-DRG data relating to its annual revenue consistent with national data for such acute care, divided by the number of patient days for the same year. The source of the data is also the MEDPAR files.[40]

Conclusion

If our nation's track record on health care funding since the inception of Medicare is any indication, it should come as no surprise that hospital reimbursements do not share the same trajectory as Joint Commission quality standards. Indeed, factoring into the equation additional variables such as annual inflation and a struggling economy only serves to further distinguish the historical paths of performance and payment.[41] As Medicare prepares for a massive shifting from cost to performance-based reimbursement,[42] a move likely followed in quick succession by other payer groups, the contradictory manner in which health care regulations reward annual improvement by reducing reimbursements speaks volumes about a system not just in transition, but in a state of confusion.

To be certain, the evolution of the reimbursement system has been shaped as much by innovation and advancements as it has by politics and a constantly changing definition of public interest. But in this age of technology, it may be prudent to take stock in the collections of data we have amassed as a means to understand and refine the delicate infrastructure of health care in the U.S. Ultimately, future congressional focus should be directed toward creating a self-sustaining system that improves the delivery of health care throughout the nation and is fair to both the individuals and institutions that participate therein. This hardly seems like an unreasonable place to start.

Endnotes

1. According to Congressional Budget Office estimates, major health programs accounted for 2.9 percent of the nation's GDP between 1971 and 2010 (averaged). Under the 2010 Patient Protection and Affordable Care Act, this figure may increase to as much as 7.1 percent by 2021. *See, e.g.,* Presentation by Douglas W. Elmendorf, Director, Congressional Budget Office, *Federal Budget Math: We Can't Repeat the Past* (June 16, 2011).
2. The Joint Commission is an independent, not-for-profit organization that accredits and certifies more than 19,000 health care organizations and programs in the United States. *See* www.jointcommission.org.
3. Established in 1945 to conduct objective reviews of osteopathic hospitals and the services they provide, HFAP surveys hospitals for compliance with the Medicare Conditions of Participation and Coverage. *See* www.hfap.org.
4. ACHC is a national health care accrediting organization designed to create a system catering to small providers. *See* www.achc.org.
5. CHAP is an independent, not-for-profit accrediting body for community based health care organizations. *See* www.chapinc.org.
6. Since 2006, the Compliance Team, Inc. has been a nationally recognized, CMS-approved accrediting body for providers of durable medical equipment, prosthetics, orthotics, and supplies. *See* www.exemplaryprovider.com.
7. HQAA provides home medical or durable medical equipment accreditation programs. *See* www.hqaa.org.
8. The newest accreditation organization for hospitals, DNV, received deemed authority from the Centers for Medicare & Medicaid Services in 2008. *See* www.dnvaccreditation.com.
9. This regulatory infrastructure exists in addition to the labyrinth of federal and state laws. *See, e.g.*, 42 U.S.C. Section 1395x(e)(ii).
10. *See* 42 CFR § 424.58. The 2003 Medicare Prescription Drug, Improvement, and Modernization Act (Pub. L. 198-173) required the federal government to implement quality standards for DMEPOS.
11. Originally P.L. 74-271, approved August 14, 1935, 49 Stat. 620, and all subsequent amendments thereto.
12. *See, e.g.*, 42 U.S.C. §§ 1302, 1395hh, 1395rr; 42 C.F.R. part 482.
13. *See* 74 Federal Register (227) 62333 (Nov. 27, 2009).
14. *Id.* (approving the Joint Commission's status through July 15, 2014); *see also Medicare Improvements for Patients and Providers Act of 2008* ("MIPPA"), § 125 (Pub. L. 110-275) (changing the process of accreditation in 2008 by revoking the Joint Commission's

statutorily-guaranteed "deeming authority" for hospitals and requiring that the Joint Commission apply to, and obtain approval from, the Centers for Medicare & Medicaid Services (CMS)).

15. *See* Roberts, James S., MD, Coale, Jack G., MA, Redman, Robert R., MA, *A History of the Joint Commission on Accreditation of Hospitals*, 258 (7) JAMA 936, 938 (Aug. 21, 1987). The article notes that in 1958, the Canadian Medical Association withdrew from the Joint Commission. *Id.*
16. *Id*.
17. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook* (Joint Commission Resources, Inc., March 2011).
18. *See id.* at FW-1 (the Joint Commission revised its mission statement in 2009).
19. The author neither addresses nor opines upon the scope of the Joint Commission's influence in the hospital accreditation process, and does not attempt to compare the Joint Commission with other entities providing similar and/or comparable oversight. Between 2002 and 2011, the author was the chief executive officer of an acute care hospital in Norwalk, California, accredited at all times by both the Joint Commission and HFAP.
20. *See, e.g.*, 42 C.F.R. §§ 482.1, 482.2, 482.11, 482.12, 482.13, 482.21, 482.22, 482.23, 482.24, 482.25, 482.26, 482.27, 482.28, 482.30, 482.41, 482.42, 482.43, 482.45, 482.51, 482.52,482.53, 482.54, 482.55.
21. *Id.* At PM-1 ("ORYX measurement requirements are intended to support Joint Commission—accredited hospitals in their quality improvement efforts. Performance measures are essential to the credibility of any modern evaluation activity for hospitals.") .
22. *See* Chassin, Mark R., M.D., Loeb, Jerod M., Ph.D., *et al*., *Accountability Measures—Using Measurement to Promote Quality Improvement*, 363 (7) NEJM 683 (Aug. 12, 2010).
23. Pub. L. 111-148.
24. PPACA, § 3022; 42 C.F.R. § 425 (proposed rules as of April 7, 2011).
25. *Evolution of Performance Measurement at the Joint Commission 1986-2010: A Visioning Document* (*available at* www.jointcommission.org/assets/1/18/SIWG_Prologue_web_version.pdf).
26. *Improving America's Hospitals: The Joint Commission's Annual Report on Quality and Safety*, p. 4 (2011).
27. *See supra,* note 24.
28. The Report, p. 29.
29. The Report, p. 20, Table 3.
30. The Report, p. 21, Table 5.
31. The Report, p. 22, Table 6.
32. *But cf.*, McCannon, Joseph, AB, Berwick, Donald M., MD, MPP, *A New Frontier in Patient Safety*, 305 (21) JAMA 2221 (June 1, 2011) (concluding that despite the investment into the nation's health care system since the 1999 report *To Err Is Human*, medical errors continue to harm hospital patients to such an extent that further change is necessary); Wachter, Robert M., *Patient Safety at Ten: Unmistakable Progress, Troubling Gaps*, 29 (1) HEALTH AFFAIRS 165, 172 (January 2010) (summarizing the success in efforts to enforce safety standards over the past five years as slightly above average).
33. *See* Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group; Department of Commerce, Bureau of Economic Analysis and Bureau of the Census; Keehan, Sean P., Sisko, Andrea M., *et al*., *National Health Spending Projections Through 2020*, 30 (8) HEALTH AFFAIRS 1594 (August 2011).
34. *Keehan, supra*, *National Health Spending Projections Through 2020,* p. 1595.
35. See Appendix B: Hospitals in California—2002 to 2009. Between 2002 and 2009, health care spending increased by 34%, and there were 40 fewer hospitals available to treat approximately 2.7 million additional residents.
36. As of fiscal year 2008, CMS changed the Medicare inpatient prospective payment system by introducing Medicare Severity Diagnosis Related Group ("MS-DRGs"), thereby creating an entirely new numbering system for DRGs in 2008 and 2009. *See* 42 U.S.C. § 1395ww; *TMA, Abstinence, Education, and QI Programs Extension Act of 2007,* P.L. 110-90 (approved Sept. 29, 2007, 121 Stat. 984), § 7(a). Information for DRG and MS-DRG descriptions obtained from the CMS website for fiscal years 2008 and 2009 (https://www.cms.gov/MedicareFeeforSvcPartsAB/).
37. *See, e.g., id.*
38. *See, e.g., id.*
39. *See, e.g., id.*
40. *See, e.g., id.*
41. A recent study of the growth in family income in the U.S. over the past decade concluded that the estimated increase from $76,000 in 1999 to $99,000 in 2009 was practically erased by the increase in household spending on monthly health insurance premiums, out-of-pocket health care costs, and tax-related expenses directed toward health care. *See* Auerbach, David I., Kellerman, Arthur L., *A Decade of Health Care Cost Growth Has Wiped Out Real Income Gains for an Average U.S. Family*, 30 (9) HEALTH AFFAIRS 1630 (Sept. 2011).
42. *See supra,* note 24.

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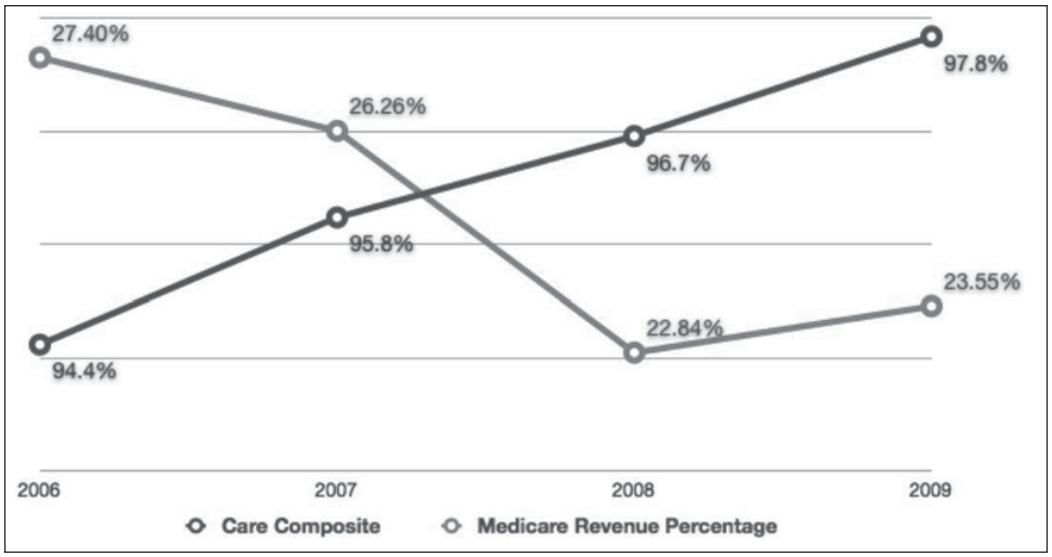
Appendix A, Table 1

Joint Commission Heart Attack Care Measure Results Compared with Medicare Revenue for Heart Failure and Shock, 2006 to 2009



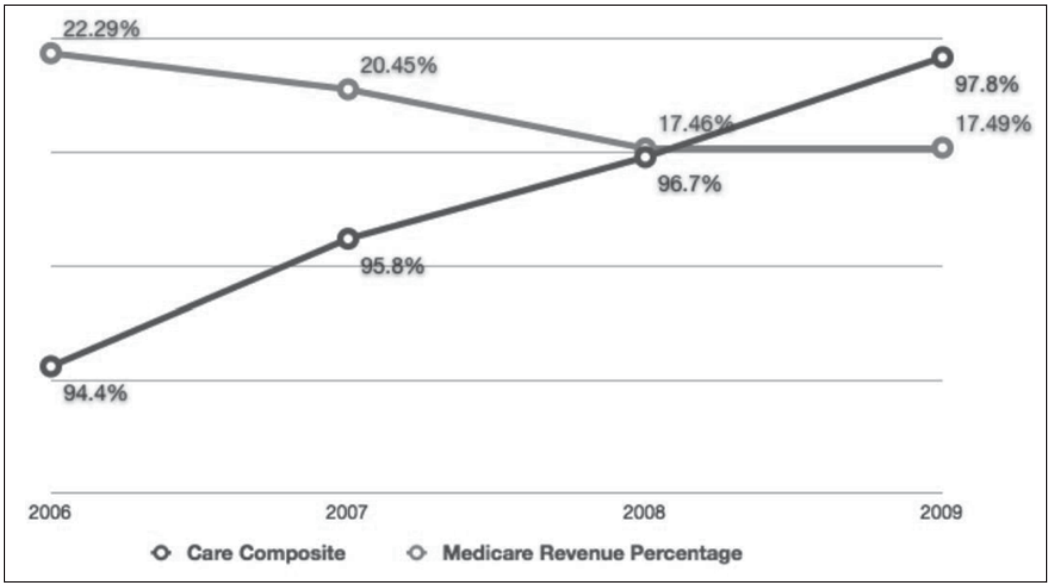
Average Medicare Revenue Per Day for Select DRGs (combined)*

2006	2007	2008	2009
$1,101.90	$1,138.49	$1,066.52	$1,170.16

*Years 2006 and 2007: DRG 127
Years 2008 and 2009: MS-DRGs 291, 292 and 293

Appendix A, Table 2

Joint Commission Heart Attack Care Measure Results Compared with Medicare Revenue for Angina Pectoris, 2006-2009



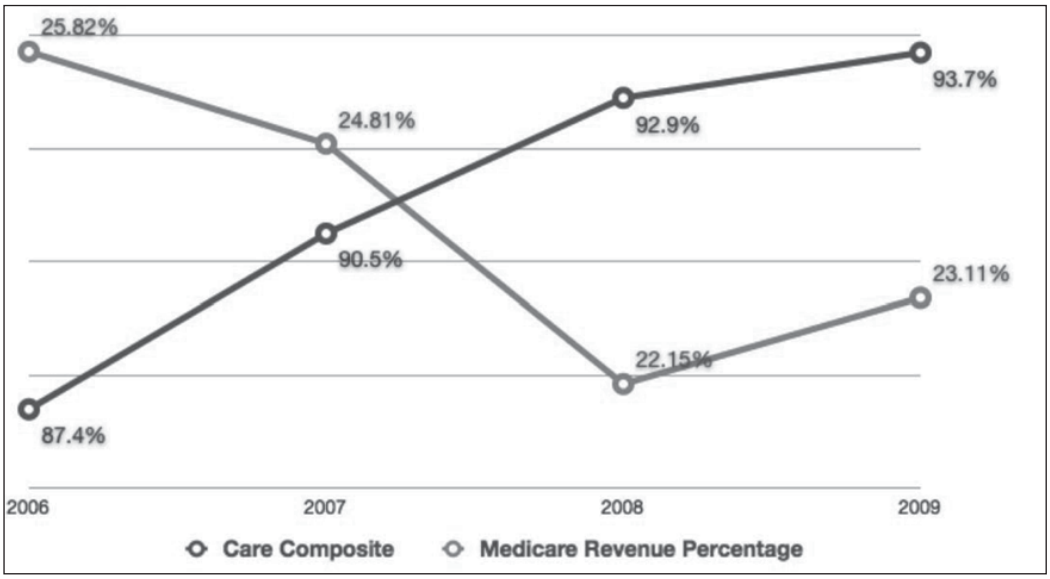
Average Medicare Revenue Per Day for Select DRGs (combined)*

2006	2007	2008	2009
$976.61	$997.35	$916.28	$933.87

*Years 2006 and 2007: DRG 140
Years 2008 and 2009: MS-DRGs 311

Appendix A, Table 3

Joint Commission Pneumonia Care Measure Results Compared with Medicare Revenue for Pneumonia and Pleurisy, 2006-2009



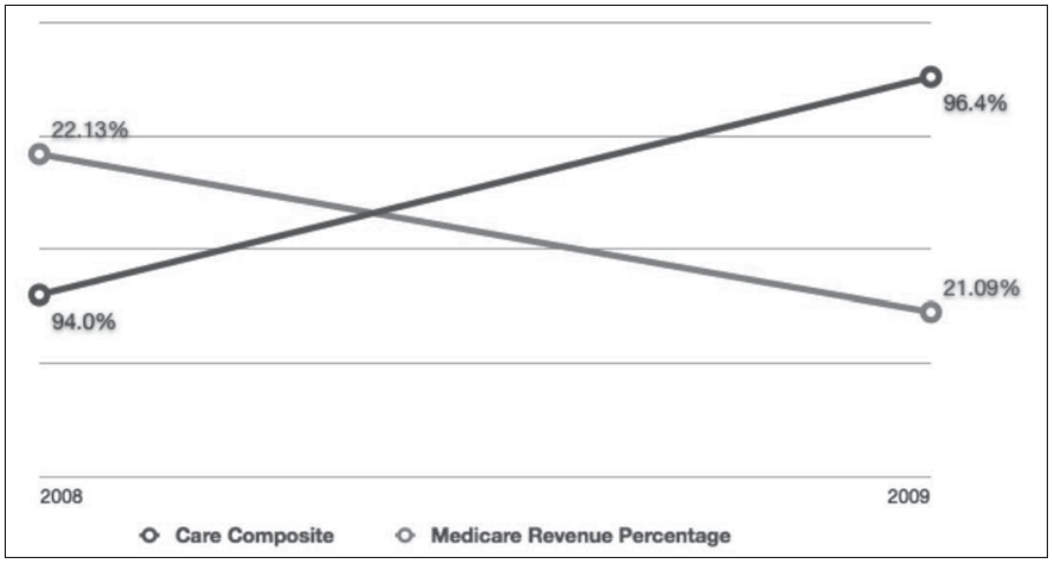
Average Medicare Revenue Per Day for Select DRGs (combined)*

2006	2007	2008	2009
$966.43	$1,001.54	$966.28	$1,068.81

*Years 2006 and 2007: DRG 89, 90 and 91
Years 2008 and 2009: MS-DRGs 193, 194 and 195

Appendix A, Table 4

Joint Commission Surgical Care Measure Results (Joint Replacement) Compared with Medicare Revenue for Joint Replacement, 2008-2009



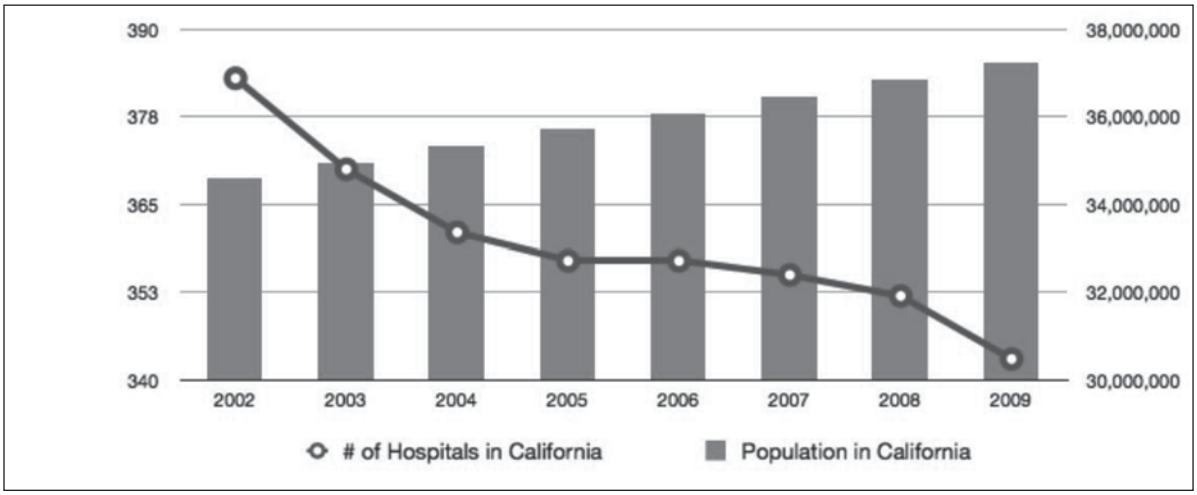
Average Medicare Revenue Per Day for Select DRGs (combined)*

2008	2009
$966.28	$1,068.81

*Years 2008 and 2009: MS-DRGs 469 and 470

Appendix B

Hospitals in California (2002 to 2009)



Year	No. of Hospitals in California	No. of Hospitals* in U.S.	California's % of Total Hospitals in U.S.	Change from 2002	Population in California**	% Increase in Population from 2002	Health Care Spending in California***	% Increase in Spending from 2002
2002	383	4927	7.8%	0	34,595,700	0	$41,100,000,000	0
2003	370	4895	7.6%	(13)	34,963,509	1.1%	$44,400,000,000	7%
2004	361	4919	7.3%	(22)	35,335,229	2.1%	$48,800,000,000	16%
2005	357	4936	7.2%	(32)	35,710,901	3.1%	$52,000,000,000	21%
2006	357	4927	7.2%	(26)	36,090,567	4.1%	$53,000,000,000	22%
2007	355	4897	7.2%	(28)	36,474,270	5.1%	$57,900,000,000	29%
2008	352	5010	7.0%	(31)	36,862,052	6.1%	$63,200,000,000	35%
2009	343	5008	6.8%	(40)	37,253,956	7.1%	$62,200,000,000	34%

*Number of community hospitals only, which represent 85% of all hospitals according to American Hospital Association data for each year. Federal hospitals, long-term care hospitals, psychiatric hospitals, and other similar institutions are not included.

**Numbers based on 2010 U.S. Census, 2000 U.S. Census, and estimates based on a comparison data from the years 2001 through 2009.

***U.S. Census Bureau's annual survey of state and local government finances.

The Health Law Section's Comments Regarding Executive Compensation and Administrative Expense Regulations

Editor's Note—On July 12, 2012, the Health Law Section sent the following comments to state agencies that issued proposed regulations limiting executive compensation and administrative expenses in agency procurements. James W. Lytle, of Manatt Phelps, who chairs the Section's Committee on Legislative Issues, was the principal author of the comments.

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July 12, 2012

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Albany, NY 12237

Re: Limits on Executive Compensation and Administrative Expense in Agency Procurements
I.D. No. HLT-22-12-00012-P

On behalf of the Health Law Section of the New York State Bar Association, these comments are being submitted in response to the regulations issued by the Department of Health to implement the provisions of Executive Order No. 38, which seeks to limit executive compensation and to reduce administrative expenses within entities that contract with the State of New York. The Health Law Section includes over 1250 health law practitioners from all across New York State, who devote all or a substantial portion of their practices to the representation of health care providers, consumers, and payors.

Our interest in the issues raised by these regulations is more than academic: we are the ones called upon to advise our clients as to how to comply with the myriad of federal and state regulatory requirements that pertain to health care and related entities. If these or amended regulations are formally promulgated, it is critically important that the rules be as clear, readily implementable and fair as possible and we hope that our comments will help ensure that outcome.

We appreciate the concerns that led to the implementation of these regulations. Even though detailed IRS requirements guide not-for-profit organizations in the establishment of reasonable levels of compensation, notable examples have been widely publicized of excessive compensation and other benefits bestowed by entities that rely on state support. And, even though many sources of funding received by entities contracting with the State already strictly limit the use of these funds for administrative purposes, particularly within the Medicaid program, we appreciate that examples have been cited of entities that devoted too much of their state funding to purposes other than program-related services.

We respectfully submit, however, that far more targeted and effective steps might be taken to address these isolated issues than the promulgation of regulations that potentially impact tens of thousands of entities that contract with one or more of thirteen state agencies. We believe that the proposed regulations will impose a much more substantial administrative and operational burden on entities that contract with the State than is acknowledged and will, at the same time, prove to be extraordinarily complicated and costly to administer by the state agencies charged with their enforcement—many of which, including the Depart-

ment of Health, are already facing significant challenges in meeting their regulatory responsibilities within their existing staff resources. The executive compensation regulations will, moreover, inevitably make it more difficult to recruit and retain the talented executive leadership required to lead the complex health care organizations of the 21st Century and will, as a result, potentially jeopardize the Administration's initiatives to reform the State's health care system, which rely principally on the capacity of entities that contract with the State to enhance the coordination and quality of health care services for New Yorkers.

After expanding upon some of these broader policy issues raised by the proposed regulations, our comments address our concerns with a number of the specific regulatory provisions. Citations in parentheses are to the applicable sections of the proposed Department of Health regulations to which the comments refer.

Disproportionate impact on Medicaid-funded providers: The regulations propose to exempt entities whose state funding or state authorized payments total less than thirty percent. (1002.2(d)(2)). While we can appreciate the wisdom of not subjecting every contracting entity to these burdensome regulations, the effect of this exemption is to place the brunt of the impact of these regulations on safety-net providers that provide a substantial amount of services to the most disadvantaged New Yorkers. As a result, those entities that provide care and services primarily or exclusively to Medicaid recipients may have such limited "non-state" funding that they could be effectively limited to a hard cap of $199,000 for executive compensation, subject only to whether a waiver may be granted for "compelling circumstances"—while entities that primarily provide health care services to more affluent New Yorkers would be largely free to ignore these regulations altogether. We fear that an unintended consequence of these regulations may be to discourage some health care providers—particularly those hovering around the thirty percent threshold—from providing care to Medicaid beneficiaries.

The need to recruit highly qualified and experienced leadership: The responsibility to administer modern health care organizations has become increasingly complex and challenging, particularly in the era of Medicaid Redesign and federal health care reform, which requires that health care entities recruit and retain experienced and talented executive teams. Entities that have been called upon to deliver or coordinate care for millions of Medicaid enrollees and oversee and manage the expenditure of billions of dollars of Medicaid funds need to be able to recruit and retain experienced health care executives—and must, as a result, be able to compete for that talent and pay what the market requires to recruit qualified health care executives. The quality of the fiscal and operational leadership of the health care executive teams is not just a concern for the governing boards of these health care organizations: given the daunting responsibilities now delegated by New York State to entities in the health care system, including those borne by health plans and Health Homes now responsible for the coordination and management of care of several million New Yorkers, the State of New York may have the greatest stake in the recruitment and retention of highly trained, experienced and competent executives of these organizations.

The uncertainty of the comparability analysis: Under certain circumstances, described below, the regulations will allow covered providers to pay in excess of $199,000 if the salaries are deemed "comparable" to similarly situated executives. Even if the compensation being paid to covered entities is actually comparable to similarly situated executives, there is no guarantee that the "compensation survey identified or recognized by the department and the director of the Division of the Budget" will accurately reflect the market for the specific health care executives in question. At a time when recruitment and retention of key executive leadership is particularly critical, the imposition of these new requirements leave health care organizations entirely unable to establish salary parameters, given the wide discretion that the State will exercise in its supervision of compensation and the potential that the State may rely on compensation data that is not as relevant to the position being filled.

Additional burdens on entities whose administrative reimbursement is already strictly limited: Notwithstanding the regulatory notice's assurance that the regulation "will require limited additional information to be reported," we do not believe that will be the case, as we note in our more detailed comments below. Not only will substantial information be necessary to try to demonstrate compliance with the executive compensation limitations, covered providers will be required to present information about their own administrative and program expenses—as well as those of related or affiliated entities—to comply with the cap on administrative expenses in a manner that is likely to be quite different than is currently required, simply because the definitions proposed to govern administrative and program expenses are not entirely consistent with other existing definitions for those categories of expenses. Virtually all Medicaid-funded health care providers already are subject to limitations on administrative expense, in any event, some of which are far less generous than the eventual fifteen percent cap on those expenditures contained in these regulations. As a result, the only impact of the administrative expense com-

ponent of the proposed regulations will be, ironically, to increase unreimbursed administrative expense, while at the same time placing additional and unnecessary burdens on state agencies that must administer these new requirements.

The absence of statutory authority for the regulations: We have serious doubts as to whether the Department of Health has the requisite legal authority to promulgate these unprecedented regulatory requirements. The purported statutory provisions from the Social Services and Public Health Laws cited in the Department of Health's regulatory notice for the promulgation of these regulations do not provide any explicit or even implicit authority to the Department to limit executive compensation or administrative expenses in the fashion proposed by the regulations. We also have significant doubts as to the authority of the Governor to promulgate an Executive Order, like Executive Order No. 38, in the absence of independent statutory or constitutional authority, see, e.g., *Rapp v. Carey,* 44 N.Y.2d 157 (1978), particularly where, as in this case, the Executive sought but did not obtain legislative enactment of the same compensation and administrative cost limitations.

Specific Comments on the Proposed Regulatory Provisions

Applicability of executive compensation and administrative expense regulations:

"Covered providers" are defined as those that receive at least $500,000 in state funding or state-authorized payments for two years and whose total state funding amounts to at least thirty percent of their total in-state revenues, which is calculated for entities with subsidiaries on a consolidated basis. (1002.2(d)). While any threshold is inherently arbitrary, as noted above, the impact of this threshold could discourage entities from providing care and services to indigent and disabled populations. In addition, the definition will most dramatically impact on those entities, including Health Homes, managed care organizations, Managed Long Term Care plans, behavioral health organizations, the proposed DISCOs for the developmentally disabled and similar entities, that have been given the responsibility for coordinating care for persons enrolled in Medicaid.

"State funds" include funds appropriated pursuant to the state budget, *but do not include* lowest price procurement contracts, capital expenses, awards to for-profit entities engaged in commercial/manufacturing activities, policy development and research. (1002.2(l)). Again, while we appreciate any efforts made to narrow the scope of regulations that we believe may be overly burdensome, these exemptions further underscore the arbitrary nature of regulations that are clearly targeted at the health and human services sector.

"State authorized payments" include payments that are not state funds but that are disbursed on a state agency's approval to entities licensed to operate programs. (1002.2(k)). While we believe the intention of this definition may have been, at least in part, to clarify that Medicaid payments are, in their entirety (including any local and federal share), subject to the regulation, the scope of the definition extends far beyond what we believe may have been intended. Specifically, the definition would include "funds that are not State funds…but which are distributed…to a provider having a State license in New York State to operate the program for which such payments are being made." (Id.) By that definition, virtually every dollar received by a provider of health care services in New York is covered, including Medicare payments, commercial insurance payments and payments made by individual patients—since a health care provider cannot bill for services unless it has the requisite state license. As a result, even health care providers that receive little if any Medicaid or other state funds would be fully subject to these requirements, including the hard cap on executive compensation—a result which we do not believe was actually intended.

The regulations also seek to extend themselves to "related entities." The regulations define a "related entity" (1002.2(i)) as an entity that: shares three or more officers, directors, trustees or employees with a covered provider; where the entity appoints twenty-five percent of the governing body or employees of the covered provider or vice versa; where the entity and the covered provider are subsidiaries owned or controlled by a common parent; where the entity has an interest in the capital or profits of the covered provider or vice versa; or where the executive compensation or financial affairs of the related entity are substantially controlled by the covered provider, or vice versa. The above definition is significantly different from the existing definition of a "related organization" set forth in the Department's regulations (*see, e.g.*, 10 NYCRR § 451.229 and § 86-1.10), which mirrors the federal Medicare definition of a "related organization." *See* 42 CFR § 413.17. Medicare also requires providers to disclose on cost reports all related organizations. Provider Reimbursement Manual -2 §140.

We see no reason why the agency would propose an entirely new definition when a well-established definition already exists in the Department's own regulations with which providers are familiar and which is easy for the government to track since this information is already reported on many cost reports. Even absent this inconsistency, in an increasingly complex health care environment, identifying what entities might fall within this broad definition may prove to be very challenging.

In addition, the definition of "related entity" should be revised to make clear that a related entity that does **not** receive any State funds or state authorized payments is **not** covered by the regulation. This is consistent with section 1002.4(e). However, the clarification is important because section 1002.4(b) simply references related entities rather than related entities that receive State funds. There are "covered providers" that have numerous affiliates, none of whom receive State funds. This change is necessary so that these affiliates are not inadvertently swept into the regulation even though they receive no State funds or State-authorized payments. There is no legal or policy justification to require these entities—with which the State may not have any direct contractual, financial or regulatory connection—to comply with these regulations.

Finally, the definition of "covered executive," as drafted, sweeps in hundreds of employees at certain related entities even if none or only a small part of the compensation of executives within those related entities is actually derived from New York funds or State-authorized payments. Executives at a related entity should only be considered "covered executives" if (i) the related entity receives State funds or State-authorized payments from a covered provider pursuant to a contract with the covered provider and (ii) more than 50% of the related entity executive's salary is derived from the state money.

Executive compensation cap:

To begin with, establishing a baseline cap of $199,000 for executive compensation (1002.4(a))—even acknowledging the potential exceptions and waivers that may prove to be available—is simply unrealistic, given the current market for highly trained and experienced health care executive leadership, particularly in the New York City Metropolitan Region. A $199,000 salary cap, apparently premised on federal civil service pay schedules, cannot reflect the wide variety of executive responsibilities and positions that will be subject to it. While we have serious reservations about setting any arbitrary cap, were one to be established, it should be set at in line with current market realities. One significant result of an unrealistically low threshold for executive compensation will be to overburden the Department, which will have to review very many executive salaries that are above the capped amount, either to determine whether the salary satisfies its "comparability" analysis or to consider whether a waiver should be granted.

The regulations define "executive compensation" to include all forms of cash and noncash benefits, including salary and wages, bonuses, dividends, and other financial benefits, such as vehicles, meals, housing, "personal and family educational benefits," below market loans, travel, and entertainment. (1002.2(e)). The breadth of the definition makes the $199,000 cap even more unrealistic, particularly for positions within those parts of the State with the highest cost of living. In addition, while it excludes mandated benefits (Social Security, Worker's Compensation, unemployment and disability insurance), health insurance and pension contributions are only excluded if the benefits are deemed to be "consistent with those provided to a covered provider's non-covered executive employees"(1002.2(e)—raising a whole additional set of complicated issues for covered providers and state agencies to dispute. A host of other issues are also likely to arise: for example, would the reimbursement of continuing education expenses incurred by an executive be included as a "personal and family education benefit" within the calculation of executive compensation, even if that continuing education was required by the State or other licensing/accrediting organizations?

As noted, the regulation also applies to executives employed by "related entities" (as defined above) that provide administrative or program services to covered providers, even if those entities do not directly receive state support—and presumably even if the executives in those related entities only devote some of their time to the management of the covered provider. Even more problematic, the regulation would seek to extend the compensation cap to "subcontractors and agents of covered providers," at least when they are also "related entities." It is not clear why any reference is necessary or appropriate to "subcontractors and agents" since related entities are already subject to the regulations. We would suggest that, as long as the related entity definition is clarified and narrowed, that the references to subcontractors and agents should be deleted.

Further, while some effort is made to exclude compensation paid to covered executives for program services rendered by executives that are outside of their "managerial or policy-making duties" (1002.4(c)), this commendable exclusion only again adds to the complexity of applying and enforcing these regulations to an enormously varied set of organizations that may employ their executives in a wide variety of ways—particularly in smaller health and human services organizations where the distinction between administrative and program responsibilities may be particularly hard to discern.

The cap strictly limits covered providers and related entities from using State funds or state-authorized payments (referred to below as "state funding") to pay executives in excess of $199,000 (1002.4(a)): in effect, if an entity receives exclusively state funding, the regulations impose a hard cap of $199,000, subject only to a highly discretionary waiver, which is only granted under "compelling circumstances." In discussions prior to the issuance of the regulations, Executive Chamber staff contemplated a substantially higher "hard cap" on executive compensation might be imposed on entities that substantially relied upon state funding and we would recommend that a substantially higher amount be reconsidered.

Even more problematic is the extension of the executive compensation regulation to funds that are neither state funds nor state-authorized payments. The regulation proposes to regulate compensation received by executives at covered providers and at related or subcontracting entities that may be derived in whole or in part from funds that have absolutely no New York State connection and that are paid out of "not only State funds and State-authorized payments but also any other sources of funding." (1002.4(b)). We believe that seeking to regulate the use of non-state funds, including potentially charitable contributions to the entity, in this fashion is beyond the Department of Health's or any other state agency's legal authority.

The regulations purports to prohibit even non-state-funded executive compensation received by covered providers in excess of $199,000 if:

- the compensation is greater than the 75th percentile of comparable executives at comparable providers in comparable geographic areas, as established by a compensation survey recognized by the applicable state agency and the Division of the Budget; or
- it was not reviewed and approved by the covered provider's board (including at least two independent directors); or if such review did not assess appropriate comparability data.

(1002.4(b))

The use of a 75th percentile test for gauging the compensation of employees is highly problematic and should be reconsidered. First, by definition, one-quarter of executives within the comparable geographic and program arena are automatically deemed to be excessively compensated, without any real evidence that these compensation levels are actually "excessive" by some objective standard. If the comparable executives are appropriately defined, the effect of the percentile test will be, over time, to ratchet down compensation, as at least some number (i.e., those without waivers) of the top quartile of executives face compensation reductions—which automatically results in a lower 75th percentile threshold in each subsequent year. While the use of any percentile-driven approach is inherently arbitrary, a far higher percentile should be utilized if the goal is to target the true "outliers."

Likewise, the use of a "compensation survey recognized by the applicable state agency and the Division of the Budget" provides little comfort to entities that will have to rely upon the accuracy and applicability of an unspecified salary survey, which may or may not accurately reflect the nature of the organization or the specifics of the executive position. Many non-profit health care entities utilize highly specific salary information, often prepared by consultants that devote their attention exclusively to only specialized components of the health care industry, which inform their compensation determinations. Covered providers should, at least in the first instance, be permitted to submit the salary information on which they relied to make their compensation determinations—which the enforcement/regulatory body could choose to reject if it appeared not to be a reasonable basis for setting compensation.

While the second of the above requirements—relating to board oversight of the compensation process—mirrors already existing IRS guidelines for tax-exempt organizations, it substantially broadens the existing IRS requirements to apply to *any* executive who receives more than $199,000, rather than just to the most highly compensated executive team members within the organization. For some organizations, the governing body's role in evaluating compensation will extend to many more employees than are currently subject to the board review,

thereby potentially lessening the quality or intensity of the compensation review process for the most highly compensated employees.

From a practical perspective, the challenge of complying with these requirements is best illustrated by how these rules will actually impact upon the recruitment of executive leadership. Assume, for example, that a covered provider is creating a new executive position—perhaps one devoted to the emerging challenges of compliance or quality assurance or health information technology—for which the salary ranges that might be deemed to be acceptable to state agencies cannot possibly be known in advance. How can a covered provider successfully recruit highly qualified individuals to perform these key executive functions without knowing, in advance, if the proposed salary might be deemed excessive by the State of New York?

The potential of receiving a waiver from these requirements provides little cause for comfort. The regulations permit the applicable state agency and the Division of Budget to grant a waiver for good cause from the compensation limits where the provider has "demonstrated compelling circumstances" to justify the waiver and provided adequate documentation to support it. (1002,5(a)(3)). While some of the factors are specified—including comparability data from other comparable providers, whether the provider could provide the same quality and availability of services without exceeding the compensation limit, the nature, size and complexity of the provider and whether an appropriate process was followed in making the compensation decision—the regulations allow the agencies to consider any other factors "deemed relevant" by the enforcement agencies. (1002.5(a)(2)). While reconsideration of a waiver denial may be requested, "any vouchers submitted by the applicant for payment" shall be deemed incomplete while the reconsideration is under way (1002.5(c)—which would appear to place in jeopardy all funds being received by the covered provider and not just those that relate to the challenged executive compensation. The regulations further specify that the decision by the state agency and the Division of the Budget on the reconsideration shall be final—albeit presumably then subject to an Article 78 proceeding based on "abuse of discretion" or other similarly limited grounds. (1002.5(c)(4)).

In addition, covered providers will have a difficult time complying with the waiver request time frames, particularly when hiring new executives. The waiver application must be submitted 60 days prior to the reporting period or "at least 60 days prior to the date of the contract or its renewal or extension, whichever is sooner." (1002.5(a)(1)) Does this mean that covered entities will have to defer hiring someone for at least 60 days or run the risk that the waiver is denied and the salary offer cannot be honored? Waivers are, moreover, time-limited, subject to revocation "in the discretion of the department" and automatically revoked if the executive's compensation increases by more than five percent—leaving no "waivered" executive with any confidence that the terms of his or her compensation will be remotely assured or predictable. Once granted, there should be some comfort that the waiver provides more sustained protection for the affected individual. Provisions should also be included to maintain the confidentiality of the waiver request and any action taken on the request by the State, consistent with already existing protections contained within the State's Personal Privacy Protection Law (Article 6-A of the Public Officers Law).

Finally, for entities that receive funding from more than one State agency, the regulations do not clarify whether the entity must seek waivers from each of those State agencies—and risk inconsistent results—or whether the entity may seek a waiver from one of its funding State agencies and know that the waiver, if granted, will be honored by the others. Provisions should be included to address this issue.

The waiver process, in sum, places the covered provider in the position of having to request permission—on a continuing basis—from its regulatory agency for its compensation decisions and grants substantial discretion to the regulatory agency to grant or withhold that permission based on specified and unspecified factors. The potential that this discretion could be abused by the regulatory agency is substantial: the prospect that a regulatory agency might even use this authority inappropriately to punish or reward covered providers cannot be entirely ruled out.

Limits on Administrative Expenses:

The definition of "administrative expenses" includes "legal services not directly attributable to program services." (1002.2(a)(1)(ii). While it may seem like special pleading for the Health Law Section to raise this issue, it will be extremely difficult for a health care provider to determine which legal services are "directly attributable" to program services and which are more properly considered "administrative." In addition, telephones, computers, dues, licenses, permits, insurance premiums and audit services are all included within administrative expens-

es—some of which involve expenditures that clearly have a direct impact on program. In the current health care environment, for example, reliance on state of the art information technology has become an essential component of the delivery of high quality health care services and those related expenses should certainly be considered within program services. On the other hand, we should note that the inclusion of direct program supervisors and quality assurance staff within "program services" was a welcome inclusion. (1002.2(h)(1)(ii)).

Overall, the definitions of "covered operating expenses," "administrative expenses," and "program services expenses" are not unreasonable attempts to define these broad cost and expense categories (subject to the concerns noted above)—but they are not necessarily consistent with the Medicaid and Medicare cost reporting requirements for various categories of health care entities. As a result, at a minimum, the new definitions contained within the regulations will inevitably impose substantially greater reporting and compliance costs on covered providers than the regulatory notice contemplates.

The regulations also contemplate that the administrative expense cap applies to subcontractors and agents of covered providers that are related to the provider, as noted above. (1002.3(h)). In some instances, all of the tasks performed by the subcontractor may be administrative in nature: it is not altogether clear how the limitations on administrative expense would apply to a subcontractor that is solely responsible for administrative services. While the regulations address how covered providers will be required to aggregate state funds from multiple programs or funding streams in the calculation of the administrative service cap (1002.3(d)), the complications created by multiple programs and multiple funding streams, each with their own definitions of administrative and program expenses, cannot be overstated, particularly for smaller covered providers.

The regulations also note that. if a more stringent limitation on administrative expenses exists, that standard applies. (1002.3(e)). This provision implicitly acknowledges that many screens, caps or other limitations on administrative expense have long existed in many Medicaid or other state-funded programs—some of which are far more stringent than these regulations. The widespread existence of these already existing limitations on administrative expense reimbursement seriously calls into question why this new regulation is necessary.

As with the executive compensation limitations, a waiver process exists by which the applicable state agency and the Division of the Budget may waive the application of the administrative expense cap for good cause and where there are "compelling circumstances" that warrant the waiver. (1002.5(b)(3)). As with the compensation cap, the amount of discretion accorded to the Department and the Division is potentially subject to abuse. Waivers must be sought sixty days prior to the commencement of the contract or within thirty days of any "unusual and unforeseen circumstance" that justifies the waiver (1002.5(b)(1))—time frames that may not be reasonable or realistic for covered providers that may be unable even to ascertain whether they even need a waiver before the cost reporting period has concluded.

As with executive compensation waiver requests, the provider is entitled to written notice if the waiver is being denied and may, within thirty days, request reconsideration—during which time, "any vouchers submitted by the applicant for payment" shall be deemed incomplete (1002.5(c)(2)), an exceedingly harsh penalty to be imposed even before the waiver reconsideration has been concluded. As with the other waivers, the decision by the state agency and the Division of the Budget on the reconsideration will be final—and no administrative hearing or other due process protections are accorded to the covered provider.

Reporting Requirements:

The regulations provide that the relevant state agencies will specify disclosure forms to be completed by contracting entities for each reporting period and contractors will be required to submit those reports or risk that their contracts or agreements will be terminated or not renewed. (1002.6(c)). While the regulatory notice issued by the Department assures covered providers that only "limited additional information" will have to be reported, much of the necessary information, as noted above, is not already reported in a format that would provide the Department with the information it needs to enforce these regulations. Although the regulatory notice further stipulates that the costs of complying with the rule will be "minimal, as most, if not all, of the information that must be reported by such providers is already gathered or reported for other purposes" (1002.6(c)), both the premise and conclusion of that statement are without any factual basis. We have every reason to believe that the reporting obligations will themselves impose a very substantial burden on covered providers, precisely because they are not entirely consistent with existing reporting obligations, and will thereby only succeed in increasing administrative costs.

Penalties/Enforcement:

We are, finally, concerned over the lack of due process accorded to a covered provider who is alleged to be in violation of these requirements. The waiver process, described above, does not provide the covered provider with sufficient opportunities to contest the waiver denial and, even when more definitive action is taken by the Department, the covered provider is not accorded even minimal due process rights.

If the State agency believes that a provider is not in compliance with these requirements, notice would be given to the provider, which would be given only fifteen days to demonstrate its compliance with the requirements. Once the notice of non-compliance becomes final, the provider would be given the opportunity to submit a corrective action plan, again in only 15 days, which the state agency would have thirty days to approve or request clarification or alteration. Once approved, the corrective action plan would have to be implemented within a six month period. (1002.7(a) and (b)). If the provider is not in compliance and/or has not implemented the corrective action plan, the relevant state agency will provide notice to the provider of the non-compliance and may take one of the following actions:

- Permit some modification of the corrective action plan or provide more time for implementation; or
- Issue a final determination of non-compliance and impose appropriate sanctions, which may include:
  - Redirection of state funds to provide program services;
  - Suspension, modification, limitation or revocation of the provider's license;
  - Suspension, modification or termination of contracts or agreements with the non-compliant provider; and, tellingly,
  - *Any other lawful actions or penalties that may be deemed appropriate* (emphasis added).

(1002.7(d)(2)(d)).

Although the covered provider would have, within ten days of a final notice of non-compliance and notice of proposed sanctions, the opportunity to request an administrative appeal, the covered provider would have only ten days to generate a detailed explanation of the factual and legal basis for the provider's challenge. The covered provider would not, even more importantly, have the right to an administrative hearing, but would only be entitled to an administrative review of the written materials that are part of the record. (1002.7(e)).

The lack of sufficient time accorded to a provider to challenge the agency's determinations and to take other steps to protect its rights subjects especially the least sophisticated and resourced providers to the whims of state agency action. The absence of the right to a formal hearing deprives providers of an important right to be heard and to confront the evidence against them: although the regulations contemplate that a right to a hearing might, at least in some circumstances, independently exist (e.g., if the State seeks to revoke the provider's license), the failure to provide a covered provider with a formal administrative process to challenge what could prove to be very severe adverse determinations may render the regulations constitutionally infirm.

We appreciate the opportunity to comment on these regulations and would be happy to provide additional information relating to these comments if that would prove helpful to your consideration. If any significant changes are made to the proposed regulations, we would strongly urge the Department to republish the revised regulations and initiate another comment period to ensure that there is a full opportunity to comment upon this potentially significant regulatory proposal.

New York State Bar Association
Health Law Section

Upcoming Events

- *Fall Section Meeting: Health Care Reform*. The Section's Fall Meeting will be held on October 26 at the Bar Center in Albany, with a program on Health Care Reform. The speakers will include:
  - Jason Helgerson, Deputy Commissioner, Office of Health Insurance Programs and New York State Medicaid Director;
  - Assemblyman Richard Gottfried, Chair of the NY State Assembly Health Committee;
  - Lisa Sbrana, Counsel to the New York Health Benefit Exchange;
  - Jeremy Creelan, Special Counsel Public Integrity & Ethics Reform for the N.Y. Governor's Office;
  - Harold Iselin, Greenberg Traurig;
  - James Lytle, Manatt Phelps;
  - Elisabeth Benjamin, Chair, Health Care for All New York.
- "*HITECH for Lawyers*." This program on the Health Information Technology for Economic and Clinical Health (HITECH) Act is scheduled for Dec. 7. Program Chair: Raul A. Tabora, Jr. of Ruffo Tabora Mainello & McKay, P.C., Albany

Recent Events

- "The Sunshine Act and the Final Rule on Conflicts of Interest in Research: Issues, Implementation and Compliance Implications." The program, held in NYC on April 4, was chaired by Tracy E. Miller of Cadwalader, Wickersham & Taft.
- "Key Issues for Health Care Providers: In-House Counsels' Perspective," held in NYC on June 11, was co-chaired by Reginald Bullock, Senior Associate General Counsel, North Shore-Long Island Jewish Health System and Jule Switzer, General Counsel Westchester Medical Center .
- "Health Information Exchanges & Electronic Health Record Systems." On September 20, at the Bar Center in Albany, the Section held a conference on Health Information Exchanges & Electronic Health Records. Speakers from government and private practice addressed, among other topics, regional health information organizations, cloud-based electronic Health records systems, vendor legal issues; health information technology assessments in the CON process.

Recent Supraspintaus Topics

(See http://nysbar.com/blogs/healthlaw)

- Medical debt load busting budgets - Times Union
- New Medicaid Inspector General Supports Less 'Adversarial' Audits - NYTimes.com
- Times Examines Effect of Peninsula's Closure
- Study: Untrained Medical Interpreters Cause More "Clinically Significant" Errors
- "I-STOP" Legislation passes both houses
- KHN/USA Today: GNYHA Members May Ask for Medicare Money Back if Mandate is Eliminated from ACA
- Doctors May Prescribe Apps to Patients for Disease Management
- DOH's "Get-Tough Approach" to Medicaid Managed Care Plans
- More than $2 Million Awarded to New York State Health Care Providers to Address Doctor Shortages

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

Section Committees and Chairs

The Health Law Section encourages members to participate in its programs and to volunteer to serve on the Committees listed below. Please contact the Section Officers (listed on page 100) or Committee Chairs for further information about these Committees.

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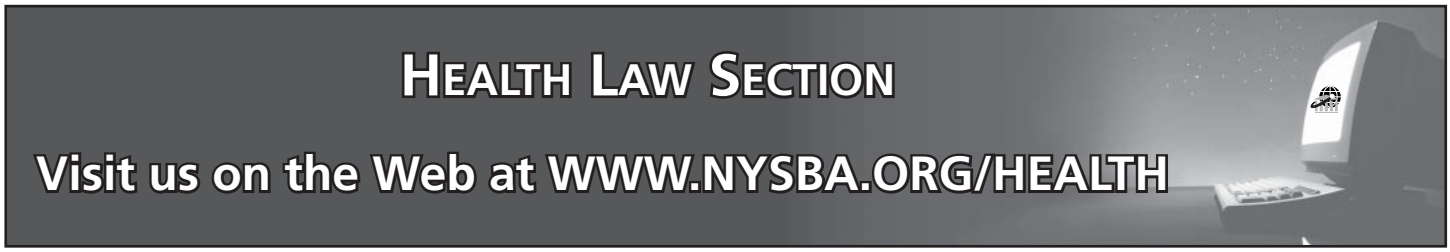

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