NYSBA SUMMER/FALL 2004 | VOL. 9 | NO. 3

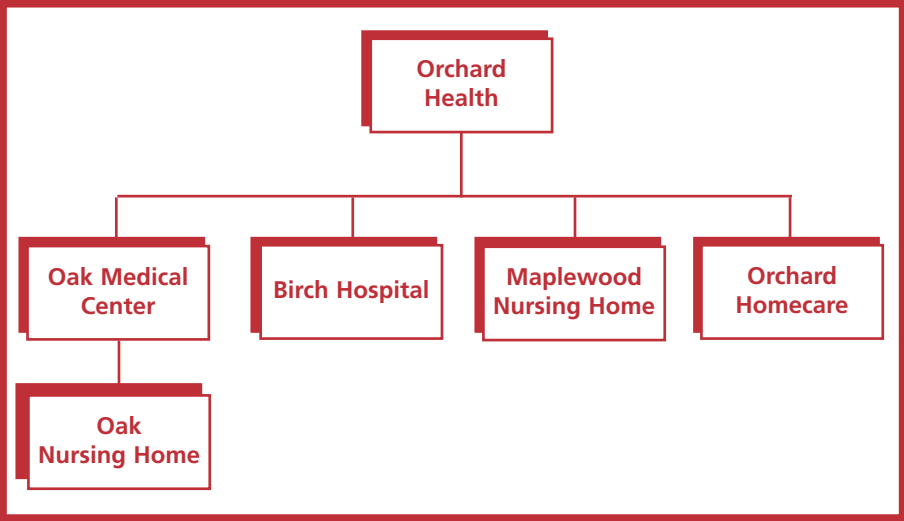
Health Law Journal

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

Published in cooperation with Albany Law School

Health Care Systems in N.Y.—Their Unique Legal Issues

Inside



NYSBA

HEALTH LAW JOURNAL

SUMMER/FALL 2004

Vol. 9, No. 3

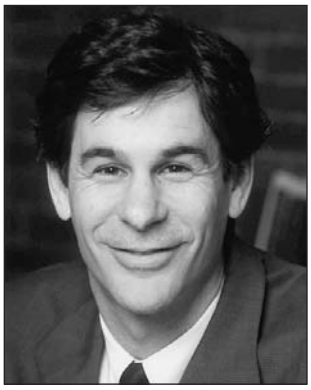
THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

in cooperation with

ALBANY LAW SCHOOL

A Message from the Section Chair

"Ask not what your Health Law Section can do for you,
but what you can do for your Health Law Section."



Okay! Okay! It is a tired cliché, but I nevertheless believe that it's an apt question as the Section plans its agenda for the upcoming year. Though the Section has some extraordinary activities coming down the pike, including a skills-based CLE on health care transactions, a "chat" with Assistant U.S. Attorneys on evolving fraud and abuse issues, programs on not-for-profit governance and the next generation of compliance, additional special (along with regular) editions of the *Health Law Journal*, an updated *Legal Manual for Physicians*, a revamped website, public service education, the second annual Barry Gold Memorial Student Writing Competition, legislative reports as well as a slate of other ideas that we hope to implement, there is room under our tent for more. Whether you want to share a concept for a program, speak at a CLE program, submit an article to the *Journal*, review proposed legislation, edify the public on its legal rights or assist with the website, step forward. You can contact me at rosenbergp@wemed.com or call me at (518) 449-8893.

Indeed, I invite you to join our growing circle of Section members who actively contribute their time and extraordinary talent to Section activities. Why do those members volunteer their time—and why do I urge you to contribute your time—when time is an ever-too-scarce commodity in our profession? Here are three reasons. First, by merely kibitzing with your colleagues in the Health Law Section, you will gain substantive knowledge in the health law area. Whether it is a casual conversation regarding the CON process, recounting a war story on a provider audit or obtaining a reality check as you negotiate a managed care contract, collaborating with Section members will provide you with insight and context for a range of issues that you may confront.

Second, from a practice development standpoint, the Section offers you a venue to strut your stuff. You can increase your visibility, and even become a recognized expert, by sharing your knowledge and experience at any number of Section forums. It's a classic case of helping yourself as you help others.

Third, less quantifiable but perhaps most enriching, the Health Law Section is a community of colleagues who will welcome you and your contribution, in whatever form that may be. Speaking from first-hand experience, you tap into our community, you will undoubtedly network with, and even befriend, many of your colleagues, and integrate a greater human touch into your professional work.

Frankly, I believe that the more you participate in, the more you will benefit from, the Health Law Section. However, regardless of the level of your participation, you should know that the Section hopes to be a resource for you. In the past year, as in prior years, there have been dizzying developments in virtually all aspects of health law, including those relating to physician self-referrals, Medicare coverage, tax exemption, medical staff credentialing, corporate governance, human subject research, antitrust enforcement, mental health, employment, and ERISA preemption. No doubt, in light of the looming government budget deficits, aging population, growing number of uninsureds, technological and medical advancements, industry consolidations and global economic interdependency, the pace of legislative, regulatory and case law changes is unlikely to abate. The Section is intent on following, reporting and imparting as much information as possible to its members and others.

In fact, this special edition of the *Health Law Journal* is one example of how the Section promotes its mission. This edition addresses the unique myriad of legal concerns relating to health care systems in New York. It will serve as valuable reference material for many of us in the months and years to come. A special thanks to all of the contributing authors as well as Robert Swidler and Professor Dale Moore, the co-editors of the *Journal*.

While the Health Law Section is one of the youngest sections of the New York State Bar Association, it has a record of accomplishments second to none. I am privileged to serve as your Chair and to have the opportunity to help build upon its record. I am also deeply appreciative of the Section's officers, the Executive Committee, the Bar Association staff and other dedicated Section members who are committed to supporting the Section this year, and to Jim Lytle, our immediate past Chair, and our other past chairs who have helped propel the Section upward.

If you have any questions or comments about the Section or want to become more involved in the Section, please contact me. Otherwise, I hope to see many of you at some point as the year unfolds.

Regards,
Philip Rosenberg

In the New York State Courts

By Leonard M. Rosenberg

Court of Appeals Upholds Kendra's Law as Constitutional

In re K.L., 1 N.Y.3d 362 (2004). In response to the death of Kendra Webdale, a woman pushed in front of a moving subway train by a man diagnosed with paranoid schizophrenia in January 1999, the New York State Legislature enacted section 9.60 of the Mental Hygiene Law. The purpose of section 9.60, or "Kendra's Law," is to provide a program of assisted outpatient treatment ("AOT") to psychiatric patients unlikely to survive safely in the community without supervision.

However, shortly after Kendra's Law was enacted, its constitutionality was challenged. In October 2000, a petition was filed seeking a court order authorizing AOT for K.L., a man diagnosed with a mental disorder and history of psychiatric hospitalizations and non-compliance with prescribed medications. The AOT plan included a regimen of outpatient care, case management, therapy and medication. However, K.L. challenged the constitutionality of Kendra's Law on several grounds, all of which were rejected by the Supreme Court and the Appellate Division. The New York State Court of Appeals has now affirmed the constitutionality of Kendra's Law.

K.L. contended that Kendra's Law violated his right to due process because a patient may be ordered to comply with an assisted outpatient treatment program without a finding that the patient is incapacitated. By analogy, K.L. argued that because a finding of incapacity is required to forcibly medicate an involuntarily committed patient, there must also be a finding of incapacity before the court may order assisted outpatient treatment for a patient. The Court of Appeals disagreed. Because Kendra's Law does not permit forced medical treatment, it held that there is no

requirement of incapacity. Significantly, the Court noted that if a finding of incapacity were required, a large number of patients would become ineligible for a program that would allow them to remain safely in the community, many of whom might otherwise require involuntary hospitalization. Additionally, the Court held that the patient's right to refuse treatment is outweighed by the state's police powers to protect the community from dangerous tendencies of the mentally ill, and its *parens patriae* powers to provide care to its citizens who are unable to care for themselves because of mental illness.

The Court also held that an AOT order does not violate a patient's right to due process because it places minimal restrictions on a patient's freedom—as a violation of an AOT order, standing alone, carries no sanction. Essentially, a violation of an AOT order triggers heightened scrutiny by the treating physician to determine whether there is a need for involuntary hospitalization. Accordingly, the Court held that the right to due process is satisfied so long as there is clear and convincing evidence that the patient is in need of assisted outpatient treatment to prevent a relapse or deterioration that is likely to result in serious harm to himself or others, and that such treatment is the least restrictive alternative.

K.L. also challenged Kendra's Law on the ground that it violates an outpatient's procedural due process rights because a non-complying assisted outpatient could be retained in a hospital for up to 72 hours to permit a physician to evaluate the need for involuntary hospital care and treatment. While the Court found that an involuntary 72-hour detention constitutes a substantial deprivation of liberty, it nevertheless concluded that the liberty interest is outweighed by the state's interest in removing from the streets non-compliant patients previously found to be at risk of causing harm to themselves or others as a result of their non-compliance. The Court also found that a pre-removal hearing would reduce the speed with which the patient could be evaluated and treated, and that the Court is not better situated than a physician to determine whether there is a need to remove the patient for a 72-hour period to evaluate the need for involuntary commitment. Further, absent removal, there is no mechanism to force a non-compliant patient to attend a judicial hearing in the first instance.

The Court also rejected K.L.'s claim that Kendra's Law violates the constitutional prohibition against unreasonable searches and seizures because the statute does not specify that a physician must have probable cause or reasonable grounds before seeking to retain a non-compliant assisted outpatient for 72 hours. The Court held that the statute indeed contemplates that any determination to remove an outpatient for 72 hours will be based on a reasonable belief that the patient is in need of such care.

In Split Decision, Court of Appeals Dismisses, for Lack of Standing, Nurses' Challenge to Department of Health Anesthesia Administration Guidelines

New York State Association of Nurse Anesthetists v. Novello, 2 N.Y.3d 207, 778 N.Y.S.2d 123 (March 30, 2004). A 6-1 majority of the New York Court of Appeals reversed two

lower courts and dismissed a challenge to Department of Health guidelines related to the administration of anesthesia in private offices. Ruling that the plaintiff, a not-for profit corporation representing over 750 certified registered nurse anesthetists ("CRNA"), had not demonstrated any injury in-fact from the issuance of the guidelines, the Court dismissed the complaint on standing grounds. In a detailed dissent, Judge Smith objected to the majority's conclusion and expressed concern over the future of the standing doctrine.

In December 2000, the Department of Health's Committee on Quality Assurance in Office-Based Surgery issued guidelines containing specifications regarding anesthesia administered in private offices ("Guidelines"). The Guidelines suggested that CRNAs administering anesthesia to patients in doctors' offices be supervised by a physician qualified to perform and supervise the administration of the anesthesia. The Guidelines further recommended that the physician perform a preanesthetic examination and remain physically present during the surgery.

Shortly before the issuance of the Guidelines, plaintiff ("CRNA Association") initiated an action seeking a declaration that the Guidelines—governing office procedures—were null and void because, under the Public Health Law, the Department of Health can regulate surgery only in a hospital setting. Plaintiff expressed concern that the Guidelines would reduce CRNA employment opportunities by effectively requiring physicians to hire an anesthesiologist. As many physicians are not qualified to administer anesthesia, and because the Guidelines no longer favored CRNAs administering anesthesia without qualified supervision, plaintiff feared that physicians would find it cost-prohibitive to hire both an anesthesiologist and a CRNA.

The Department of Health moved to dismiss the action on ripeness and standing grounds. The Supreme Court assumed standing, denied the Department's motion to dismiss, and granted summary judgment in favor of the CRNA Association, invalidating the Guidelines. The Appellate Division affirmed the trial court by finding that the plaintiff had standing to sue, and holding that the Guidelines were beyond the Department of Health's purview.

The Court of Appeals reversed the ruling of the Appellate Division after an analysis of the test for determining standing when governmental action is challenged. To have standing in such a case, a plaintiff must demonstrate injury in-fact (i.e., actual harm) and show that such injury falls within the zone of interests covered by the challenged provision. The majority based its ruling on the first prong of the standing test, injury in-fact. Chief Judge Kaye, writing for the majority, held that plaintiff's showing of injury was "founded on two layers of speculation"—that the Guidelines would be enforced as rigorously as regulations, and that such enforcement would harm CRNAs. The majority found this argument to be too uncertain, and held that the injury in-fact test had not been satisfied. Thus, the complaint was dismissed and the Appellate Division reversed.

Judge Smith's dissent reviewed the trial court record extensively and reasoned that plaintiffs had shown sufficient injury in-fact to satisfy the first prong of the standing test. Quoting from the complaint, various affidavits submitted by Plaintiff, the Guidelines, and even an e-mail sent during the drafting of the Guidelines, Judge Smith argued that the CRNA Association had made a "powerful factual showing of injury." One affidavit submitted by plaintiff was from an eye surgeon who stated that he would eliminate all CRNA positions from his office because the Guidelines compelled him to hire anesthesiologists. Judge Smith found evidence in the record that many physicians are not, or do not feel, qualified to supervise or administer anesthesia (despite being permitted by law to do so). The natural result, he reasoned, was that physicians would be forced to hire anesthesiologists to perform those services that the Guidelines no longer allowed CRNAs to perform alone.

Judge Smith described the Department's response to such evidence as "virtual silence," and questioned the majority's lack of analysis of the extensive record supporting plaintiff's showing of injury in-fact. The dissent expressed concern over the future of the standing doctrine itself: "I find decisions like the present one . . . to be troubling because they render the law of standing unpredictable." Noting that standing was a complicated subject "at best," Judge Smith concluded with the warning that "there is always the danger that [standing] will become a black box, from which a judicial conjurer can extract the desired result at will."

Constitutional Challenge to Insurance Law Amendment Permitting Conversion of Empire Blue Cross to For-Profit Status Survives Motion to Dismiss

Consumers Union of U.S., Inc. v. State of New York, 7 A.D.3d 416, 777 N.Y.S.2d 444 (1st Dep't, May 20, 2004). Various organizational and individual plaintiffs challenged the validity of a 2002 amendment to Insurance Law § 4301(j) that permitted Empire Blue Cross and Blue Shield ("Empire") to convert from a non-profit charitable corporation to a for-profit provider of health services. The trial court granted Empire's motion to dismiss the complaint of four plaintiffs—Multiple Sclerosis Society, Housing Works, Disabled in Action of Metropolitan New York, and New York Statewide Senior Action Council ("Standing Plaintiffs")—for lack of standing. The trial court also granted Empire's motion

to dismiss the complaint as to the remaining plaintiffs for failure to state a claim, with leave to file an amended complaint. The trial court denied Empire's subsequent motion to dismiss the amended complaint for failure to state a claim, except as to claims against individual members of Empire's board of directors, which were dismissed.

On appeal, the Appellate Division, First Department unanimously affirmed the trial court's decision. As to the standing issue, the First Department noted that two of the four standing plaintiffs had members who are Empire subscribers. However, the Court ruled, all of the standing plaintiffs had "failed to demonstrate that the interests they assert are germane to their purposes so as to warrant the court in finding that they are appropriate representatives of those interests." Their complaints were thus properly dismissed by the trial court for lack of standing.

The remaining plaintiffs' amended complaint alleged that the legislature's amendment of Insurance Law § 4301(j) violated a provision of the state Constitution contained in Article III, § 17, prohibiting the grant of an exclusive privilege or immunity to any private corporation. Empire argued that the challenged amendment did not fall within the scope of this constitutional prohibition, and that the state's exclusive grant of privilege to Empire was "appropriate under the circumstances." The Court reasoned that, notwithstanding the presumption of validity favoring legislative enactments, the constitutional language and its subsequent interpretation compelled the denial of defendants' motion to dismiss the amended complaint.

CPH File on Physician's Treatment Ruled Admissible in Physician Misconduct Hearing

Rowley v. New York State Department of Health, 771 N.Y.S.2d 195 (3d Dep't 2004). Petitioner physician brought an Article 78 proceeding to challenge a determination by a hearing committee of the New York State Board for Professional Medical Conduct ("BPMC"), that found her guilty of misconduct and imposed five years' probation.

In June 2000, Petitioner contacted the Medical Society of the State of New York's Committee for Physician's Health ("CPH") to inform them that she was suffering from Xanax addiction, post-traumatic stress disorder and suicidal ideations. CPH referred Petitioner for inpatient treatment, but Petitioner left the treatment center prior to completion of treatment. Accordingly, CPH reported her to the BPMC, which charged her with being a habitual user of narcotics and having a psychiatric condition that impairs her ability to practice medicine. After a hearing, at which CPH's files concerning Petitioner were admitted into evidence, Petitioner was found guilty of being a habitual user of narcotics, and of having a psychiatric condition that impairs her ability to practice medicine. Petitioner was placed on probation, subject to random drug and alcohol testing, and a practice monitor.

Petitioner brought an Article 78 proceeding to challenge the determination. The Court focused on her contention that it was an error for the Administrative Law Judge to have admitted into evidence the file compiled by CPH. That file contained memoranda of telephone calls between Petitioner and caseworkers, and CPH communications with treatment entities and medical societies of other states where Petitioner was licensed to practice medicine. The Petitioner argued that although Public Health Law § 230(11)(a) obligates CPH to report suspected physician misconduct to BPMC, the statute requires that "[s]uch reports shall remain confidential and shall not be admitted into evidence in any administrative or judicial proceeding."

However, the Court ruled that the term "report" refers to an initial complaint to CPH. The Court refused to construe the term "report" to encompass the information gathered or investigatory file compiled by CPH as a result of the initial complaint of misconduct, as that would shield the physician from appropriate disciplinary action. Such a result, ruled the Court, would be inconsistent with the statutory purpose of encouraging proper investigation of physician misconduct.

Court Prohibits Disclosure of Names of Cardiac Rehab Patients Who Witnessed Accident

Gunn v. Sound Shore Medical Center, 772 N.Y.S.2d 714 (2d Dep't 2004). The Appellate Division, Second Department held that a defendant hospital cannot be compelled to disclose the names and addresses of patients who were present at the time plaintiff sustained injuries while at a cardiac rehabilitation center owned by the hospital.

Plaintiff, who was injured when an elevated treadmill was allegedly lowered onto her foot, sought discovery of the names and addresses of the patients who were present at the time of the occurrence. The Supreme Court directed the hospital to release the requested information.

Reversing the Supreme Court, the Appellate Division held that disclosure of the patients' names would violate the physician-patient privilege contained in section 4504(a) of the Civil Practice Law & Rules. The Court found that although "the plaintiff's request to discover the names of the other patients . . . was not a request to discover their medical information per se," disclosure was prohibited because, in effect, that disclosure "would reveal that they were undergoing treatment for cardiac-related conditions." Such disclosure would violate the statutory confidentiality found at CPLR 4504-a, which shields a patient's medical information from disclosure. In reaching that conclusion, the Court cited to the Health Insurance Portability and Accountability Act of 1996

("HIPAA") as an indication that the modern-day legislative trend is to protect patient privacy. The Court did not analyze whether HIPAA also prohibited the disclosure, because that issue was not raised by the hospital.

Reports and Documents Prepared by Nursing Home Quality Assurance Committee Are Deemed Privileged Under Federal Law and Public Health Law § 2805-j; Public Health Law § 2801-d Does Not Establish a Private Cause of Action

Bielewicz v. Maplewood Nursing Home Inc., 778 N.Y.S.2d 666 (Sup. Ct., Monroe Co. 2004). A lawsuit was brought against a nursing home, alleging negligent supervision of a resident patient who purportedly was left unattended and drove his wheelchair into a location where he fell. Plaintiff filed motions seeking discovery and amendment of complaint.

The first issue confronting the Court was the discoverability of reports and documents prepared by the defendant nursing home's quality assurance committee. As the Court noted, such committees are governed in New York by Article 28 of the Public Health Law, a statute that in part effectuates a federal scheme set out with respect to nursing homes in the Federal Nursing Home Reform Act ("FNHRA"), which requires states to impose on all nursing homes the obligation of maintaining quality assurance committees. Because the FNHRA prohibits the state from requiring disclosure of such materials, the Court denied plaintiff's discovery request.

The Court made the further finding that such reports and documents were also immune from discovery under Public Health Law § 2805-j. The Court recognized that the plain language of Public Health Law § 2805-j only confers the quality assurance privilege upon "general hospitals," a term that, by statute, specifically excludes nursing homes. But, characterizing such language as a "drafting error," the Court refused to adhere to a technical reading of the statute. It concluded that it would be wrong and inconsistent to hold that nursing homes, like general hospitals, are required to institute quality assurance committees, but that their quality assurance committees are not entitled to the same privilege under state law as those of general hospitals.

The Court also rejected plaintiff's attempt to amend its complaint to add an additional cause of action under Public Health Law § 2801-d. That provision establishes a private cause of action for violation of specified patient rights. That statute was designed "to expand the existing remedies for conduct that, although constituting grievous and actionable violations of important rights, did not give rise to damages of sufficient monetary value to justify litigation." As the Court remarked, that statute did not create a new personal injury cause of action when, as was true in the case before the Court, that remedy already existed through the assertion of a common-law negligence claim. Nor was the statute meant to authorize a private cause of action in every negligence case.

Whistle-blower Law Claim Under Labor Law § 740 Fails Where Employee Does Not Allege the Specific Law, Rule or Regulation Violated by Supervisor or How Supervisor's Activities Posed a Substantial and Specific Danger to Public Health and Safety; Assertion of Section 740 Claim Waives Other Causes of Action Arising Out of or Related to Underlying Wrongful Discharge

Owitz v. Beth Israel Medical Center, 1 Misc. 3d 912, 2004 WL 258087 (Sup. Ct., N.Y. Co. 2004). Plaintiff, who was a cardiovascular perfusionist, sued the medical center that employed him and his supervisor. He claimed that he was wrongfully discharged after he complained to the supervisor about the latter's poor work performance and inappropriate behavior, which included creating unjustified overtime and using his computer to access pornography and to send sexually explicit e-mails to employees such as plaintiff. Based upon what he viewed to be a retaliatory discharge, plaintiff filed suit for a violation of New York's whistle-blower law under Labor Law § 740, defamation and human rights violations.

The Court dismissed plaintiff's claim in its entirety. It found that the Labor Law § 740 claim was not sustainable because plaintiff failed, as required by that statute, to specify the law, rule or regulation that was actually violated by defendant's behavior, and to describe how defendant's activities endangered the health or safety of the public.

The Court then relied upon the election of remedies provision of section 740 to dismiss plaintiff's other claims. That provision states that the institution of a section 740 claim results in a "waiver of the rights and remedies available under any other contract, collective bargaining agreement, law, rule or regulation or under the common law." Because plaintiff's claims all arose out of the same course of conduct and concerned the alleged retaliatory discharge—indeed, they were worded virtually identically—they fell victim to the waiver language of the statute.

The Court also concluded that the waiver was irrevocable. A plaintiff may not avoid the impact of the election of remedies provision by withdrawing a section 740 claim that it may perceive to be weak in an effort to preserve other causes of action, where all the claims arose out of the same course of conduct. Thus, the Court denied plaintiff's request to amend his complaint by dropping the Labor Law § 740 claim.

Federal Court Dismisses Medical Resident's Claims for Discriminatory "Termination" and Breach of Contract

Gourdine v. Cabrini Medical Center, 307 F. Supp. 2d 587 (S.D.N.Y.

2004). In a case recently decided by the District Court for the Southern District of New York, the Court granted a Medical Center's motion to dismiss federal discrimination and state law claims that had been brought by of one of its former medical residents. The Court found that, even given a most liberal reading of her pro se complaint, neither Plaintiff's Title VII claims nor the state law claims for breach of contract, forgery and fraud, were viable. The Court dismissed all but one of the Plaintiff's claims with prejudice and noted that a cause of action for unlawful "discharge" or "termination" could not be sustained—even on a motion to dismiss—simply because Plaintiff failed to obtain a second-year residency position after her one-year agreement expired.

In 1999, Cabrini hired plaintiff Monique Gourdine ("Plaintiff"), an African-American female, as a medical resident in its Department of Podiatry under a one-year written contract. The agreement provided that Cabrini would provide an educational program that would meet the standards of the Accreditation Council for Graduate Medical Education and the Council on Podiatric Medical Education. The agreement expressly stated that the Plaintiff's term of employment ended on June 20, 2000, and that there was no guarantee that, "at the next level," a house staff position would be offered.

Plaintiff began her employment, along with three other podiatric medical residents, two white males and an African-American male. At the expiration of her one-year agreement, Cabrini had only one available position for a second-year podiatric resident and offered the position to one of the white male residents. Plaintiff filed a complaint with the Equal Employment Opportunity Commission, which ripened into a federal suit. The suit alleged that Cabrini, its Director of Podiatry and the white male resident who obtained the second-year residency position were liable for discrimination, harassment and retaliation on the grounds of her race, gender and military status in violation of Title VII, as well as breach of contract, fraud and forgery.

In support of her race and gender discrimination claims, Plaintiff alleged that during her residency, the white male resident harassed her by unfairly criticizing her work in front of others and that, despite her complaints to the Chief Resident, the Director of Podiatry and the Human Resources Department, no steps were taken to correct the problem. Plaintiff claimed that in retaliation for her complaints, the Director of Podiatry made inappropriate comments to her, such as referring to her "big mouth," treated her less favorably than the other residents, gave her less desirable shifts and training, intentionally did not invite her and the other African-American resident to mandatory meetings, and denied her a surgical certificate. She further alleged that Cabrini and its Director of Podiatry did not properly accommodate her reservist commitment to the United States Navy. Plaintiff also alleged that Cabrini did not abide by its internal policies for addressing discrimination complaints.

Plaintiff's state law claims were based on her contention that she was "led to believe" that her residency was for podiatric surgery and not podiatric medicine and that, at the conclusion of the one-year program, Cabrini wrongfully "terminated" her without issuing a medical certificate. Plaintiff's allegations of forgery and fraud were based upon a verification document that bore Plaintiff's signature that Cabrini produced to demonstrate that Plaintiff was aware that a second-year residency position was not guaranteed.

In consideration of defendants' motion to dismiss, Cabrini admitted that Plaintiff and the white male resident had "personality conflicts" but denied that the defendants failed to respond to Plaintiff's complaints or treated her differently or in a discriminatory manner. Cabrini maintained that, with only one second-year residency available, it chose the best qualified resident. Cabrini also argued that it could not be liable for breach of contract in view of the written agreement and Plaintiff's verification, both of which acknowledged that there was no guarantee of employment beyond the one-year term. Accordingly, Cabrini argued that there had been no "discharge" or "termination" of Plaintiff's employment. As for the alleged wrongful denial of a medical certificate, Cabrini argued that Plaintiff had not completed proper training, and that, even if she had, the Council on Pediatric Medical Education ("CPME"), and not Cabrini, had the authority to issue a certificate.

The Court, noting that individual liability is not actionable under Title VII, quickly disposed of Plaintiff's federal claims against the individual defendants. The Court then found that all of Plaintiff's claims against Cabrini under Title VII failed to state a cause of action. The Court found that there were no factual allegations that would lead to a reasonable inference that Cabrini had discriminated or retaliated against the Plaintiff, noting that the mere fact that Cabrini selected a white male, rather than her, for the single available second-year residency was insufficient. The Court similarly found that Plaintiff's conclusory allegations of harassment, based upon offensive comments or criticisms that were unrelated to race or gender, failed to meet the "severe and pervasive" standard required to sustain a claim for hostile work environment. Additionally, the Court found no factual support for Plaintiff's claims that the alleged acts of retaliation—including allegations that she received less training and was compelled to work less desirable shifts than her colleagues—were related to Plaintiff's race or gender. And, the Court noted, discriminatory treatment based upon one's "military sta-

tus" did not state a valid claim under Title VII.

The Court exercised supplemental jurisdiction over Plaintiff's state law claims and dismissed them on the merits. First, the Court dismissed Plaintiff's forgery claim, noting that even if the Plaintiff could establish that her signature on the disputed verification was a forgery, it would not give rise to a cognizable civil cause of action. Second, the Court dismissed Plaintiff's fraud claim, which was related to the allegedly forged verification. The Court found that the complaint failed to set forth allegations to show that Plaintiff had relied on the authenticity of the verification in any way or that defendants made a false representation to Plaintiff. Consequently, the Court determined that the fraud claim was insufficient as a matter of law.

Turning to Plaintiff's final state claim for breach of contract, the Court considered Plaintiff's allegations that the type of residency program offered under the written agreement was different from the type of program that Cabrini asserted she was offered. The Court dismissed the contract claim, but did so without prejudice to replead, finding that although a colorable claim might exist, Plaintiff had not clearly alleged that she met the "requisite training requirements that would trigger a contractual obligation by Cabrini to issue a surgical certificate."

Court Dismisses Medical Resident's Discrimination Suit

Hall v. New York Hospital, 2003 WL 22902125 (S.D.N.Y. 2003). Plaintiff, a white medical resident at New York Hospital (NYH), was terminated by NYH for unsatisfactory work performance. Plaintiff sued, alleging that he was terminated in retaliation for attempting to vindicate the rights of two black patients. With respect to one patient, Plaintiff alleged that he had asked several unidentified senior white physicians to authorize the transfer of that patient to another hospital because NYH, in Plaintiff's opinion, could not provide appropriate care. With respect to a second black patient, Plaintiff claimed that several unidentified senior white physicians rebuffed his requests for assistance in performing surgery on this patient, a child. Notably, Plaintiff made no allegations that these senior white physicians knew the patients' race.

After complaining to his supervisors that NYH departed from the standard duty of care owed to these black patients, Plaintiff claims that his privileges were revoked and that his employment was terminated in retaliation for his whistle-blowing activities. Plaintiff then brought suit in federal District Court against NYH and his supervisors claiming, among other things, discriminatory retaliation in violation of 42 U.S.C. § 1981. His section 1981 discrimination claim was based on two allegations: (i) a black patient lost an eye because several senior white physicians refused to authorize the patient's transfer to another facility; and (ii) various senior white physicians intentionally refused to assist him in his attempt to treat a child.

The District Court, in considering NYH's dismissal motion, first determined that a white individual may bring a discrimination claim under section 1981, citing the seminal case of *DeMatties v. Eastman Kodak Co.,* 511 F.2d 306 (2d Cir. 1975). *DeMatties*, a white male, brought suit under section 1981 alleging that he was terminated because he sold his house (located in a white neighborhood populated mostly by other Kodak employees) to a black fellow employee. The Court held that *DeMatties,* despite being white, had standing to sue under section 1981 because he was fired for his actions in advocating the section 1981 rights of others.

Unlike *DeMatties*, the Plaintiff does not allege what section 1981 rights of his patients were violated, nor how or when any such rights were violated. The Court further found that Plaintiff failed to allege that any of the unidentified senior white physicians were even aware that the two patients were black, nor any facts showing a departure from the standard duty of care on the basis that these patients were black. Plaintiff even failed to allege that the individuals who terminated him had any knowledge that the subject patients were black. The Court also noted that nowhere in the complaint did Plaintiff claim that he complained of disparate treatment provided to blacks as compared to whites, or that the issue of race was ever discussed in connection with the patients' care. The mere fact that the patients were black and the senior physicians were white did not suffice to create an inference of discrimination. Having failed to allege any facts to create an inference of discriminatory intent or racial animus, the Court dismissed Plaintiff's section 1981 discrimination claim.

Court Upholds Revocation of Physician's License Based in Part on Submission of Inaccurate CV to OPMC

Clarke v. New York State Board for Professional Medical Conduct, 3 A.D.3d 798, 771 N.Y.S.2d 255 (3d Dep't 2004). Physician brought Article 78 proceeding to review a determination of BPMC, which revoked his license to practice medicine. The Appellate Division found that there was substantial evidence to support the determination.

The Court found that the charges of gross negligence were sustainable where the Physician provided one patient with a prescription for marijuana, failed to evaluate the seriousness of another patient's condition, and failed to stabilize another patient who was suffering from heavy vaginal bleeding. The Court further found that the Physician issued two illegal prescriptions to a patient for cannabis sativa in violation of Public Health Law § 3330 and "did so knowing that [the

patient's] motivation for obtaining the prescriptions was to avoid the legal consequences of marijuana use." Of particular note, the Court found that the Physician's knowing submission of an inaccurate curriculum vitae to an investigator for the Office of Professional Misconduct, notwithstanding his correction of the inaccuracies some five months later, was sufficient to sustain charges of fraudulent practice and moral unfitness.

Third Department Upholds Revocation of Physician's License for Committing Insurance Fraud

Zharov v. New York State Department of Health, 772 N.Y.S.2d 111 (3d Dep't 2004). Petitioner brought an Article 78 proceeding to review a determination of BPMC which revoked her license to practice medicine. Petitioner pleaded guilty to the crime of insurance fraud in the fourth degree, a Class E felony. The conviction was based on the physician's filing of a fraudulent medical report with an insurance company. Following her plea, BPMC charged Petitioner with professional misconduct. The Hearing Committee sustained this determination and revoked Petitioner's license.

Petitioner challenged the penalty of revocation. The Court declined to disturb the penalty, because it did not find it "so disproportionate to the offense as to shock one's sense of fairness." The Court noted that "[t]his court has consistently upheld the penalty of revocation in cases involving criminal convictions for insurance fraud," and that Petitioner's fraud "violated the public trust." Significantly, the Court noted that the lack of financial gain to petitioner, or absence of patient harm, did not preclude a penalty of license revocation. The Court also held that Petitioner's unwillingness to acknowledge her intentional involvement in the insurance fraud, contrary to her pleas allocution in criminal court, was a "significant factor in assessing the appropriate penalty."

Compiled by Leonard Rosenberg, Esq. Mr. Rosenberg is a partner in the firm of Garfunkel, Wild & Travis, 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, professional discipline, and directors' and officers' liability claims.

In the New York State Legislature

By James W. Lytle

At press time, the New York State Legislature is in the process of enacting the most overdue state budget in our history—and depending on the approach taken by the Governor to their fiscal handiwork, the budget may be later still. Because so much of state legislative activity relating to health care has a fiscal component, the budget delay postponed action on a number of key legislative items, and an array of proposals—including proposals relating to health care decision making and stem cell research—were delayed to avoid the controversy generally sought to be skirted during election years.

The following is a thumbnail sketch of some of the key fiscal and programmatic legislation that occupied the just-concluding legislative session.

The 2004–05 State Budget

As part of the state budget, the Legislature enacted a number of provisions and programs relevant to the health care system in New York State—and rejected a whole slew of proposals advanced by the Governor designed to curb the growth of Medicaid spending. While the ink is barely dry on the budgetary enactments, the following were among the key health care provisions:

- **Forge-Proof Prescriptions:** Legislation was enacted requiring the use of serialized prescription forms as a means to reduce fraud and forgery and to reduce Medicaid expenditures;
- **Long-Term Care Insurance:** Tax credits for long-term care insurance were increased from 10 to 20 percent, and a new outreach and education program was authorized, along with a study on investment product options to finance long-term care;
- **Child Health/Family Health Program changes:** A number of changes were enacted relating to eligibility for Child Health Plus, including a provision that required certain disabled children to be transferred from Medicaid to Child Health Plus, subject to certain transition provisions. The legislation also provides for the eventual state assumption of the local share of Family Health Plus.

New initiatives included a demonstration program in disease management and a telemedicine initiative, two long-term care demonstration programs designed to encourage community-based care and smaller residential health care models, a Medicaid adjustment for financially distressed nursing homes, and a $250 million capital program for health care facilities.

Legislation Passed by Both Houses

The following health-related bills had, by press time, passed both houses and had either been acted upon by the Governor or were pending gubernatorial review. The status, if available, of each of these bills is noted.

Health Insurance Legislation. In the context of continuing debate over the conversion of not-for-profit insurers to for-profit status (in which various proposals to allow conversion for insurers other than Empire Blue Cross/Blue Shield remain under consideration), two proposals passed both houses that are intended to strengthen not-for-profit insurers and HMOs:

- **Article 43 Capital Accounting Standards (A.252D/S.1173A).** Permits not-for-profit health insurers licensed under Article 43 of the Insurance Law and not-for profit health maintenance organizations to recognize investments in real estate at market value on their balance sheets.
- **Investment Requirements by Article 43 Corporations (S.5220C/A.8779A).** Allows health insurers licensed under Article 43, with substantial assets and reserves and a significant portfolio of conservative investments, the right to invest a portion of their funds in certain stock and bond investments on the same terms as for-profit health insurers.

Other insurance or health plan-related proposals include:

- **Third-Party Payment of CHPlus Premiums (S.7587).** This bill would permit a third party, on behalf of an eligible child, to make premium payments for CHPlus. This bill would have prevented the disenrollment of children from CHPlus, in the event that the family fails to pay its premium if a third party makes the payment on the child's behalf. The Governor, however, vetoed the legislation.
- **Managed Long-term Care Premium Risk Adjustment (S.7052A/A.11309).** Requires the Commissioner of Health to implement risk-adjusted premiums for managed long-term care plans by January 2006—replacing a permissive authorization for risk-adjusted premiums that has existed since the managed long-term care program was initiated.
- **HMOs Participating in Public Programs (A.9699/S.5918A).** Exempts HMOs that exclusively serve enrollees in public health insurance programs from offering coverage in the individual market.

- **Eating Disorder Care Centers and Mandated Coverage (S.5646A/A.11396).** Directs the Commissioner to identify comprehensive care centers for eating disorders, facilitate research regarding eating disorders, and make grants to promote the development of comprehensive care centers, the delivery of services, and research. The bill also mandates health insurance reimbursement of covered services when provided by a comprehensive care center. The bill was signed by the Governor on June 21, 2004.

Health Program Legislation

- **Adult Day Health Program (A.11435A/S.7514).** Expands the number of adult day health care slots for certain counties by up to 20 slots to meet waiting list demand. Requires a finding of cost savings to state and local governments; sunsets 9/1/08.
- **Assisted Living Legislation (S.7748/A.11820).** After several years of intense negotiation, legislation was passed by both houses to establish a regulatory structure for the oversight and regulation of assisted living programs.
- **Clinical Laboratory Technology Act (S.3762B/A.8094B).** Establishes new professional licensing requirements for clinical laboratory employees with three new titles (clinical laboratory technologists, clinical laboratory technicians and cytotechnologists), and establishes the credential necessary for licensure and grandfathers in individuals currently performing as clinical laboratory technology practitioners.
- **Accessibility of Medical Records (S.4964A/A.8602B).** Provides that the holder of a power of attorney from a patient or his or her estate, or the heir of a deceased patient, may authorize production of medical records, as recommended by the Chief Administrative Judge.
- **No-Interest Loans for Physicians in Shortage Areas (S.6809/A.10338).** Authorizes the state to use existing economic development funds to support the purchase of medical equipment for physicians in rural, shortage practice areas.
- **Nursing Home Diversion Program (S.7073/A.11350A).** Directs the Department of Health to seek a federal waiver to provide home and community based services to be reimbursed by Medicaid to certain individuals who have resided in a nursing home, or who require nursing home-level care, but are capable of living in the community. This legislation is based on the Traumatic Brain Injury Waiver program.
- **Residential Health Care Facility Right Sizing Program (S.7568/A.8815B).** Creates a voluntary residential health care facility demonstration program which will allow nursing home facilities to temporarily decertify or permanently convert a portion of their existing certified beds to another type of program or service. Demonstration would be limited to no more than 2,500 beds and the Department must consider a series of factors before approving applications under this program. If an application is approved, the reimbursement methodology for the facility would be modified accordingly.

Mental Hygiene Legislation

- **Appointment of Guardian (A.8838A/S.6830A).** Amends provisions governing guardianship proceedings and powers of guardians.
- **Licensure of Clinical Social Workers (S.7613/A.9102A).** Creates two new professional licenses—licensed clinical social worker and licensed master social worker—and removes reference to uncertified social worker; grandfathers in existing multidisciplinary licensed limited liability companies involving social workers for a limited time. Signed by Governor on July 27, 2004.
- **Mandated Reporting of Abuse and Maltreatment to OMRDD (A.9867A/S.6750A).** Mandates reporting of abuse or mistreatment of persons with mental retardation or developmental disabilities by various health care professionals, school officials, social services workers, day care center workers, and law enforcement officials.
- **Limited Liability Companies Authorized to Provide Chemical Dependency Services (S.5114/A.11497).** Amends the Mental Hygiene Law to authorize limited liability companies to provide chemical dependency services, without requiring an amendment of their certificate of incorporation. Current law limits providers to persons, partnerships or corporations only. The consolidation of the alcoholism and substance abuse services and chemical dependence services licenses would require providers to amend their certificates of incorporation if this change were not made.
- **Home and Community Based Waiver Programs for Developmentally Disabled Children (S.6437/A.11293).** Consolidates the four authorized programs within the home and community based model waiver program for developmentally disabled children into a single waiver program.
- **Criminal Record Check for Personnel Serving Mentally Ill, Mentally Retarded, and Developmentally Disabled (S.7562/A.11641).** Authorizes providers of services to the mentally disabled and developmentally disabled to conduct criminal background checks. Authorizes promulgation of regulations to implement these changes.

In the New York State Agencies

By Francis J. Serbaroli

Health Department

Personal Care Services Reimbursement

Notice of adoption. The Department of Health amended section 505.14 of Title 18 N.Y.C.R.R. to revise Medicaid reimbursement regulations to include a two percent penalty for late submission of cost reports for personal care services. Filing date: February 24, 2004. Effective date: March 10, 2004. *See* N.Y. Register, March 10, 2004.

Adult Day Health Care Regulations

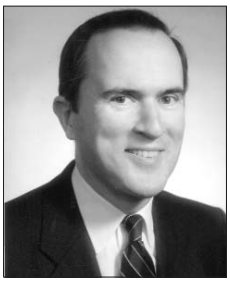
Notice of adoption. The Department of Health amended Parts 711 and 713, repealed Parts 425 through 427 and added a new Part 425 to Title 10 N.Y.C.R.R. to ensure that individuals receive adult day health care when appropriate and that providers are accountable for providing necessary and appropriate care. Filing date: February 27, 2004. Effective date: March 17, 2004. *See* N.Y. Register, March 17, 2004.

Managed Care Organizations

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend Subpart 98-1 of Title 10 N.Y.C.R.R. to provide a clearer guidance to the health care industry concerning the certification and operational requirements for managed care organizations. *See* N.Y. Register, March 31, 2004.

Resuscitation Equipment in Public Places

Notice of proposed rulemaking. The Department of Health gave notice of its intent to add a new section 801 to Title 10 N.Y.C.R.R., which provides for the availability of resuscitation equipment in certain public places including restaurants, bars,



theaters, and health clubs, to encourage emergency response by individuals who are trained in cardiopulmonary resuscitation who may not otherwise respond for fear of personal health risks. *See* N.Y. Register, April 7, 2004.

Need Methodology for Residential Health Care Facility Beds

Notice of adoption. The Department of Health amended section 709.3 of Title 10 N.Y.C.R.R. to update the need methodology for residential health care facility beds to reflect the 2000 census and changes in long-term care services. Filing date: April 20, 2004. Effective date: May 5, 2004. *See* N.Y. Register, May 5, 2004.

Environmental Laboratory Standards (Bioterrorism)

Notice of emergency rulemaking. The Department of Health added a new section 55-2.13 to Title 10 N.Y.C.R.R. to establish minimum standards for laboratory testing of biological and chemical agents of terrorism. Filing date: June 8, 2004. Effective date: June 8, 2004. *See* N.Y. Register, June 23, 2004.

Animals in Health Care Facilities

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend sections 405.24 and 415.29 of Title 10 N.Y.C.R.R. to bring current standards for accessing service animals that provide assistance to the disabled into compliance with the Americans with Disabilities Act and to update additional standards for animal-assisted therapy programs in nursing homes. *See* N.Y. Register, June 30, 2004.

Treatment of Opiate Addiction

Notice of emergency rulemaking. The Department of Health amended section 80.86 and added a new section 80.84 to Title 10 N.Y.C.R.R. to permit the treatment of opiate addiction in an office-based setting while curtailing the illicit use of controlled substances. Filing date: July 2, 2004. Effective date: July 2, 2004. *See* N.Y. Register, July 21, 2004.

Expedited HIV Testing of Women and Newborns

Notice of emergency rulemaking. The Department of Health amended section 69-1.3 of Title 10 N.Y.C.R.R. to enhance protection of newborns by requiring birth facilities to test for HIV exposure status within twelve hours after the infant's birth for all newborns whose mothers have not been tested for HIV during their current pregnancy or for whom HIV test results are not available at delivery. Filing Date: July 9, 2004. Effective Date: July 9, 2004. *See* N.Y. Register, July 28, 2004.

Part-Time Clinics

Notice of emergency rulemaking. The Department of Health amended sections 703.6 and 710.1 of Title 10 N.Y.C.R.R. in order to clarify and enhance the regulatory requirements that apply to part-time clinics and require prior limited review of all part-time clinic sites. Filing date: July 19, 2004. Effective date: July 19, 2004. *See* N.Y. Register, August 4, 2004.

Nursing Home Pharmacy Regulations

Notice of emergency rulemaking. The Department of Health

amended section 415.18(g) and (i) of Title 10 N.Y.C.R.R. to make a wider variety of medications available in nursing home emergency medication kits and to allow verbal orders from a legally authorized practitioner in order to respond quickly to the needs of residents. Filing date: July 19, 2004. Effective date: July 19, 2004. *See* N.Y. Register, August 4, 2004.

Controlled Substances in Emergency Kits

Notice of emergency rulemaking. The Department of Health amended sections 80.11, 80.47, 80.49 and 80.50 of Title 10 N.Y.C.R.R. to allow Class 3a facilities (nursing homes, adult homes and other long-term care facilities) to maintain controlled substances in emergency kits and administer them to a patient in an emergency situation. Filing date: July 19, 2004. Effective date: July 19, 2004. *See* N.Y. Register, August 4, 2004.

Payment for Psychiatric Social Work Services

Notice of emergency rulemaking. The Department of Health amended section 86-4.9 of Title 10 N.Y.C.R.R. to permit Medicaid billing for individual psychotherapy services provided by certified social workers in Article 28 Federally Qualified Health Centers. Filing date: July 14, 2004. Effective date: July 14, 2004. *See* N.Y. Register, August 4, 2004.

Insurance Department

Charges for Professional Health Services

Notice of proposed rulemaking. The Department of Insurance amended section 68.1 and Appendix 17C of Title 11 N.Y.C.R.R. to establish maximum permissible charges for professional health care services provided in no-fault insurance claims. *See* N.Y. Register, March 24, 2004.

Physicians and Surgeons Professional Insurance Merit Rating Plans

Notice of emergency rulemaking. The Department of Insurance amended Part 152 of Title 11 N.Y.C.R.R. to establish guidelines and requirements for excess medical malpractice merit rating plans and risk management plans. Filing date: May 3, 2004. Effective date: May 3, 2004. *See* N.Y. Register, May 19, 2004.

Claim Submission Guidelines

Notice of emergency rulemaking. The Department of Insurance added Part 217 to Title 11 N.Y.C.R.R. to create claim payment guidelines that establish when a health care insurance claim is considered complete and ready for payment in order to resolve conflicting views between the health care industry and the insurance industry as to compliance with New York's prompt payment statute. Filing date: April 30, 2004. Effective date: April 30, 2004. *See* N.Y. Register, May 19, 2004.

Healthy NY Program

Notice of emergency rulemaking. The Department of Insurance added section 362-2.7 and amended sections 362-2.5, 362-3.2, 362-4.1, 362-4.2, 362-4.3, 362-5.1, 362-5.2, and 362-5.3 of Title 11 N.Y.C.R.R. to simplify the Healthy NY application process by establishing a standardized application and clarifying household income eligibility requirements, and to reduce Healthy NY premium rates to enable more uninsured businesses and individuals to afford health insurance. Filing date: June 10, 2004. Effective date: June 10, 2004. *See* N.Y. Register, June 30, 2004.

Compiled by Francis J. Serbaroli, Esq. Mr. Serbaroli is a partner in Cadwalader, Wickersham & Taft's 17-attorney health law department. He is the Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and serves on the Executive Committee of the New York State Bar Association's Health Law Section. He is the author of *The Corporate Practice of Medicine Prohibition in the Modern Era of Health Care*, published by BNA as part of its Business and Health Portfolio Series. **The assistance of Ms. Joanne Oh and Ms. Vimala Varghese, associates at Cadwalader, Wickersham & Taft LLP, in compiling this summary is gratefully acknowledged.**

In the Journals

By Dale L. Moore

***Health Matrix: Journal of Law-Medicine*, Winter 2004 (Volume 14, Number 1)**

- John D. Blum, *Feng Shui and the Restructuring of the Hospital Corporation: A Call for Change in the Face of the Medical Error Epidemic*
- James F. Blumstein, *Health Care Law and Policy: Whence and Whither?*
- Roger B. Dworkin, *Bioethics? The Law and Biomedical Advance*
- Barry R. Furrow, *From the Doctor to the System: The New Demands of Health Law*
- Jesse A. Goldner, *A Tribute to Mentors*
- Mark A. Hall & Carl E. Schneider, *Where Is the "There" in Health Law? Can It Become a Coherent Field?*
- Clark C. Havighurst, *I've Seen Enough? My Life and Times in Health Care Law and Policy*
- Sandra H. Johnson, *Five Easy Pieces: Motifs of Health Law*
- Timothy Stoltzfus Jost, *Comparative and International Health Law*
- Patricia A. King, *Reflections on Race and Bioethics in the United States*
- Rand E. Rosenblatt, *The Four Ages of Health Law*
- Arnold J. Rosoff, *The Growth of Health Law and Bioethics*
- Robert L. Schwartz, *Where is Health Law Going?: Follow the Money*
- Nicholas P. Terry, *A Medical Ghost in the E-Health Machine*
- Walter Wadlington, *Some Reflections on Teaching Law and Medicine in Law School Since the '60s*

***Indiana Health Law Review* 2003–2004 (Volume 1, Number 1)**

- Naomi Seiler, Holly Taylor & Ruth Faden, *Legal and Ethical Considerations in Government Compensation Plans: A Case Study of Smallpox Immunization*
- H. Tristram Engelhardt, Jr., *Giving, Selling, and Having Taken: Conflicting Views of Organ Transfer*
- Karen A. Jordan, *Recent Modifications to the Preemption Doctrine & Their Impact on State HMO Liability Laws*
- George P. Smith II, *The Vagaries of Informed Consent*
- Keith D. Barber, David B. Honig & Neal A. Cooper, *Prolific Plaintiffs or Rabid Relators? Recent Developments in False Claims Act Litigation*
- Glenn T. Troyer, David E. Jose & Andrea D. Brashear, *Governance Issues for Nonprofit Healthcare Organizations and the Implications of the Sarbanes-Oxley Act*
- Leslie Pickering Francis, *Legitimate Expectations, Unreasonable Beliefs, and Legally Mandated Coverage of Experimental Therapy*
- Shelley S. Fraser, *Hospital Liability: Drawing a Fine Line with Informed Consent in Today's Evolving Health Care Arena*

***Journal of Health Law*, Winter 2004 (Volume 37, Number 1)**

- Thomas R. Barker, Peter Urbanowicz, & Louise Joy, *Health Lawyers Teleconference: EMTALA Update*
- Brian Kamoie, *EMTALA: Dedicating an Emergency Department Near You*
- Erin M. McHugh, *The New EMTALA Regulations and the On-Call Physician Shortage: In Defense of the Regulations*
- Joe G. Hollingsworth & Eric G. Lasker, *The Case Against Differential Diagnosis:* Daubert, *Medical Causation Testimony, and the Scientific Method*
- Philip L. Pomerance, *Multijurisdictional Practice and the Health Lawyer: Will Your Practice Benefit from the New ABA Model Rules of Professional Conduct?*
- James A. Christopherson, *Physician/Hospital Joint Ventures in the Wake of St. David's: Reference Material*

***Journal of Health Law*, Spring 2004 (Volume 37, Number 2)**

- Joan H. Krause, *Healthcare Fraud and Quality of Care: A Patient-Centered Approach*
- Alice G. Gosfield, T*he Doctor-Patient Relationship as the Business Case for Quality: Doing Well By Doing Right*
- Barbara Bennett, *Application of the HIPAA Privacy Rule to Employer Benefit Plans and a Compliance Theory of Statutory Interpretation*
- Elizabeth A. Pendo, *Images of Health Insurance in Popular Film: The Dissolving Critique*
- Keith J. Halleland, *Prompt-Pay Laws: A State-by-State Analysis*

Other Articles:

- Carl H. Coleman, *Rationalizing Risk Assessment in Human Subject Research*, 46 ARIZONA L. REV. 1 (2004).
- Diane Hoffman & A. Tarzian, *Achieving the Right Balance in Oversight of Physician Opiod Prescribing for Pain: A Survey of State Medical Boards*, 89 J. MED. LICENSURE AND DISCIPLINE 159 (2003).
- Sharona Hoffman & Andrew P. Morriss, *Birth After Death: Perpetuities and the New Reproductive Technologies*, 38 GEORGIA L. REV. 575 (2004).
- Lisa C. Ikemoto, *Racial Disparities in Health Care and Cultural Competency*, 48 ST. LOUIS UNIV. L.J. 75 (2003).
- Erik Lillquist & Charles A. Sullivan, *The Law and Genetics of Racial Profiling in Medicine*, 39 HARVARD CIVIL RIGHTS-CIVIL LIBERTIES L. REV. 391 (2004).
- Richard S. Saver, *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 NORTHWESTERN UNIV. L. REV. 145 (2003).
- Allyn Taylor, *Global Health Governance and International Law*, WHITTIER INT'L L. REV. 253 (2003).

For Your Information

By Claudia O. Torrey

The Joint Commission on Accreditation of Healthcare Organizations ("JC") states that its mission is to "continuously improve the safety and quality of care provided to the public, through the provision of health care accreditation and related services that support performance improvement in healthcare organizations."[1] The JC is a not-for-profit organization that issues voluntary standards for the accreditation of healthcare entities (hospitals, nursing homes, rehabilitation centers, etc.). Generally, because of the JC's gold-standard reputation, hospitals that achieve a JC accreditation are deemed compliant with the Centers for Medicare & Medicaid Services' ("CMS") conditions of participation ("COP") requirements for Medicare payments.[2] Thus, the JC standards are deemed more comprehensive than the Medicare COP.

Since its founding in 1951, the JC has been a leader in initiatives to strengthen the quality of health care delivery in this country. The JC's policies, standards, and goals emphasize a systems-oriented approach to providing safe, high-quality health care.[3] On July 20, 2004, the Government Accountability Office ("GAO") issued a report to Congress entitled "CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals."[4] The report concerns potential removal of the JC's preferred hospital accreditation status, especially as such relates to Medicare COP.[5] Time will tell whether the JC's new unannounced survey process, implemented in January 2004, will improve alleged deficiency detection. Limited governmental authority over the JC, which has conferred on it a unique legal status, essentially prevents the CMS from taking against the JC the same sort of action it can use against other health care accreditation entities. The JC welcomes some governmental oversight, but hastens to state that Congress should not make decisions based upon an incomplete portrayal of the JC's effectiveness.[6]

On July 1, 2004, shortly before this recent report to Congress, the 2003 JC Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery ("Protocol") became effective.[7] The protocol, applicable to accredited hospitals as well as ambulatory care and office-based surgery facilities, is an outgrowth of the JC's 2003 and 2004 National Patient Safety Goals. There are four main components to the Protocol: a pre-operative verification process; marking the operative site; a documented "time out" just before starting the procedure; and utilizing these three components in a non-operating room ("OR") setting, including bedside procedures. There are also limited exemptions under both the marking-site component and the procedures for the non-OR situations component.[8]

This Protocol is particularly encouraging in view of the JC project begun in January 2004 to determine the capabilities of hospitals across the nation to address issues of language and culture.[9] The project, funded by the California Endowment, is scheduled to last two-and-a-half years, and will recommend best practices for hospitals to employ in order to make their services more culturally and linguistically appropriate.[10]

Endnotes

1. Setting the Standard, JC 2004 Report, www.jcaho.org (last viewed on July 23, 2004).
2. *Id.* at 1.
3. *Id.*
4. www.gao.gov/new.items/d04850.pdf (last viewed on July 26, 2004).
5. *Id.*
6. www.jcaho.org/news+room/press+kits/gao/statement.htm.
7. www.jcaho.org.
8. *Id.*
9. *Id.*
10. *Id.*

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

SPECIAL EDITION:
Orchard Health: A Case Study on the Unique Legal Issues of Health Care Systems in N.Y.

Introduction

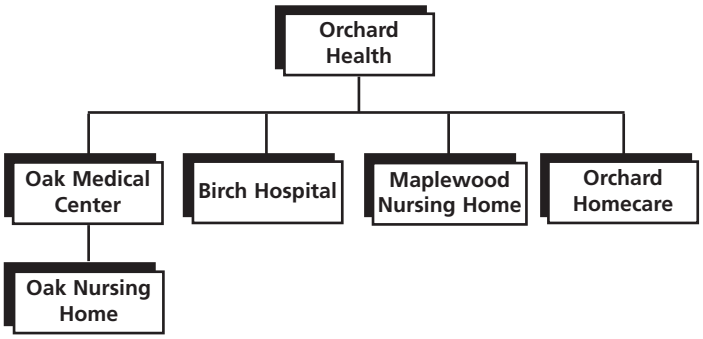
By Robert N. Swidler

Orchard Health ("Orchard") is a fictional not-for-profit health system with its principal administrative office in Westchester County. It was formed in 1998 to be the sole member (i.e., common parent) of nearby Oak Medical Center ("Oak"), a 500-bed hospital, and Birch Hospital, Inc., a 250-bed community hospital about 10 miles east. Oak is itself the parent corporation of Oak Nursing Home and the operator of three primary care sites.

Since 1998, two other providers have become part of Orchard Health: Maplewood Nursing Home joined in 2000 by making Orchard its sole member, and in 2001 Orchard created Orchard Home Care, a home care services agency.

In 2002, Orchard and its affiliates elected the same twelve persons as the board of directors of each corporation.

Now in 2004, Orchard's structural chart looks like this:



Orchard Health is a relatively simple example of a health care system. Other nonfictional examples in New York State are far more complex, and include a greater number and greater variety of facilities. Such systems might include, for example, an assisted living program or adult home, a foundation, a medical college, and a for-profit subsidiary. Moreover such systems, or parts of them, might participate in joint ventures with entities outside the system.

But Orchard Health is complex enough. It faces all the issues faced by hospitals, nursing homes and home care providers. In addition, its administration and attorneys confront a range of legal questions that are unique to health care systems.

Among them:

- Can Orchard reserve the right to approve the budget of Oak Nursing Home?
- How does the Orchard board handle conflicts between the interests of affiliates?
- Can the Orchard affiliates share protected health information?
- If an Orchard affiliate learns that a doctor is a serious quality risk, can the other Orchard affiliates act on that information?
- What is Orchard permitted to do to promote referrals within its system?
- Can Orchard negotiate with HMOs on behalf of its affiliates?
- Can Orchard consolidate its credentialing? Its quality assurance? Its IRB?
- Can Orchard affiliates donate or loan funds to other Orchard affiliates?
- How would a vote to unionize at one affiliate affect the others?

The health system model appears to be increasingly prevalent in New York State and elsewhere. Yet there appear to be remarkably few books, articles or conferences that focus on their unique legal problems. Moreover, there are few statutes or regulations that govern or even acknowledge the existence of health systems. In 2002, the NYSBA Annual Meeting included an informative and contentious program on Not-for-Profit Law issues raised by health care systems. But as the questions above illustrate, the legal challenges that systems face go far beyond that topic.

In this Special Edition of the *Health Law Journal*, health care lawyers discuss a broad range of unique issues faced by health care systems, using Orchard Health as their frame of reference. Perhaps most importantly, this edition will promote the recognition of health systems as a distinct topic for analysis, with legal issues beyond those faced by the system's parts, and beyond the transactional issues that arise in connection with mergers, affiliations and joint ventures.

The Editors of the *Journal* are very grateful to the many lawyers from across the state who contributed their effort and experience to this very special edition. They must also be commended for their willingness to enter into largely uncharted territory.

In addition, we once again thank our dedicated columnists.

Corporate Governance Issues Faced by Orchard Health

By Edward Kornreich

I. Introduction: A Trend Toward Affiliation

Health care systems such as Orchard Health ("Orchard") reflect the recent trend of consolidating services in the health care industry. As health care facilities struggle to stay afloat, there is significant movement toward establishing health care systems—affiliated not-for-profit medical entities with a common corporate member or overlapping boards established for the purpose of combining medical, administrative and financial management. Participation in a consolidated system brings numerous advantages, including economies of scale, central purchasing and planning, and mutual support. Another potential advantage is that some affiliates may gain increased bargaining power with insurance companies and health care management organizations. The system also offers important opportunities to link clinical information and coordinate care.

"Participation in a consolidated system brings numerous advantages, including economies of scale, central purchasing and planning, and mutual support."

For-profit corporate structures routinely involve parent/subsidiary relationships that allow the maintenance of separate corporate identities by the system participants, joint contracting (they are considered a single entity for antitrust purposes) and limited liability (in the absence of an abuse of the corporate form, each entity is liable for its own obligations and not those of the other system members). This structure fits easily within traditional for-profit governance; for-profit entities share a relatively simple primary mission—maximizing the interests of the ultimate owners (i.e., shareholders) of the enterprise—and integration appears to serve these interests in a straightforward manner.

In contrast, integrated not-for-profit health care systems like Orchard do not easily fit in the traditional not-for-profit corporate governance model. Their unique structure complicates board duties and raises governance issues that may not be obvious or have simple solutions. On the one hand, there is an absence of overt statutory and regulatory recognition of complicated corporate governance structures like Orchard. On the other hand, there is a growing terrain of not-for-profit regulation in the wake of recent corporate governance scandals, with implications for systems. This article contemplates some of the potential corporate governance issues facing Orchard, recognizing that (i) not-for-profit organizations function in a world as complex and difficult as their for-profit counterparts, and they are as much in need of the benefits of being integrated without being a single corporate entity; and (ii) not-for-profit corporate law is an evolving field, particularly in this new era of heightened awareness of governance issues and continual governance reform.

II. Conflicts of Interest in the Context of Not-for-Profit Health Care Systems

The not-for-profit corporate model used by health care systems like Orchard must be distinguished from the for-profit corporate model in several respects. As noted, a typical for-profit corporation is organized for the purpose of corporate profit and shareholder gain, is owned by and accountable to its shareholders, and distributes net profits through dividends to shareholders. In contrast, a not-for-profit corporation is organized for the purpose of furthering the charitable mission set forth in its charter or certificate of corporation. The not-for-profit's corporate activities and net income are dedicated solely to the corporation's purposes or mission. At least technically, this obligation does not change when the not-for-profit corporation joins a system.

In the for-profit corporate structure, there is a complete uniformity of interest between the parent and a wholly-owned subsidiary: the board members of both must act to increase overall profit and shareholder gain. By contrast, board members of not-for-profits face conflicting obligations. Board members of entities like Oak Medical Center and Birch Hospital that elect to participate in the Orchard system are subjected to dealing with not only the mission of the entity on whose board they sit, but also the mission of the overarching system. Significantly, "subsidiaries" like Oak Medical and Birch Hospital may be competing facilities,[1] and the question arises as to how the board members' fiduciary obligations to their respective entities co-exist with the entities' (and therefore their boards') obligations to the health system as a whole.

III. Fiduciary Duties of Boards in Not-for-Profit Health Care Systems

Although the fiduciary obligations for directors of not-for-profit corporations are often described as similar to those existent in the for-profit model (i.e., the business judgment rule), courts frequently subject board members of not-for-profits to a higher standard of fiduciary obligation.[2] In these cases, a not-for-profit corporation is treated like a public trust, and the directors are held to the higher standard of duty applied to trustees. (Although the trustee standard is theoretically higher, it is hard to find a case where the standard of review was determinative.) Regardless, the most important fiduciary obligations of not-for-profit corporate board members include the duty of loyalty, which is the duty of undivided and unqualified loyalty to the corporation; the duty of care, which requires trustees to act with the degree of diligence, care and skill of prudent persons; and the duty of obedience, which requires knowledge of and devotion to the corporation's mission. The board members of every entity in the Orchard system must attend to these duties.[3]

These duties govern both the initial decision to create or join a system, and subsequent actions within the system. Initially, and most critically, the board must assess (in compliance with its duties) whether joining the system is the right decision. This determination should reflect careful consideration of the benefits afforded by system participation and the burdens thereof (including the ceding of some power to the system). Joining a system must entail a determination that the financial and strategic benefits of such participation warrant the loss of complete independence.

This fundamental decision to join the system, then, has implications for decisions that the board of the system entities makes, particularly when confronting decisions that involve a conflict between the system entity and its "parent" entity, or other system entities.

IV. Management of Conflicts of Interest in Not-for-Profit Health Care Systems

As described in the preceding section, various conflicts arise for board members in systems like Orchard. Board members are concerned with their fiduciary duties to the entity on whose board they sit, while also struggling to take account of the needs of the system. A member of the Maplewood Nursing Home ("MNH") board may find, for example, that the needs of Orchard conflict, in some instances, with her fiduciary obligations to MNH. There may be a conflict of interest for those who sit on the boards of two or more system-affiliated entities or those who sit on the board of the governing health care system entity as well as on the boards of hospitals or other medical entities that serve as the system's "subsidiaries." That is to say, conflicts may arise for an individual sitting on the board of MNH and Birch Hospital or the board of MNH and Orchard.

Unfortunately, there is no uniform approach for not-for-profit board members facing such conflicts. By joining the system, the board of the newly affiliated hospital has recognized that the hospital needs or wants the benefits of such affiliation, and must therefore accept the trade-off—the imposition of a new system consciousness in regard to hospital decisions. One possible approach is to apply a balancing test, whereby the board members of an entity weigh the significance of certain actions for effect on a particular entity and against the effect on the health care system on the whole. Any decision to protect the system at the expense of a constituent hospital would be permissible only if it furthered the mission of all of the system members, including the negatively impacted hospital.

"Board members are concerned with their fiduciary duties to the entity on whose board they sit, while also struggling to take account of the needs of the system."

For example, it may be that the system can sustain only one unit of a particular new technology (e.g., PET) that is then located at two hospitals operated as separate corporations, and the system decides to allocate the unit to one of them. The hospital site denied the unit is not individually benefited by this decision (at least in comparison to the other "winning" hospital). How does the board of the losing hospital approve the closure of its unit? The answer lies in the benefits that the hospital obtains from being part of the system. While it may not have a PET scanner on site, it is protected from the financial losses attendant to such operation, and also can benefit from the related efficiencies, economics and the financial and operational support that make system participation worthwhile. Of course, if these benefits were not anticipated, justification for the system affiliation in the first instance would not have existed. Simply put, every decision by each separate corporate entity within the system must demonstrate an awareness of and compliance with the corporation's mission. System affiliation, without more, does not eliminate this duty. The key is finding the mission benefit in system participation, and the ultimate mission benefit (which may include a strengthened system) from actions that may facially appear to weaken the particular member. Different approaches may be possible, however, and the

emerging "best practices" suggest only the following rule: a board member can contemplate the needs of a health care system like Orchard if the interests of the entity on whose board she sits are served by the system.

Section 715 of the New York Not-for-Profit Corporation Law (hereinafter the "N-PCL") regulates interested directors and officers. A contract or transaction between the corporation and its directors or officers, or between the corporation and another entity in which one of its directors or officers has a substantial financial interest or for which they also serve as directors or officers, must be fair and reasonable to the corporation. Non-abiding contracts or transactions may be voided when this test is not met. There is a presumption of substantive fairness and reasonableness of such transactions when disclosures are made and due diligence is performed, and approval of the transaction by the members or disinterested directors is obtained. There is also a presumption of fairness and reasonableness for grants made from one not-for-profit to another not-for-profit.

Many transactions will not be able to satisfy these formal procedural requirements to obtain the presumption of reasonableness, and the objective standard—was the transaction "fair and reasonable" to the corporation or corporations with conflicted board members—will apply.[4] Thus any contract or transaction between an Orchard entity, or Orchard itself, and an interested director must be fair and reasonable to the entity or system. In the context of health care system decision-making, the determination of what is "fair and reasonable" must incorporate recognition of the benefits of system participation, and the implication of such participation on decision-making. Thus, if the losing hospital were to convey the PET assets to the winning hospital, it should be based on a documented fair market value analysis of the assets conveyed, and the conveyance itself should be justified, as noted above, by the benefits to the system (with indirect reasonable benefits to the conveying hospital).

V. Day-to-Day Operational Issues and "Piercing" Concerns

There is no prohibition in the N-PCL against a director serving on multiple boards, including "mirror" or overlapping boards. Moreover, there is no requirement of separate meetings of boards or committees, although for many reasons, including "piercing" concerns, as well as formal legal requirements, it is critical that corporate action (e.g., votes) be handled discretely for each corporation, and the board members must understand the entity for which they are voting at the time they take action.

In order to avoid having the separate existence of the various Orchard entities denied and liability of one entity for another entity's acts imposed, the system must carefully respect the corporate form of each entity within it. Each board must continue to meet, take action separately, and maintain all records of meeting and actions. The actions of one corporate entity should never be deemed the acts of another, and the board members must understand the separate corporations on whose board they sit, and for whom they are acting at any given time. The corporate form should be respected in all transactions within the system.

"As a general rule, the law treats corporations as having an existence separate and distinct from that of their shareholders and consequently, will not impose liability upon shareholders for the acts of the corporation."[5] This general principle also applies in the context of corporate groups, and New York courts have held that as a general rule, "a parent is not liable for the acts of a subsidiary."[6] This rule applies both to individual and corporate shareholders. The N-PCL treats not-for-profit corporate members like shareholders in regard to corporate liability (see Section 517(a)) and the same legal analysis should apply. There is a strong presumption against disregarding the corporate entity. The corporate veil will be pierced only upon a show of overwhelming control by the parent that is used to perpetrate a fraud or other wrongdoing on a third party, or to "'prevent fraud or achieve equity.'"[7] In most cases, the maintenance of discrete corporate entities will create a burden of proof too high to overcome this presumption.

VI. Miscellaneous Issues

A. Purposes and Powers

The purposes and powers of the member entities in Orchard must be reviewed at the point of entry of the members into or the creation of the system to ensure that the purposes and powers of the entering corporation are consistent with system participation. If changes in the purposes and powers are required, the revisions must be judicially approved upon notice to the Attorney General. As a general matter, participation in Orchard Health should further the corporate purposes of the constituent entities, and no changes will be required. The creation of certain retained powers in the corporate member (or parent) should not be deemed a change to the entity's powers requiring notice to the Attorney General.[8]

In this regard, the creation of the system or an entity's decision to join a system, and in either case to surrender board control and perhaps afford certain substantial rights (e.g., budget approval) to the parent, should not be deemed a transfer of "all or substantially

all of the assets" of the joining entity or a merger requiring judicial approval.[9]

B. Donations and Solicitations

One of the powers that not-for-profit corporations may exercise is the power to make donations for the public welfare "irrespective of corporate benefit."[10] This section appears to free the decision of the board to make such grants from the duty of obedience to mission; the duty of care and the duty of loyalty remain. Any donation within the Orchard corporate family should still be reviewed against the broader standard of weighing the benefit of such donation to the system and the indirect benefit to the donor entity.

"By joining a system, the board of the newly affiliated entity makes a commitment to support the system and consider the impact of its actions on the system."

While not-for-profit entities may make donations, they may not solicit contributions for a hospital without Public Health Council approval.[11] Thus, the Council must approve fundraising on behalf of Oak Medical by any entity other than the hospital.

VII. Conclusion

Health care systems, such as Orchard, require a new paradigm for board decision-making. The broader focus of such systems, the shared services and mutual support, all require a broader context for board consideration of key issues. By joining a system, the board of the newly affiliated entity makes a commitment to support the system and consider the impact of its actions on the system. However, the board can never lose sight of the entity's charitable mission, which the system should support. Any review of actions taken by a system subsidiary's board must reflect recognition of these principles.

Endnotes

1. The antitrust issues raised by Orchard are discussed elsewhere in this edition of the *Health Law Journal*.
2. *See, e.g., Manhattan Eye, Ear & Throat Hospital v. Spitzer*, 186 Misc. 2d 126 (Sup. Ct., N.Y. Co. 1999).
3. The power of board members, of course, may be modified by the certificate of incorporation or the bylaws; even in this era of corporate governance reform, the law permits the delegation of board duties to the corporate members (i.e., the parent or others), if the certificate so provides. (Of course, when exercising such powers, the members (or any other such individuals or entities) have the same fiduciary obligations to the corporation as board members would.) *See* N.Y. Not-for-Profit Corp. Law § 701(b). Indeed, the New York Department of Health's regulations permit hospitals to delegate operating authority to a parent or other entity if that entity has received approval by the Public Health Council as an Article 28 network. 10 N.Y.C.R.R. § 401(j).
4. It may be possible to obtain the benefit of the presumption, in many cases, by having the members approve the transaction. Since the members in the Orchard hypothetical are as conflicted as the board, it is difficult to accept that such approval would suffice for application of the presumption but, as a technical matter, there does not appear to be any prohibition on interested members approving a transaction. However, the real-world benefit (i.e., favorable judicial consideration) of obtaining a presumption of reasonableness regarding a conflicted transaction by a vote of conflicted members (who are the same people as the conflicted board) appears dubious.
5. *Billy v. Consolidated Mach. Tool Corp.*, 51 N.Y.2d 152, 163, 432 N.Y.S.2d 879, 885–86, *appeal denied*, 52 N.Y.2d 829, 437 N.Y.S.2d 1030 (1980).
6. *Port Chester Elec. Constr. Corp. v. Atlas*, 40 N.Y.2d 652, 656, 389 N.Y.S.2d 327, 331 (1976); *see Dempsey v. Intercontinental Hotel Corp.*, 126 A.D.2d 477 (1st Dep't 1987).
7. *Morris v. State Dep't of Taxation and Fin.*, 82 N.Y.2d 135, 140, 603 N.Y.S.2d 807, 810 (1993) (citation omitted).
8. *See Nathan Littauer Hosp. Ass'n v. Spitzer*, 734 N.Y.S.2d 671 (N.Y. App. Div., 3d Dep't 2001).
9. *See generally Nathan Littauer Hosp. Ass'n.*
10. N-PCL § 202(a)(14).
11. N-PCL § 404(o).

Edward Kornreich is a partner of Proskauer Rose in New York City. His principal practice areas are health care and non-profit/exempt organizations. **The author wishes to express his appreciation for the assistance of associate Leah Newkirk, and summer associate Jami Gaffe, in the preparation of this article.**

Antitrust Issues Faced by Orchard Health

By Darrell E. Jeffers and Jason LaFlam

Introduction

Orchard Health ("Orchard"), as a multi-provider network, inherently raises issues under federal and state antitrust laws, because such networks, by bringing together formerly independent providers, could significantly lessen competition. Orchard's structure could result in both horizontal and vertical restraints on competition.

Horizontal restraints can arise from the affiliation of similar types of providers that have a competitive relationship, such as the two hospitals within Orchard, Oak Medical Center and Birch Hospital, or the two nursing homes, Oak Nursing Home and Maplewood Nursing Home. Examples of horizontal restraints on competition are price-fixing, group boycotts and allocation of services between providers. Therefore, if Orchard were to negotiate rates on behalf of its affiliates, such conduct, depending on the specific facts, could be price-fixing. Any allocation of services between Oak Medical Center and Birch Hospital could be a restraint on competition.

"[A] health system that meets a level of integration qualifying it as a single entity for antitrust purposes may negotiate price terms on behalf of its affiliates without fear of antitrust liability."

Vertical restraints can arise from the affiliation of entities that compete in different markets, such as the hospitals and the nursing homes in Orchard. The health system could use its power in one market to restrict competition in another. For example, if the Orchard nursing homes were limited to sending their patients only to hospitals within the health system, this could result in restricting hospital competition for patients.

The assessment of any potential Orchard antitrust liability is a factual undertaking involving:

- Analysis of the exact nature of the suspect conduct and whether it would be viewed as per se illegal or qualifying for rule of reason analysis;
- Determination of market share; and
- Weighing pro-competitive effects of the conduct against anti-competitive effects.

Another important factor would be the reaction of payers to the conduct of Orchard. Government antitrust investigations almost always are the result of complaints from payers. In addition, payers, as well as others that can claim harm from alleged antitrust activity, have a private right of action. However, there are also situations when payers are not adverse to network conduct such as joint negotiation of contracts, as the payer can save administrative costs and work. Generally, this type of payer reaction occurs when the network does not have significant market share.

This article focuses primarily on the key factors in evaluating the antitrust issues faced by Orchard, in particular if Orchard were to negotiate rates with payers on behalf of its affiliates.

Integration Is the Key Factor

If all of the affiliates of Orchard were merged into a single entity and Orchard were to negotiate rates or allocate services, such activities would be permissible (provided the merger itself was not challenged). Where a health system is so integrated as to function as a single entity, section 1 of the Sherman Antitrust Act, prohibiting contracts, combinations, or conspiracies that restrain trade, does not apply.[1] Thus, a health system that meets a level of integration qualifying it as a single entity for antitrust purposes may negotiate price terms on behalf of its affiliates without fear of antitrust liability.

Therefore, the more Orchard functions as a single entity, the less likely that any of its activities would be viewed as anti-competitive. In the antitrust context, integration is viewed as creating efficiencies. Consequently, the more integration that occurs, the greater the likelihood that efficiencies come about.[2] The degree of integration within a health system such as Orchard can mean the difference between certain business practices being evaluated under a rule of reason analysis, or being deemed a per se violation under the antitrust laws. An activity deemed a per se violation is "so plainly harmful to competition and so obviously lacking in any redeeming pro-competitive values," that no further analysis is necessary.[3]

In all other cases, a business practice is evaluated under a rule of reason analysis. A rule of reason analysis weighs the anti-competitive effects of the activity against pro-competitive efficiencies produced by the activity.[4] When the activities of a health system are evaluated under a rule of reason analysis, the relevant geo-

graphic and product markets are defined and the competitive aspects and potential efficiencies of the health system's conduct are examined. "The greater the network's likely anti-competitive effects, the greater must be the network's likely efficiencies."[5]

Where substantial integration exists, the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC"), the federal agencies charged with enforcing the federal antitrust laws, have indicated that conduct usually deemed a per se violation, such as price-fixing, would be evaluated under a rule of reason analysis.[6] Such conduct, however, must be "reasonably necessary to accomplish the pro-competitive benefits of the integration."[7] Therefore, absent some form of system integration, Orchard would be best advised not to negotiate price terms on behalf of its affiliates,[8] or engage in any other possible per se violation.

Market Share

The determination of market share involves an analysis of the relevant product and geographic markets in order to assess whether the entities are competitors. Product market relates to the service components provided by Orchard (e.g., inpatient, outpatient, skilled nursing). For each of these service components or product markets, there is a geographic market. The geographic market for a service is the geographic boundaries within which the network effectively competes in providing that service. Thus, Orchard's market share for inpatient services may be different than its market share for skilled nursing care. Even within the scope of inpatient services, Orchard's market share for tertiary specialty services may be different than that of other inpatient services. The determination of market share is a complex undertaking usually involving the gathering and analysis of pertinent data by consultants.

The two hospitals in Orchard are located about 10 miles apart in the Westchester County area. Birch Hospital is described as a community hospital while Oak Medical Center is a 500-bed hospital. Therefore, it seems likely that the two hospitals would be competitors for at least some inpatient services. However, it is also likely, as the hospitals are located in the Westchester County area, that there would be other competing hospitals in close proximity, thereby providing consumers with alternatives. More information would be needed to determine Orchard's market share for its various services.

Financial Integration

The DOJ and FTC have identified two types of integration, financial and clinical, that might rise to the level of substantial integration that invokes the use of a rule of reason analysis. Financial integration would require that Orchard take on significant financial risk. The DOJ and FTC provide the following examples in which substantial financial risk could be shared between competitors:

- Agreement by the venture to provide services to a health plan at a "captitated" rate;
- Agreement by the venture to provide designated services or classes of services to a health plan for a predetermined percentage of premium or revenue from the plan;
- Use by the venture of significant financial incentives for its provider participants, as a group, to achieve specified cost containment goals; and
- Agreement by the venture to provide a complex or extended course of treatment that requires substantial coordination of care by physicians in different specialties offering a complementary mix of services, for fixed, predetermined payment, where the cost of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors.[9]

Additionally, the DOJ and FTC recently indicated that pay-for-performance arrangements may qualify as substantial financial risk for purposes of measuring financial integration.[10] Pay-for-performance arrangements create direct economic incentives, usually through reimbursement enhancements, to improve quality of care.

If Orchard were to engage in one of the risk sharing arrangements set forth above, or some other arrangement by which Orchard assumed substantial financial risk with a payer, negotiation of rates on behalf of its affiliates would be evaluated under a rule of reason analysis. It should be noted, however, that the rule of reason analysis would not necessarily apply to all of Orchard's rate negotiations, but only to those negotiations involving reimbursement where substantial financial risk would be undertaken.

Additional Financial Integration Factors

Several different factors may point toward financial integration in a health system other than those listed by DOJ and FTC in their "Statements of Antitrust Enforcement Policy in Health Care." For example, integration within Orchard could occur through:

- Unified benefit plans for employees;
- Unified insurance policies such as medical malpractice;
- A single Board of Directors;
- Shared medical staff;

- Unified employment of employees through the parent entity;
- Unified management of clinical services;
- Unified administrative functions such as billing, human resources, customer relations, and marketing;
- Unified credentialing through the parent entity; and
- Unified administrative policies, bylaws, and employment policies.

This list is not meant to be exhaustive, but rather just an indication of the types of functions that may be shared in a health system to more closely tie together the affiliates and lead to cost savings and other pro-competitive benefits. The more ties that are established among the affiliates of the parent to foster cost efficiencies, the more integrated the health system would be viewed.

With regard to Orchard, although each affiliate appears to have a separate Board of Directors, the same twelve persons serve on each Board. This is an important factor as the common boards, if they so desire, can exercise control over all of the affiliates and, therefore, require integrated activities such as those listed above.

Clinical Integration

Clinical integration of a multi-provider network such as Orchard would involve implementation of policies and protocols having a direct impact on the clinical practice of the network's participants. According to DOJ and FTC, to pass antitrust scrutiny, clinical integration must produce significant pro-competitive efficiencies and any anti-competitive conduct of the network must be related to the achievement of those efficiencies.[11]

The DOJ and FTC have indicated that clinical integration may be evidenced where a network's clinical program includes:

- Established mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care;
- Selectively choosing network physicians who are likely to further these efficiency objectives; and
- The significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.[12]

An FTC opinion letter dated February 19, 2002, provides additional information on what activities might be deemed substantial clinical integration. The FTC found that an Independent Practice Association (IPA), MedSouth, Inc., was unlikely to create significant anti-competitive effects as the IPA's clinical program would create substantial efficiencies.[13] MedSouth, Inc. intended to create these efficiencies by developing and implementing clinical protocols covering the majority of MedSouth's physicians, establishing measurable performance goals, making physicians commit to the goals and protocols, reviewing physician compliance with the goals and protocols, and expelling physicians not in compliance. MedSouth also proposed investing in and implementing a state-of-the-art information system that would allow MedSouth to collect and analyze data on individual physicians, and on performance of the network as a whole.

In a July 2004 report entitled "Improving Health Care: A Dose of Competition," DOJ and FTC discussed clinical integration in the context of physician joint ventures.[14] The report notes that commentators and industry experts have expressed four categories in which clinical integration may arise:

- The use of common information technology to ensure the exchange of all relevant patient data;
- The development and adoption of clinical protocols;
- Care review based on the implementation of protocols; and
- Mechanisms to ensure adherence to protocols.

The FTC and DOJ declined to give more specific guidance on clinical integration due to the risk of "channeling market behavior rather than encouraging market participants to develop structures responsive to their particular efficiency goals."[15] Thus, clinical integration presents an intriguing manner by which Orchard's affiliates could be integrated, one that would result not only in improved quality of care but also, potentially, in permissible joint negotiation of rates. However, clinical integration is a relatively new concept and there is a need for additional guidance from antitrust regulators.

Range of Health System Integration

Other than the "Statements of Antitrust Enforcement Policy in Health Care" issued by DOJ and FTC, little guidance exists to assess whether Orchard would be properly integrated for antitrust purposes. Case law provides few examples of application of antitrust principles to health systems.[16] However, some of the case law that does exist may serve as an illustration. *Healthamerica v. Susquehanna Health System*[17] and *Spitzer v. Saint Francis Hospital*[18] represent the two opposite poles of the health system integration spectrum.

Healthamerica represents a level of health system integration that exceeds what is anticipated by the DOJ and FTC "Statements of Antitrust Enforcement Policy in Health Care." In *Healthamerica*, Susquehanna Health System ("SHS"), a non-profit organization, was formed to manage the delivery of health services by Providence

Health System, North Central Pennsylvania Health System, and their affiliates.

Within SHS, there are three affiliated hospitals, two of which were competitors prior to formation of SHS. Upon formation of SHS, both Providence Health System and North Central Pennsylvania Health System retained their legal identity and ownership of their assets. However, the affiliates of SHS are required to receive the approval of SHS prior to purchasing or selling assets, or incurring capital indebtedness.

Moreover, SHS affiliated hospitals share a risk manager, a facilities manager, the chief nursing officer, a human resources department and policies, benefit plans, administrative policies, a compliance officer, operating budget, capital budget, and managers for clinical departments. SHS also handles all marketing and personnel matters, and employs all staff. The affiliate hospitals, however, pay for the salaries and benefits of the staff.

The court in *Healthamerica* found that the health system was so substantially integrated that it was essentially a single entity for antitrust purposes. Therefore, SHS could negotiate rates with payers on behalf of its affiliated hospitals. Additionally, the court stated that a rule of reason analysis would not be applied where antitrust liability was based on section 1 of the Sherman Act, as section 1 does not apply to unilateral conduct.

In contrast, *Saint Francis Hospital* provides an example of a health system that the court felt lacked sufficient integration to escape a per se price-fixing violation under the antitrust laws. A separate legal entity, Mid-Hudson Health, had been created to facilitate the provision of certain services on behalf of its affiliate hospitals, Vassar Brothers Hospital and St. Francis Hospital. Initially, Mid-Hudson, as a joint venture of the two hospitals, was empowered with authority to operate certain new clinical services. However, Mid-Hudson's role expanded over time to encompass the negotiation of rates on behalf of the hospitals and the allocation of services between the two hospitals. Mid-Hudson, unlike SHS, was not viewed by the court as an integrated health system. Both member hospitals of Mid-Hudson maintained their individual autonomy. The hospitals did not substantially unify their operations, create a single parent board, or unify their medical staffs.

Healthamerica and *Saint Francis Hospital* provide some guidance on the integration that is necessary for Orchard to negotiate rates on behalf of its affiliates. Orchard must provide tangible pro-competitive efficiencies similar to those in *Healthamerica*. This is not to say that Orchard must be a single entity. But to minimize antitrust liability, any restraint on competition imposed by Orchard should be related to providing the pro-competitive benefits intended by the health system.

New York State Factors

Orchard's potential antitrust liability also arises under New York State's Donnelly Act,[19] which was modeled after the Sherman Act and is generally applied in a similar fashion.[20] A different interpretation, however, will be given to the Donnelly Act where "State policy, differences in the statutory language, or legislative history justify such a result."[21] The Office of the Attorney General of the State of New York ("Attorney General") is charged with enforcing the Donnelly Act and can also bring actions under the federal antitrust laws (as was the case in *Saint Francis Hospital*). However, an important question with regard to any actions brought by New York's Attorney General is the extent to which the Attorney General feels compelled to follow the guidance issued by the FTC and DOJ. Such guidance constitutes federal advice and may not be binding on the state.

"There is little case law on health care antitrust enforcement by the Attorney General."

There is little case law on health care antitrust enforcement by the Attorney General. *Saint Francis Hospital* is the primary example. However, the Attorney General has investigated systems for antitrust violations. It has been reported that the Attorney General was investigating Long Island Health Network, an affiliation of eleven hospitals on Long Island that have implemented clinical integration.[22]

Any antitrust analysis of Orchard also needs to consider New York State's Certificate of Need laws. The facts presented do not state whether Orchard is the established operator under Article 28 of the Public Health Law of its affiliate hospitals and nursing homes (or under Article 36 of the Public Health Law in relation to its home care services agency). If Orchard has certain decision-making authority over its hospitals and nursing homes as specified in 10 N.Y.C.R.R. § 405.1(c), Orchard would need to receive establishment approval from the Public Health Council and would be considered an "active" parent.

While managed care contracting is not listed in 10 N.Y.C.R.R. § 405.1(c) as one of those decision-making authorities, the Department of Health ("DOH") has indicated that such activity might be considered of such importance as to be part of one of the listed decision-making authorities, approval of "hospital operating policies and procedures."[23] DOH's letter implies that since hospital parent entities that are "passive" do not have decision-making authority, such parents may not have the requisite authority to perform managed care

contracting. However, there have been no further pronouncements by DOH on this issue since the February 2002 letter.

"In general, the more aggressive Orchard is in implementing activities that by their nature are anti-competitive, the more Orchard needs to be integrated."

Nevertheless, a system that has an established operator for its components is more likely to be seen as exercising control that results in cost-efficient integration among the affiliates.

Conclusion

The discussion is intended to raise antitrust issues that Orchard may face, and provide an overview of how such issues should be analyzed. In general, the more aggressive Orchard is in implementing activities that by their nature are anti-competitive, the more Orchard needs to be integrated. The facts presented do not provide enough detail to ascertain the degree of integration within Orchard. However, without some form of integration that is more than superficial, whether that integration be through financial risk sharing, governance and administration, or clinical, Orchard would be best advised not to undertake activities such as negotiating rates on behalf of its affiliates.

Endnotes

1. *Healthamerica Pa., Inc., v. Susquehanna Health Sys.*, 278 F. Supp. 2d 423, 437 (M.D. Pa. 2003).
2. *See generally* John J. Miles, *The Importance of Integration in Healthcare Antitrust Counseling: Yakima and Susquehanna*, 8 Health Laws. News 17 (March 2004).
3. *Capital Imaging Assoc. P.C. v. Mohawk Valley Med. Assoc., Inc.*, 996 F.2d 537, 542 (2d Cir. 1993).
4. U.S. Dep't of Justice & Fed. Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care* 112 (August 1996) [hereinafter "*Policy Statements*"] (reprinted in Philip A. Proger, et al., Health Care Networks and Managed Care: Antitrust Aspects of Integration and Exclusion, 4701–4737 (BNA's Health L. & Bus. Series No. 2500 1999)), *also available at* http://www.ftc.gov/reports/hlth3s.pdf.
5. *Policy Statements*, *supra* note 4, at 123.
6. *Id*. at 107–108.
7. *Id*.
8. However, Orchard could have a role in negotiating rates through use of the messenger model.
9. *Id*. at 10.
10. Fed. Trade Comm'n & Dep't of Justice, *Improving Health Care: A Dose of Competition*, ch. 1, 25 (July 2004) [hereinafter "*Improving Health Care*"], *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.
11. *Policy Statements*, *supra* note 4, at 108.
12. *Id*. at 73.
13. Letter from Jeffrey W. Brennan, Ass't Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober, Kaler, Grimes & Shriver, *Advisory Opinion* for *MedSouth, Inc.* (Feb. 19, 2002), 2002 WL 463290, *available at* http://www.ftc.gov/bc/adops/medsouth.htm.
14. *Improving Health Care, supra* note 9, at ch. 2, 36–41.
15. *Id*. at 40.
16. Proger, *supra* note 4, at 204.
17. 278 F. Supp. 2d 423.
18. *Spitzer v. St. Francis Hosp.*, 94 F. Supp. 2d 399 (S.D.N.Y. 2000).
19. New York Gen. Bus. Law § 340 (McKinney 2004).
20. *New York v. Rattenni*, 81 N.Y.2d 166, 171, 597 N.Y.S.2d 280, 283, 613 N.E.2d 155, 159 (1993).
21. *Id*.
22. *See* Claude Solnik, *Attorney General Pursues Antitrust Investigation of Long Island Health Network*, Long Island Bus. News (July 11, 2003).
23. Letter from Dennis P. Whalen, Exec. Dep. Comm'r, N.Y.S. Dep't of Health, to Hosp. Adminstr., *Non Hospital Entities Execution of Managed Care Contracts on Behalf of Hospitals* (February 1, 2002).

Darrell E. Jeffers is a partner in the health law practice of the Albany office of Wilson, Elser, Moskowitz, Edelman & Dicker LLP. Mr. Jeffers represents health care providers in connection with the formation of affiliated entities, reimbursement issues, regulatory compliance, certification, managed care contracting, survey and enforcement actions, payment audits, and HIPAA privacy issues.

Jason LaFlam is an associate at Wilson, Elser, Moskowitz, Edelman & Dicker LLP, where he is a member of the firm's health law practice. He is a recent graduate of Albany Law School.

Tax Exemption Issues Faced by Orchard Health

By Michael Cooney and Anita Pelletier

Not-for-profit status under state corporate law does not by itself provide the benefits of tax-exempt status. Rather, each individual entity in the system must make application for, and continue to operate consistently with, exemption from federal income taxes, state franchise tax, state sales and use tax, real property tax, and so on. Each of these benefits acts to lower the cost of doing business, mitigating the not-for-profit form's lack of access to investment capital and stock option incentives. Furthermore, the interrelationship between and among the entities in the health care system impacts their qualification for tax-exempt status. The result is a complicated puzzle of relationships, in which a change in the corporate or regulatory status of any one entity can have a material impact on the exempt status of another, and vice versa. The Orchard Health system provides an example of how these concerns intersect in a basic health care system, consisting of a parent organization and several health care provider subsidiaries.

Federal Tax Exemption

Federal income tax exemption under Internal Revenue Code ("Code") § 501(c)(3) is the linchpin to other tax qualifications, also making the entity involved eligible to receive tax deductible contributions and bequests[1] and the proceeds of tax-exempt bonds.[2] In granting state or local tax exemptions, state taxing authorities often rely upon the existence of an Internal Revenue Service ("IRS") determination letter.

The Code provides, with certain limited exceptions, that an organization cannot attain exempt status under Code § 501(c)(3) unless it applies for recognition of exempt status on Form 1023, Application for Recognition of Exemption.[3] Regulations provide that the application must be made within fifteen months from the end of the month in which the organization was formed.[4] The exemption, once received, is retroactive to the date of incorporation. The exemption application and all accompanying materials (including the corporation's Certificate and Bylaws) must then be made available for public inspection.[5]

The exempt world of Code § 501(c)(3) entities divides itself into public charities and private foundations, the latter being subject to a higher level of regulatory scrutiny commonly avoided in the modern health care system.[6] For the purposes of our discussion, we presume that each entity in the Orchard Health system is a separate and distinct organization with its own tax-exempt status as described below[7]:

Entity	Tax-exempt Status	Public Charity Status
Orchard Health	Code § 501(c)(3)	Code § 509(a)(3)
Oak Medical Center	Same	Code § 170(b)(1)(A)(iii) and 509(a)(1)
Birch Hospital	Same	Code § 170(b)(1)(A)(iii) and 509(a)(1)
Oak Nursing Home	Same	Code § 509(a)(2)
Maplewood Nursing Home	Same	Code § 509(a)(2)
Orchard Homecare	Same	Code § 509(a)(2)

Common requirements

Each tax-exempt organization in the system must meet both an organizational and an operational test to qualify under Code § 501(c)(3). The organizational test requires that the entity be separately organized as a corporation, fund, trust or other form of eligible organization; the not-for-profit corporation is the most common form.[8] The entity's organizational documents must include specific language regarding the exempt purposes for which it was formed, be they charitable, scientific or educational.[9] The purposes clause is thus vitally important from a corporate, regulatory and tax perspective. New or amended purposes must be analyzed from each viewpoint.

The organizational documents must also include specific language providing that no part of the organization's net earnings may inure to the benefit of a private individual or shareholder, the entity will not engage in political activities, and lobbying will be restricted.[10] The governing documents must also contain specific language regarding the transfer of assets upon dissolution.[11] In a multi-corporate system such as this one, it is common to designate the parent entity as the recipient of assets on dissolution of the operating entities.

This last point has garnered great attention from the Attorney General's Charities Bureau in New York State, and has its corollary in the tax law as well. Similar to the *cy pres* doctrine, the IRS requires tax-exempt organizations to expend funds solely for its exempt purposes. Any changes in such purposes must be reported to the

IRS on the organization's annual Form 990 filing. Because of this limitation, it is also important that the operating entities in the system also provide in their Certificates the corporate authority to support the general activities of the health care system, which are then described in the exemption process with the IRS. In the past, advisors to health systems would regularly request a private letter ruling covering each of the entities in the system to assure this continuity of purpose to support the entire system, as well as to permit transfers of assets within the system, borrowings on behalf of all system members, and so on. This practice is less prevalent now, but the issues remain important ones to resolve.

"Different types of health care organizations must meet different requirements in order to qualify for tax-exempt status."

The operational test focuses on the organization's activities. The Code requires that tax-exempt entities be operated exclusively for charitable purposes,[12] though the Regulations use a **primarily** engaged test.[13] An organization will not meet this test if more than an insubstantial part of its activities are not in furtherance of its exempt purposes. Once again, it is essential that the activities of the entity, especially as described in communications to the public and its Board minutes, relate directly to the accomplishment of an exempt purpose. This relationship will be clearly drawn in the corporation's exemption application, and should persist throughout its existence.

With that general understanding, we now turn to the basis for exemption for each of the entities within the Orchard Health system. Different types of health care organizations must meet different requirements in order to qualify for tax-exempt status.

Hospitals

The promotion of health is not an exempt purpose described in Code § 501(c)(3). Accordingly, in order for the two acute care hospitals in the system to gain and retain exempt status they must rely on the IRS rulings equating the promotion of health with purely charitable purposes.[14] Even physician-controlled clinics can achieve exempt status as long as these charitable requirements are met.

The specific requirements for a hospital to qualify as a tax-exempt organization have evolved over the years. Initially, the IRS required the following:

(a) the hospital must be organized as a non-profit charitable organization for the purpose of caring for the sick;

(b) its operations must include care for those unable to pay or pay at a reduced rate to the "extent of its financial ability" and it cannot refuse to care for those who cannot pay for such services;

(c) it cannot restrict use of its facilities to a specific group of doctors (e.g., medical partnerships or associations), but limitations due to the size of the facility may be imposed; and

(d) net earnings cannot inure to the private benefit of a shareholder or individual.[15]

In a 1969 ruling, the IRS held that a hospital qualified as a Code § 501(c)(3) organization even though it operated at a surplus, provided charity care only to the extent that its emergency room was open to all persons, and limited general admissions to those able to pay the costs either directly or through third-party reimbursement. This ruling effectively removed the specific requirement for charity care. Rather, the IRS will look at whether the hospital has a community board, whether it has a defined policy for granting admission privileges to doctors, and whether members of the community are benefited as a whole by the hospital.[16]

The hospitals in this system should identify the particular bases upon which they qualify for exemption; they may differ even as between the two facilities. They are then well-advised to have an annual review of those points by their governing Boards, and a recital of them annually in their Form 990 information returns, filed with the IRS and available to the public.

Hospitals have been subject to a long-running debate about whether their exempt status should be tied specifically to the provision of charity care, even to the extent of tying the availability of various exemptions to the amount of charity care provided in a particular time period.[17] Currently, no such federal legislation has been enacted, nor does any exist in New York State.

The hospitals qualify for public charity status because their principal purpose is providing medical or hospital care.[18] As such, contributions to hospitals are tax deductible, subject to specified limits.[19]

Nursing homes

Nursing homes are subject to a dramatically different standard under the tax laws, even though the regulatory regime in New York considers them to be closer to acute care hospitals. In some instances, it may be possible to qualify a nursing home as a hospital under federal tax law. Generally speaking, nursing homes are

considered under the broad category of elder care facilities, which can also accommodate lower levels of care from a regulatory perspective.

In order to be considered tax-exempt, a nursing home must operate in a manner designed to satisfy the three primary needs of the elderly: housing, health care, and financial security.[20]

The need for housing is generally met if the home provides residential facilities specifically designed to meet the physical, emotional, recreational, social, religious and similar needs of the elderly. The need for health care is met if the home either directly or indirectly provides some form of health care to maintain the physical, and if necessary, the mental well-being of its residents. The need for financial security (i.e., the aged person's need for protection against the financial risks associated with later years of life) is met if two conditions exist:

- the home establishes a policy (written or used in actual practice) for allowing residents who become unable to pay regular charges to maintain residency at the home through use of the home's own funds, obtaining funds from government welfare units or soliciting funds from a sponsoring organization, members or the general public; and
- the home operates so it provides its services at the lowest feasible cost.

Nursing homes that accept Medicaid and Medicare funds will meet the financial security requirements.[21] Otherwise, a nursing home must establish a fund to meet this requirement. In the health care system, this fund might be held at the individual nursing home entity, within the parent, or even a separate foundation. It is important, however, that the fund be restricted for the specific purpose of providing funds to allow residents to remain in residence at the nursing home, regardless of their ability to pay.

The nursing homes qualify for public charity status under Code § 509(a)(2) based upon their income, which must come from a broad cross-section of the public and not from investment income. This is in contrast to hospitals, which earn public charity status based upon what they do. Nursing homes in New York State often easily meet this standard, though for smaller or better endowed facilities it is important to review the test annually in conjunction with the filing of the entity's IRS Form 990 information return.

Home health care

The IRS treats a home health care organization similarly to a hospital. Such organizations provide home nursing and therapeutic care and serve the health needs of a community that hospitals have traditionally met.[22] The IRS will look to the following factors:

- low-cost home health care on a non-profit basis;
- services available to the general public;
- organization qualified as a "home health agency" under the Social Security Act;[23]
- professional nursing services and other therapeutic services provided to patients in their homes based on courses of treatment prescribed by physicians; and
- most of the organization's receipts come from the Social Security Administration in the form of payments made on behalf of patients.[24]

New York State provides for two types of home care agencies: licensed home care service agencies and certified home health agencies.[25] Presence of tax-exempt status is not part of either process.

Like the nursing homes, the home care agency will qualify for public charity status under Code § 509(a)(2) based upon receipts.

Parent organization

From a corporate and regulatory perspective, the parent organization of Orchard Health system is superior to its operating affiliates—electing Boards, controlling budgets and so on. From a tax perspective, however, the system is turned on its head and the parent is considered a "supporting organization" to the operating entities within the system. In this sense, the exempt status of the parent is purely derivative, dependent on the exempt activities of those entities of which the parent is sole corporate member or otherwise controls.[26]

The corporate purposes of the exempt parent organization will be to oversee the health care system, provide planning and other resources on a coordinated and consolidated basis so as to improve the quality or costs of services. From an IRS perspective, the parent must act as an integral part of the health care organizations, indicated by the parent's actual power to direct and control its subsidiary organizations. An organization qualifies as tax-exempt under Code § 501(c)(3) if it is controlled by a hospital and provides a function that the hospital could perform directly because it is consistent with its exempt purpose.[27] This integral-part test will become important as well when looking at transactions between the parent and its affiliated corporations.

The parent organization must also be concerned with qualifying as other than a private foundation under Code § 509(a). Generally, such organizations will qualify as supporting organizations under Code § 509(a)(3). Once again, supporting organization status is

derivative from the public charity status of one or more related charities,[28] classified under Code § 509(a)(1) or (a)(2).[29]

For Orchard Health to qualify as a supporting organization, it must be "supervised or controlled in connection with" its supported organizations. This requires the control or management of Orchard Health to be with the same individuals who control or manage the individual health care organizations.[30] This requirement is generally met if a majority of Orchard Health's Board consists of Board members from its supported organizations. If there is an overlap of less than a majority, then there must be a sufficient number of common members to clearly show that each supported organization can ensure that the supporting organization will be responsive to its needs or demands and will be an integral part of its operations. Whether or not the overlap is sufficient is based on all of the facts and circumstances of the relationship.[31]

Orchard Health's Certificate of Incorporation must also identify the organizations it will support. It can either specifically name these organizations, or it can identify a class of supported organizations, obviating the need to future amendment.[32] This might be accomplished by providing that Orchard Health "will support the activities of any organization for which it is the sole member providing that such organization is tax-exempt under Code § 501(c)(3) and not a private foundation under Code §§ 509(a)(1) or (2)."

Conflicts of interest

The IRS has concerns similar to those of the state Attorney General when it comes to conflicts of interest.[33] The prohibition against private inurement and the limitations on private benefit make a clear and well-functioning conflict of interest policy essential. Having such a policy will allow Board members to make decisions objectively without undue influence by individuals with private interests in a transaction. The IRS requires tax-exempt organizations to adopt and follow a conflict of interest policy, including the following:

- a requirement that an interested party must disclose his/her financial interest in a transaction, as well as all material facts relating to the transaction;[34]
- procedures for determining whether a financial interest results in a conflict of interest;
- procedures for addressing a conflict of interest, such as requiring the interested party to leave the meeting where the transaction is being discussed, appointing a disinterested person/committee to review alternatives, requiring a majority of disinterested directors to approve the transaction by vote after a determination that the transaction is in the organization's best interests and is fair and reasonable, and taking necessary disciplinary and corrective actions when the policy is violated;
- procedures for adequate record-keeping, including making sure that Board and committee minutes include a thorough record of discussions relating to such transactions including individuals present during the discussions, the results of any votes, and the names of individuals present both during the discussion and vote;
- procedures to ensure that all Board members and officers receive a copy of the policy, including a signed acknowledgment that the individual has received, read, understands and agrees to comply with the policy; and
- procedures for applying the policy to compensation decisions.

The same concerns that arise under the corporate law about Board members serving on the governing Board of more than one entity within a health care system need to be considered from a tax perspective.

Unrelated business income tax

Being tax-exempt under Code § 501(c)(3) does not automatically shelter all income received by the entity. Rather, net income from a trade or business regularly carried on which is unrelated to the exempt function of the charity is subject to unrelated business income tax ("UBIT") at regular corporate rates, both federal and state.[35] The annual Form 990 information return requires each entity to break out sources of income and designate whether they are related or not. There are also certain exceptions to this UBIT rule, especially the "convenience exception" for patient care[36] and the "passive income exceptions,"[37] which are important to keep in mind when structuring services or deals.[38] Further, the presence of debt-financing can cause certain income to be subject to UBIT even where an exception might otherwise apply.[39]

The Orchard Health system needs to consider UBIT issues not only with respect to the individual entities within the system, but also with respect to services rendered between the exempt entities or for another provider's patients. Orchard Health, for example, may provide a range of services to the entities within the system, whether directly or by contracting out to a third party. Any net income from these services to the parent entity should ideally be considered related to its exempt purposes, and thus not subject to UBIT.[40] In this regard it is important to be aware of the special exemption for cooperative hospital service organizations, which is limited as to the services involved,[41] the way in which the entity is operated,[42] and the potential beneficiaries.[43]

Code § 501(e) should be generally avoided if the system and its parent are correctly established.[44]

For-profit subsidiaries

One issue not presented by the Orchard Health system is the creation of a for-profit subsidiary. Generally, for federal income tax purposes, a parent corporation and its subsidiary organizations are treated as separate for tax purposes as long as the subsidiary carries on business activities.[45] The IRS has stated that the activities of a subsidiary will be attributed to a parent only when there is evidence to clearly show that the subsidiary is "merely a guise" to allow the parent to carry out prohibited purposes or where the subsidiary acts as an agent of the parent.[46] Such evidence must be clear and convincing.

Therefore, if a for-profit subsidiary is created, it is important to maintain its separate existence. In order to ensure separate organizational structures, Orchard Health should maintain separate bank accounts, contracts, Board meetings and minutes, and so on. The capitalization of the subsidiary also has a trap for the unwary, in that the deductibility of interest expense to the parent for a loan of working capital may result in UBIT at the parent level.[47]

Reasonable compensation

Code § 501(c)(3) provides general requirements concerning the use of charitable assets and the payment of only reasonable amounts in pursuit of charitable purposes. There is a specific provision, however, dealing with compensation and other benefits to certain control persons which needs to be taken into account. Also, in the context of a health system, compensation paid to individuals employed by more than one entity must be considered cumulatively.[48]

The Code provides that a tax will be imposed on "excess benefit" transactions with disqualified persons.[49] "Excess benefit" in this context looks to a similar standard for unreasonable compensation arising in the general business tax context.[50] The penalty excise tax is imposed on both the disqualified person and the managers who approved the transaction. A disqualified person for these purposes is an individual in a position to exercise "substantial influence" over the affairs of an organization at any time during the five-year period before the transaction was entered into.[51] Family members and 35% controlled entities of such persons are also considered disqualified persons.

Orchard Health and its subsidiaries are well-counseled to establish as part of their governance process a structure for the review by independent Board members of the compensation of disqualified persons within the system. The establishment of such a structure and the appropriate documentation of its actions provides the Board with certain burden-shifting benefits under the tax law, as well as good arguments under the corporate law as to the appropriateness of compensation. Remember that compensation includes all forms of cash and non-cash compensation, including salaries, fees, bonuses, and severance payments. It also includes all other compensatory benefits, whether or not included in gross income for income tax purposes, including payments to welfare benefit plans (such as plans providing medical, dental, life insurance, severance pay and disability benefits), and most taxable and nontaxable fringe benefits.

New York State Franchise Tax and Sales and Use Tax Exemptions

Organizations that are exempt from federal tax under Code § 501(c)(3) also qualify for exemption from New York State franchise tax and sales and use tax.[52] A franchise tax exemption application is submitted to the New York State Tax Department, Corporation Tax Division, on Form CT-247. A sales and use tax exemption request is submitted on Form ST119.2 to the Taxpayer Service Division - Exempt Organization, New York State Tax Department.[53]

New York State Real Property Tax Exemptions

New York State Real Property Tax Law provides an exemption from real property taxation for real property "owned by a corporation or association organized or conducted exclusively for religious, charitable, hospital, educational, or moral or mental improvement of men, women or children purposes, or for two or more such purposes, and used exclusively for carrying out thereupon one or more of such purposes either by the owning corporation or association or by another such corporation or association . . ."[54] To qualify for the exemption, an organizational and use test must be met.

The property must be owned by a "corporation or association" organized for one or more of the eligible purposes enumerated in the statute and used exclusively for carrying out one or more of such purposes. For leased or subleased properties, each entity in the lease chain must be organized for one or more of the eligible purposes and either own real property that is exempt from taxation or, if it owned real property, such property would be exempt from taxation. Finally, rent payments for leased property may not exceed the carrying, maintenance and depreciation charges allocable to such property, including debt service on any mortgages encumbering such property.

Because the determination of exemption is done at the local level and the standard under New York law is sometimes different from that under Code § 501(c)(3),

local assessors have met with some success in challenging real property exemptions, particularly for elder care facilities.[55] Once again, the system is well-counseled to establish clearly the basis for its exempt status and act within those parameters.

Endnotes

1. Code §§ 170(b)(1)(A)(iii), 170(b)(1)(A)(viii), 2055(a)(2), 2522(a).
2. Code § 103.
3. Code § 508(a).
4. Reg. § 1.508-1(a)(2)(i). An automatic twelve month extension will also be extended. Reg. § 301.9100-2.
5. Code § 6104(a).
6. The qualifications for public charity status are set forth in Code § 509(a). A newly formed entity may enjoy an advance determination letter as to its public charity status, though it is still an exempt entity under Code § 501(c)(3).
7. Other exemptions are available, including those for quasi-governmental entities under Code § 115, title-holding companies under Code § 501(c)(2), and hospital cooperative service entities under Code § 501(e). Health care systems that include for-profit subsidiaries or investments have additional concerns, described later in this article.
8. Note that it is possible to create a separate limited liability company without any of the organizational prerequisites described here, and still have that entity qualify for tax-exempt status as long as its sole member is a Code § 501(c)(3) organization. The separate tax status of the LLC is disregarded for federal income tax purposes, but not for state law liability purposes. Announcement 99-102, 1999-2 C.B. 545.
9. Code § 501(c)(3).
10. There is a strict prohibition against public charities engaging in political activity. However, public charities may engage in lobbying activities so long as such activities do not constitute a "substantial part" of the charity's activities. The "substantial part" test is a subjective one measuring levels of lobbying activity (including volunteer activity) and so is not easily defined. Determining the level of permitted lobbying activity is especially important because a public charity can lose its tax-exempt status and be subject to excise taxes and penalties if the level is exceeded. Often, charities will make an election under Code § 501(h), which provides a level of certainty to the lobbying analysis.
11. Examples of the specific language required are provided in IRS Publication 557, Tax-Exempt Status for Your Organization.
12. Code § 501(c)(3); Reg. § 1.501(c)(3)-1(a)(1).
13. Reg. § 1.501(c)(3)-1(c).
14. Rev. Rul. 69-545, 1969-2 C.B. 117 states that the promotion of health, education, and research has long been recognized as a charitable purpose. The presence of education (community or academic) and research also bolsters the exempt status of the hospitals.
15. Rev. Rul. 56-185, 1956-1 C.B. 202.
16. Rev. Rul. 69-545, 1969-2 C.B. 117. However, it should be noted that a hospital may have charity care obligations if it receives certain types of federal funding.
17. *See* Charity Care and Hospital Tax-Exempt Status Reform Act, H.R. 790, 102d Cong., 1st Sess., 137 Cong. Rec. E395-97 (1991).
18. Code §§ 509(a)(1) and 170(b)(1)(A)(iii).
19. Code § 170(b)(1)(4)(iii).
20. Rev. Rul. 72-124; 1972-1 C.B. 145.
21. *Id*.
22. Rev. Rul. 72-209, 1972-1 C.B. 148.
23. 42 U.S.C. § 1395x(o).
24. 42 U.S.C. § 1395x(m).
25. N.Y. Public Health Law §§ 3605 and 3606.
26. The IRS will also review whether an organizational structure is created to circumvent Code § 501(e). The Supreme Court has held that Code § 501(e) is the exclusive provision under which cooperative service organizations can obtain tax-exempt status. *HCSC—Laundry v. United States*, 450 U.S. 1 (1981). Therefore, when several hospitals control a parent organization, the provisions of Code § 501(e) must be met by the parent and subsidiary organizations and any organizations providing services not specifically provided under Code § 501(e) cannot qualify for exempt status.
27. Rev. Rul. 78-41, 1978-1 C.B. 148 (providing that a trust fund created to cover medical malpractice claims was tax-exempt because it was an integral part of a tax-exempt hospital).
28. Reg. § 1.509(a)-4(g) contemplates a relationship where the supported organization is the parent and the supporting organizations are the subsidiaries.
29. Code § 509(a)(3). For example, it is not possible to have a supporting organization of a supporting organization.
30. Reg. § 1.509(a)-4(h)(1).
31. A more common and easily maintained relationship is the "operated, supervised or controlled by" test under which the parent entity appoints or elects the Board members of each of the subsidiary operating entities.
32. Reg. § 1.509(a)-4(d)(2)(b).
33. A complete discussion of conflict of interest policies, including a sample policy, may be found in the IRS CPE article, *Tax-Exempt Health Care Organizations Community Board and Conflicts of Interest Policy*, available at http://www.irs.gov/pub/irs-tege/topic-c.pdf. The sample policy has certain shortcomings, however, and should not be relied upon as a final product.
34. Consonant with the requirements of current New York Not-for-Profit Corporation Law § 715 ("N-PCL").
35. Code § 511(a).
36. "Unrelated trade or business" does not include any trade or business which is carried on, in the case of an organization described in Code § 501(c)(3), by the organization primarily for the convenience of its members, students, patients, officers or employees. Code § 513(a)(2). This exception also applies to services such as a cafeterias, gift shops and pharmacies.
37. Code § 512(b) provides that income from the following sources is excluded from UBIT: dividends, interest, payments relating to securities loans, consideration received for entering into certain types of agreements, royalties, rents (subject to certain exceptions as provided in Code § 512(b)(3)), and gains or losses from the disposition of stock in trade or inventory.
38. There is also a $1,000 specific deduction from UBIT. Code § 512(b)(12).
39. Code §§ 512(b)(4) and 514.
40. Reg. § 1.502-1(b) sets forth some of the discussion with respect to the "integral part" standard. This allows what would be otherwise non-exempt activities if considered on their own (e.g., accounting services) to be deemed part of a larger exempt function where the requisite element of control is present.
41. Services are limited to: data processing, purchasing, warehousing, billing and collection, food, clinical, industrial engineering, laboratory, printing, communications, record center, and personnel services (i.e., selection, testing, training and education). Code § 501(e)(1)(A).

42. All net earnings get paid out on a cooperative basis. Code § 501(e)(2).
43. Services must be performed for two or more hospitals. Code § 501(e)(1)(B).
44. Code § 513(e) also provides an exception for services to small hospitals (serving not more than 100 inpatients) provided at actual cost, including straight line depreciation and a reasonable amount for return on capital goods. This exception is still limited to the list of services set forth in Code § 501(e)(1)(A), however.
45. *Moline Properties, Inc. v. Comm'r*, 319 U.S. 436 (1943); *Britt v. United States*, 431 F.2d 227, 234 (5th Cir. 1970) (holding that where a corporation is organized for a bona fide business function its existence may not be disregarded for tax purposes); *Krivo Industrial Supply Co. v. National Distillers and Chemical Corp.*, 438 F.2d 1098 (5th Cir. 1973) (holding that where a parent corporation so controls the affairs of a subsidiary that it is merely an instrumentality of the parent, the corporate entity of the subsidiary may be disregarded).
46. GCB 33912, I-2782 (Aug. 15, 1968); see also GCM 35719, I-67-73 (March 11, 1974) (holding that acts of a taxable company controlled by a foundation are not attributable to the foundation).
47. Code § 512(b)(13).
48. *See, e.g.*, Reg. § 53.5948-4(a)(2)(iv), Ex. 3.
49. Code § 4958.
50. Code § 4958(b)(1).
51. Code § 4958(f)(1).
52. N.Y. Tax Law § 1116(a)(4); 20 N.Y.C.R.R. § 1-3.4.
53. Form CT-247 is available at http://www.tax.state.ny.us/pdf/2003/fillin/corp/ct247_803_fill_in.pdf. Form ST119.2 is available at http://www.tax.state.ny.us/pdf/1997/st/ST119_2_797_fill_in.pdf.
54. N.Y. Real Property Tax Law § 420-a.
55. *Greer Woodcrest Children's Services v. Fountain*, 138 A.D.2d 709 (2d Dep't 1988), *aff'd*, 74 N.Y.2d 749 (1989); *Belle Harbor Home of Sages, Inc. v. Tishelman*, 81 A.D.2d 886 (2d Dep't 1981).

Michael Cooney is a partner of Nixon Peabody, and Anita Pelletier is an associate of the firm. Both are located in the firm's Rochester office, and both concentrate on matters relating to nonprofit and educational organizations and their corporate governance, fundraising, state regulation and taxation.

Anti-Kickback and Stark Law Issues Faced by Orchard Health

By Robert Belfort

One of the chief goals of health systems such as Orchard Health is to promote clinical integration among a group of health care providers that are under common ownership or control. By creating a continuum of care for their patients that may include community hospitals, tertiary care facilities, nursing homes, physician organizations, home health agencies and durable medical equipment suppliers, health systems ideally seek to improve the coordination of health services, promote quality care and save money.

In implementing their vision of clinical integration, however, health system executives must be careful that they do not treat transactions and other financial relationships among the system's facilities as mere internal bookkeeping matters without substantial legal consequence. The inclination to do so is not surprising. The system's management may view each facility as if it were a division of a single, integrated company, dismissing the system's actual corporate structure as a legal formality of little practical significance. Unfortunately, the system's corporate structure may be quite significant from a fraud and abuse standpoint. As a result, the radar that sophisticated health care executives have developed for detecting potentially problematic financial relationships with outside referral sources must also be activated when contemplating transactions among the system's facilities.

"An anti-kickback analysis is necessary whenever referrals of government health care program business flow from one person or entity to another and remuneration of any kind flows back in the other direction."

The Broad Reach of the Anti-kickback Statute

The federal anti-kickback statute prohibits any person from knowingly or willfully offering, paying, soliciting or receiving remuneration in any form in return for the referral of patients for, or the recommending or arranging of, the purchase, lease or ordering of items or services covered by Medicare, Medicaid or other federal health care programs. A violation of the statute is a felony and may also be punished by the imposition of civil monetary penalties and program exclusion.[1]

An anti-kickback analysis is necessary whenever referrals of federal health care program business flow from one person or entity to another and remuneration of any kind flows back in the other direction. Given the web of financial arrangements among the facilities and practitioners of most health systems, it is not surprising that these threshold criteria are met frequently in a system such as Orchard Health. To provide only a few examples, arrangements within the Orchard Health system that might raise anti-kickback issues include:

- The purchase of new medical equipment by well-endowed Oak Medical Center for financially struggling Birch Hospital to enable Birch to better diagnosis certain complex medical cases that are then referred to Oak Medical Center for treatment;
- The provision of information technology services and administrative staff by Birch Hospital to Orchard Homecare; and
- The deficit financing of chronically money-losing Oak Nursing Home by Orchard Health, with funds transferred up to Orchard Health by Oak Medical Center.

The Absence of a Safe Harbor for Integrated Delivery Systems

In an effort to circumscribe the exceptionally broad reach of the anti-kickback statute, the U.S. Department of Health and Human Services Office of Inspector General (the "OIG") has promulgated a number of safe harbors.[2] While compliance with a safe harbor is not mandatory, satisfying all of the required elements of a safe harbor will insulate an arrangement from prosecution under the anti-kickback statute.

Many Orchard Health executives probably assume there is some type of safe harbor covering transactions between two or more entities that are under common control. This is not the case. Indeed, in 1999, the OIG explicitly considered and ***rejected*** the creation of a safe harbor for integrated delivery networks. In conjunction with issuing a final rule establishing several new anti-kickback safe harbors, the OIG noted that it had been asked by several commenters on the proposed rule to create additional safe harbors "to protect and encourage the development of integrated health care delivery systems . . ." These commentators urged, in particular, that safe harbor protection be granted for "payments

between wholly-owned entities, including parent entities and their wholly-owned subsidiaries."[3]

In response to these comments, the OIG reiterated prior guidance that "the anti-kickback statute is not implicated when payments are transferred within a single legal entity, for example, from one division to another . . ." However, the OIG expressly refused to extend anti-kickback protection to affiliated, but separately incorporated legal entities. In this regard, the OIG stated:

> We are concerned, however, that integrated delivery systems, including arrangements involving wholly-owned subsidiaries, may present opportunities for the payment of improper financial incentives that result in overutilization of services and increased program costs and that may adversely affect quality of care and patient freedom of choice among providers. This is primarily of concern where payment by the Federal health care programs is on a fee-for-service basis, as may occur, for example, with a hospital's referrals to a wholly-owned home health care agency . . . Accordingly, we do not anticipate providing safe harbor protection for integrated delivery systems and arrangements between wholly-owned entities at this time.[4]

As a result, compliance with the anti-kickback statute may hinge on the seemingly incidental fact of whether the facilities involved in a transaction are part of the same legal entity. If so, referrals between the facilities are "self-referrals" that are not subject to the statute. If not, the mere fact that the facilities are owned or controlled by the same parent entity does not insulate the arrangement from anti-kickback scrutiny and transactions between the facilities must be analyzed on a case-by-case basis.

It is true that there have been no high-profile anti-kickback prosecutions to date based on financial relationships between health system affiliates. This has led many in the health care industry to assume that such relationships present a low level of risk. While this may be the case, in the past, the federal government has demonstrated its willingness to challenge arrangements that reflect widespread industry practices previously thought to pose little compliance risk, as is evident from the PATH audits and the investigation of drug company marketing practices. As a result, facilities that are part of systems such as Orchard Health cannot assume that their transactions are completely outside the reach of the anti-kickback law.

Potentially Applicable Safe Harbors

Safe harbor protection is most likely to be available for transactions in which one member of a health system is purchasing items or services from another. The OIG has issued safe harbors for real property and equipment leases as well as personal and management services contracts, all of which require, among other things, that:

- The term of the agreement is at least one year;
- The aggregate cost of the items or services is fixed in advance;
- The payments for items or services do not vary with the volume or value of referrals between the parties; and
- The payments are consistent with fair market value.[5]

It is generally advisable for facilities within a health system to purchase items and services from one another under arrangements that fall within one of the safe harbors described above. To the extent there is a desire to provide financial support to a facility purchasing or providing items or services to another facility within the system, it is usually best to find other mechanisms for achieving this goal rather than hiding subsidies within a lease or services agreement.

There are many financial arrangements within a health system, however, that do not involve the purchase of items or services. The purpose of these arrangements may be to flow economic support from one member of the system to another, making fair market value principles inapplicable. Such arrangements present special challenges under the anti-kickback law.

Analyzing Relationships Outside the Safe Harbors

The question that must be asked of any arrangement that falls outside the safe harbors is whether the parties intend remuneration to serve as an inducement for referrals. Analyzing the unwritten and possibly unspoken intention of parties is always a difficult task. This is particularly true under the anti-kickback law because of the "one purpose test," which makes a transaction illegal even if only one of multiple purposes behind the remuneration was to induce referrals.[6]

Under this standard, how would one analyze the arrangement suggested above, under which Oak Medical Center provides free medical equipment to Birch Hospital to enable the Hospital to diagnose cases that will be referred to the Medical Center for treatment? Is the absence of a quid pro quo (i.e., the equipment in return for the referrals) sufficient? Does it make a difference if the equipment is provided under a system-wide quality improvement plan adopted by Orchard Health?

Does it matter if a nearby competitor of Oak Medical Center is generally recognized as more effective than Oak at providing the referred service? Is it relevant that Birch Hospital is struggling financially? How is each facility's intent determined if the many individuals within each facility who are involved in the transaction each have different reasons for pursuing the transaction?

One approach to addressing these uncertainties is for Orchard Health, a mere holding company that does not receive referrals, to provide financial support to the other members of the system, avoiding the direct provision of remuneration between facilities exchanging referrals. Orchard Health, however, is not an operating entity and may have to rely on its member facilities for most of its funds. Should the scenario described above be analyzed any differently if Oak Medical Center transfers funds up to Orchard Health, which then purchases the equipment for Birch Hospital? Does it matter if there is a separation in time between these two actions or if the amount transferred by Oak Medical Center to Orchard Health is part of a regular surplus distribution rather than a one-shot pass-through payment?

There are no certain answers to these questions. Absent a change in the law, systems such as Orchard Health will simply have to do their best to structure inter-corporate transactions in a manner that minimizes anti-kickback risk or explore alternative ways of providing financial support to needy facilities.[7]

Stark Law Issues

The Stark Law prohibits physicians from referring patients for certain designated health services reimbursed by Medicare or Medicaid to entities with which they have a financial relationship.[8] Under the Stark Law, conduct is illegal unless it is covered by an exception; the intent of the parties is irrelevant. Stark violations are punishable with civil monetary penalties and program exclusion but not criminal sanctions. [9]

Although the "bright line" nature of Stark Law compliance precludes well-intentioned arrangements that do not fit within an exception, with respect to intra-health system transactions, satisfying the Stark Law is likely to be much easier than addressing anti-kickback concerns. This is primarily due to the fact that the Stark Law, unlike the anti-kickback statute, applies only to referrals by physicians; it does not directly cover referral relationships among the institutional components of a health system.

It is true that, to the extent an institution's referrals are being directed by physicians, the Stark Law is implicated. In most cases, though, referring physicians do not have a direct ownership interest in, or compensation arrangement with, other system facilities to which they refer patients.[10] The Stark regulations *do* make it clear that a financial relationship may be indirect.[11] For example, a physician employed by Birch Hospital would have an indirect financial relationship with Oak Medical Center if the Medical Center provides economic support to Birch. However, the Stark rule's definition of an indirect compensation arrangement is largely devoured by the rule's indirect compensation exception. This exception protects compensation received by a referring physician if, among other things, the compensation is consistent with the fair market value of the physician's services and does not take into account the volume or value of any referrals or other business generated by the referring physician for the facility receiving referrals.[12] It is rare that a physician's compensation will be linked to the volume or value of referrals made by the physician to another facility. As a result, the indirect compensation exception should cover most inter-facility referral relationships within a system such as Orchard Health.

The Stark regulations also make it clear that a health care facility may require a physician, as part of an employment agreement or personal services contract, to refer patients for designated health services to other entities with which the facility is affiliated. This does not constitute compensation impermissibly based on the volume or value of referrals as long as the referrals are within the scope of the arrangement (e.g., the requirement does not cover unrelated private practice referrals), the requirement advances legitimate purposes behind the arrangement, the physician can make exceptions for medical necessity and the patient's freedom of choice is preserved.[13] Although there is less explicit regulatory guidance on this point, directing the referrals of employed or contracted physicians to affiliated entities is probably consistent with the anti-kickback statute as well if the employment or personal services contract otherwise satisfies a safe harbor.[14]

Policy Arguments and Continuing Concerns

There is a forceful public policy argument to be made that transactions among affiliated entities generally should not be subject to the anti-kickback statute. Underlying this argument is the principle that a group of entities under common control are fundamentally no different in their economic activities than a single legal entity, and that a parent organization should not be restricted by the anti-kickback statute from shifting funds from one entity to another, in much the same way a single corporation allocates resources across its divisions, to maximize the effectiveness of the entire system. Moreover, to the extent particular transactions among affiliated entities, such as referrals by hospitals to home health agencies or durable medical equipment suppliers, raise special fraud and abuse concerns, these

transactions can and have been subject to special statutory restrictions.

Unfortunately, the OIG has shown no sign of accepting this argument. The OIG has not reversed its 1999 decision or even suggested in advisory opinions or otherwise that the matter is under reconsideration.

"[H]ealth systems should continue to tread carefully to avoid running afoul of the fraud and abuse laws while achieving their economic and clinical goals."

This leaves systems such as Orchard Health in the difficult position of assessing transactions among their affiliated institutions, many of which cannot be fit within any safe harbor, on a case-by-case basis. As a result, health systems should continue to tread carefully to avoid running afoul of the fraud and abuse laws while achieving their economic and clinical goals.

Endnotes

1. 42 U.S.C. § 1320a-7b; 42 C.F.R. § 1003.102.
2. 42 C.F.R. § 1001.952.
3. 64 Fed. Reg. 63520 (November 19, 1999).
4. *Id.*
5. 42 C.F.R. § 1001.952(b), (c) and (d).
6. *See, e.g., United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).
7. For example, Orchard Health might raise charitable funds through a related foundation that is not an operating entity, and use the foundation rather than Oak Medical Center as a source of financial support for other system facilities.
8. 42 U.S.C. § 1395nn. Designated health services are clinical laboratory services, radiology, radiation therapy, durable medical equipment, prosthetic and orthotic devices, home health care, physical therapy, outpatient prescription drugs, occupational therapy, parenteral and enteral nutrients, and inpatient and outpatient hospital services.
9. *Id.*
10. To the extent physicians refer patients to facilities in which they have a *direct* financial relationship, such as a joint venture entity owned by a hospital and the physician, the Stark analysis is likely to be more complicated.
11. An indirect financial relationship exists if (i) there is an unbroken chain of financial relationships from the physician to the facility receiving the referral, (ii) the aggregate compensation received by the physician varies with or otherwise reflects the volume or value of referrals or other business generated between the parties and (iii) the facility has actual knowledge, or acts in reckless disregard or deliberate ignorance, of the fact that the physician receives such compensation. 42 C.F.R. § 411.354(c)(2).
12. 42 C.F.R. § 411.357(p).
13. 42 C.F.R. § 411.354(d)(4).
14. This assumes, however, that the physician is providing bona fide clinical or administrative services and is not merely being paid for referrals. *See, e.g.*, OIG Advisory Opinion No. 98-9 (July 13, 1998). If the employee or contractor is being paid solely for referrals, at least one court has opined that the safe harbor is not applicable. *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998).

Robert Belfort is a partner of Manatt, Phelps & Phillips, LLP.

DOH Regulatory Issues Faced by Orchard Health

By Francis J. Serbaroli and Aielleen Fajardo

During the past fifteen years, the economics of health care in New York has undergone dramatic and far-reaching changes. Among other things, the rise of managed care, the deregulation of inpatient hospital rates, and the encouragement of greater competition where little or none previously existed have forced health care institutions to rethink their strategies. Many institutions that had been steadfastly independent entered into mergers, were taken over, or became part of larger systems. In most of these situations, the institutions involved have followed the law and regulations applicable to such consolidations and obtained state approval. But in a few instances, systems formed under a so-called "passive" parent corporation have been actively managed by the parent to the point that they are probably violating state law and regulations.

"In assembling its system, Orchard Health presumably expects to strengthen its various provider organizations through improved quality of care, integration of services, and greater cost savings."

To help distinguish between active and passive parent corporations, this article will analyze the regulatory implications of the hypothetical not-for-profit corporation, Orchard Health. Orchard Health faces a wide range of varied and complex regulations as the common parent of its various providers: Oak Medical Center, a hospital (which itself is the parent corporation of Oak Nursing Home), Birch Hospital, Maplewood Nursing Home, and Orchard Homecare.

The threshold issue is whether Orchard Health itself must be licensed under the New York Public Health Law in order to function as the parent of these several licensed entities. The distinction between an "active" and "passive" parent is determined by state regulations enumerating activities that constitute the active operation of a hospital under Article 28. Further guidance as to whether a parent non-profit corporation is "active" is found in state regulations that specify the powers of a governing authority to operate a certified home health agency or licensed home care services agency under Article 36 of New York Public Health Law ("PHL"), and from pre-merger reporting requirements under federal antitrust statutes.

"Active" vs. "Passive" Parent

In assembling its system, Orchard Health presumably expects to strengthen its various provider organizations through improved quality of care, integration of services, and greater cost savings. As an integrated system, it may gain a better negotiating position with HMOs, managed care organizations, and other third-party payors. Moreover, bringing its multiple providers together would enable it to create a joint obligor group to seek more advantageous credit and financial options.

As a "passive" parent, Orchard Health would have little or no ability to take on the central decision-making power to accomplish these goals. Instead, it would have very limited authority, such as the ability to appoint the governing body of its affiliated licensed providers. On the other hand, instead of having to rely upon the voluntary cooperation of its affiliates, Orchard Health may want to be an "active" parent with the ability to exercise centralized powers and to implement programs and policies to accomplish system-wide goals. The corresponding advantages and disadvantages are clear. As a "passive" parent, Orchard Health would not be subject to licensure and regulation by the New York State Health Department. But as an "active" parent, Orchard Health would be so directly involved in the operation of its affiliated licensed providers that the Health Department could hold Orchard and its governing board and officers accountable for problems or deficiencies that may occur at the provider level.

Oak Medical Center and Birch Hospital

Article 28 of PHL governs the licensure and regulation of hospitals, hospices, nursing homes, diagnostic and treatment centers, ambulatory surgery centers, and certain other health care facilities (collectively referred to in the PHL as "hospital") and sets forth the requirements for their establishment and incorporation. Hospitals and operators of hospitals must first file "certificate of need" ("CON") applications with the Department of Health. These applications are reviewed by Department staff according to criteria such as financial feasibility, the "character and competence" of the proposed operator, the need for such a facility in the community and so on. The Health Department staff forwards the application along with the Department's recommendation to the State Hospital Review and Planning Council, which in turn reviews these materials and makes its own recommendation. The application then is submitted to the

New York State Public Health Council ("PHC"), which has the final say on any establishment application.[1] CON approval must be obtained for the establishment of any hospital and to file the certificate of incorporation of any business or not-for-profit corporation whose purpose is to establish or operate a hospital, or to solicit contributions for such purpose.[2] In addition, CON approval is required for a change in the operator of a hospital.[3]

The question as to what constitutes the "operation" of a hospital arises when a not-for-profit corporation, such as Orchard Health, seeks to become either the "passive" or "active" parent of an Article 28 licensed facility. A hospital's not-for-profit corporate parent must be licensed under Article 28 when it is an "active" rather than a "passive" parent. If a corporation is an "active" parent, it will be considered an operator of the hospital.[4]

Health Department regulations enumerate specific actions that constitute hospital operation. For example, 10 N.Y.C.R.R. § 405.1(c) provides that an entity is an operator of a hospital if it has decision-making authority over any of the following:

> (1) appointment or dismissal of hospital management-level employees and medical staff, except the election or removal of corporate officers by the members of a not-for-profit corporation;
>
> (2) approval of hospital operating and capital budgets;
>
> (3) adoption or approval of hospital operating policies and procedures;
>
> (4) approval of certificate of need applications filed by or on behalf of the hospital;
>
> (5) approval of hospital debt necessary to finance the cost of compliance with operational or physical plant standards required by law;
>
> (6) approval of hospital contracts for management or for clinical services; and
>
> (7) approval of settlements of administrative proceedings or litigation to which the hospital is party, except approval by the members of a not-for-profit corporation of settlements of litigation that exceed insurance coverage or any applicable self-insurance fund.

If Orchard Health satisfies these criteria or is otherwise found to have "active" control in these areas, it will be considered a hospital operator, and therefore must seek Article 28 establishment approval to operate its hospital affiliates. Moreover, any management contract with an Article 28 licensed facility must be submitted for approval by the Commissioner of Health.[5]

Moreover, under the Health Department's regulations, a hospital must maintain management control over its operations.[6] This mandate is also reflected in 10 N.Y.C.R.R. § 600.9(d), which states:

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

In essence, a hospital may not turn over control of its management to a party that has not received PHC approval.[7] Therefore, if a parent corporation seeks to act as a contract manager of a hospital, it must be licensed under Article 28.[8]

The regulations also prohibit the sharing of revenues for providing health-related services between an Article 28 licensed entity and a non-licensed entity.[9] Therefore, if an Article 28 licensed hospital shares any of the revenue that it receives for health-related services with its corporate parent, the parent must also be licensed under Article 28. As a result, Orchard Health, as the parent corporation of its providers, must be licensed under Article 28 to be a hospital operator if it intends to share in the revenues of any of its affiliated Article 28 licensed entities.

Orchard Homecare

Article 36 of the PHL governs the licensure and regulation of home care services agencies and sets forth the

requirements for their establishment and approval. A "home care services agency" is an organization primarily engaged in providing or arranging for the provision of nursing services, home health aide services, and other therapeutic and related services.[10] Article 36 requires any licensed home care services agency or certified home health agency[11] to receive written approval from the PHC.[12] The CON application to establish such an entity must also be reviewed by the Hospital Review and Planning Council before it can receive the written approval of the PHC.[13] PHC approval must also be obtained for any change in the operator or owner of a licensed home care services agency or certified home health agency.[14] Only an agency licensed under PHL § 3605 or certified under PHL § 3608 can hold itself out as a home health services agency, a home health agency, or a home care services agency.[15]

A "governing authority" or "operator" is the policy-making body of a government agency (in the case of a municipally owned provider), or the board of directors or trustees of a corporation, or the proprietor or proprietors of a proprietary facility, agency or program to which the department has issued an operating certificate, certificate of approval, or license.[16] PHC approval under Article 36 is necessary when an unlicensed entity acts as the "operator" or is otherwise the "governing authority" of a licensed home care services agency or certified home health agency. As with hospital operation, what will count in whether Orchard Health acts as an "operator" or "governing authority" of Orchard Homecare is whether Orchard Health behaves as an "active" parent—specifically, whether Orchard Health is engaging in the activities specified as active operation of an agency under Article 36 and 10 N.Y.C.R.R. §§ 763.11, 763.12, 763.14, 766.9, 766.10, 766.11 and 766.12. If Orchard Health satisfies these criteria, it will be considered an "active" as opposed to "passive" parent of Orchard Homecare and consequently will be required to obtain Article 36 establishment.

If Orchard Homecare is an approved Medicare provider, it is classified as a certified home health agency.[17] Like a hospital, a certified home health agency must maintain control over its operations. For example, the "governing authority" of a certified home health agency must, among other things:

> (1) ensure compliance of the agency with the applicable federal, state and local statutes, rules and regulations;
>
> (2) ensure adequate personnel resources to effectively conduct administrative functions of the agency and provide care in the home;
>
> (3) adopt the agency's budget, control assets and funds, and provide for annual fiscal audits;
>
> (4) prohibit personnel paid directly by the agency from being reimbursed by any party other than the agency for services provided by the agency;
>
> (5) prohibit the splitting or sharing of fees between a referral agency, facility, individual or other home care services agency and the agency;
>
> (6) adopt and amend policies regarding management and operation of the agency and the provision of patient care services;
>
> (7) enter into agreements and contracts, where applicable, to provide agency services or to assure services needed by the agency;
>
> (8) ensure the development and implementation of a patient complaint procedure; and
>
> (9) ensure that, at least annually, an overall evaluation of the agency's program is conducted.[18]

In addition, the governing authority of a certified home health agency may not delegate its responsibility for operating the agency to another organization, a parent or subsidiary corporation or through a management contract, except when such a contract has received the prior written approval of the Commissioner of Health.[19] An improper delegation may be found to exist where the governing authority no longer retains authority over the operation and management of the agency.[20] A management contract will not be approved if the governing authority does not retain sufficient authority and control to discharge its responsibility as the certified operator, as set forth in 10 N.Y.C.R.R. § 763.11(d)(3). This provision prohibits delegating the following elements of control to a managing authority:

> (1) direct independent authority to hire or fire the administrator;
>
> (2) independent control of the books and records;
>
> (3) authority over the disposition of assets and the authority to incur on behalf of the agency liabilities not normally associated with the day-to-day operation of an agency; and

(4) independent adoption of policies affecting the delivery of health care services.

Other activities that are considered operation of a home health agency are found in 10 N.Y.C.R.R. § 763.12 (entering into contracts) and 10 N.Y.C.R.R. § 763.14 (control over medical and business records).

If Orchard Homecare is not a certified Medicare provider but is a licensed home care services agency, then similar regulations require it to retain control of its operations. For example, 10 N.Y.C.R.R. § 766.9 requires that the governing authority or operator, as defined in Part 700 of this Title, of a licensed home care services agency:

> (a) be responsible for the management and operation of the agency;
>
> (b) ensure compliance of the home care services agency with all applicable Federal, State and local statutes, rules and regulations; . . .
>
> (m) ensure that any management contract complies with the following: . . .
>
> (m)(2) . . . Management contracts shall include the following: . . .
>
> (iii) a provision which states that notwithstanding any other provision of the contract, the governing authority retains:
>
> (a) direct, independent authority to hire or fire the agency's administrator or manager;
>
> (b) independent control of the agency's books and records;
>
> (c) authority over the disposition of assets and authority to incur on behalf of the agency liabilities not associated normally with the day-to-day operation of the agency; and
>
> (d) authority for the independent adoption and enforcement of policies effecting the delivery of health care services.

Furthermore, a contract with another entity to manage the agency must be approved by the Commissioner of Health.[21] Approval will be granted only if the governing authority retains sufficient control to discharge its responsibilities as the agency operator and does not delegate the four elements set forth above.[22]

As in the hospital situation, if Orchard Health engages in these activities or is otherwise found to have "active" control over any of the areas described in these sections regarding the operation of a certified home health agency or home care services agency, it will be considered Orchard Homecare's governing authority, and therefore must seek Article 36 establishment and approval from the PHC to operate Orchard Homecare.[23]

Federal Pre-Merger Reporting Requirements

In the course of creating a health care system, what is sometimes overlooked are the New York State regulatory implications of representations made in the course of federal antitrust review. These arise most often during Hart-Scott-Rodino review. The Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act") was enacted to require a thirty-day pre-merger notification to the Federal Trade Commission and the Department of Justice for transactions satisfying three criteria.[24] One of the criteria is the "size of the transaction" inquiry, which requires that the transaction result in the acquiring party holding either (1) 15% of either the voting securities or assets of the acquired party, or (2) voting securities and assets of the acquired party with a total aggregate value of $15 million or more.[25] If the transaction passes either one of these criteria, it must be reported unless one of the exceptions in the HSR Act applies.[26]

"In the course of creating a health care system, what is sometimes overlooked are the New York State regulatory implications of representations made in the course of federal antitrust review."

In assembling its system, Orchard Health may satisfy the HSR Act's requirements as the "acquiring party" if it attains a significant degree of control over any one of the licensed providers under the "size of the transaction" inquiry. If such control is accompanied by some of the activities enumerated in the regulations, it is quite possible that Orchard Health, as the "acquirer for HSR purposes," could also be seen as an operator for PHL establishment purposes. In addition, the HSR Act's use of "acquiring" and "acquired" to describe the parties to the proposed transaction implies that the resulting organization will be one in which the acquiring party has an "active," as opposed to "passive," role in the management of the acquired party, thus making the acquiring party a *de facto* operator requiring licensure under PHL Article 28 and Article 36.

Summary of "Active" vs. "Passive" Parent Powers

If Orchard Health is engaging in any of the activities outlined by state regulations it will probably be

considered an "active" parent. The application of antitrust and corporate law can also mean that being an "acquirer" or a "dominant" or "controlling" parent demonstrates that Orchard Health is an "active" parent that needs establishment approval under Article 28 and Article 36 to operate its affiliates.

An "active" parent has management control over the day-to-day operations of its affiliates, including but not limited to: approval of capital and operating budgets; appointment or approval of the CEO; adoption or approval of a facility's operating policies and procedures; approval of CON applications submitted by the facility; approval of facility debt; approval of facility management contracts; and approval of litigation settlements. A "passive" parent has a much lesser role limited to such functions as: serving as the corporate member; appointing trustees; approving amendments to corporate bylaws; recommending that the affiliate consider adopting policies and procedures; and making recommendations regarding strategic direction, compliance, legal services and administrative support services.

Endnotes

1. *See* N.Y. Public Health Law § 2801-a(1).
2. *Id.*
3. *See* PHL § 2801-a(4)(a).
4. Under these regulations, an active parent equals a hospital operator.
5. 10 N.Y.C.R.R. § 505.3(f)(2).
6. *See* 10 N.Y.C.R.R. §§ 405.2, 405.3.
7. *See id.*
8. *See id.*
9. *See* 10 N.Y.C.R.R. § 600.9(c) ("An individual, partnership or corporation which has not received establishment approval may not participate in the total gross income or net revenue of a medical facility.").
10. *See* PHL § 3602(2); 10 N.Y.C.R.R. § 700.2(6).
11. A certified home health agency can be a Medicare provider; a licensed home health care agency cannot. *See* PHL §§ 3602(3); 3608(1); 10 N.Y.C.R.R. § 700.2(7).
12. *See* PHL §§ 3605(2), 3606(1).
13. *See* PHL §§ 3605(3), 3606(2).
14. *See* PHL § 3611-a.
15. An agency may be exempt from this requirement if it provides personal care or home care services exclusively to individuals pursuant to a program administered, operated or regulated by another state agency. *See* PHL § 3619.
16. 10 N.Y.C.R.R. § 700.2(c)(8).
17. If it is not a Medicare provider, then it is classified as a licensed home care services agency. In either situation, state regulations contain similar provisions for the operation of a home health agency and a home care services agency.
18. *See* 10 N.Y.C.R.R. § 763.11.
19. 10 N.Y.C.R.R. §§ 763.11(c) and (d)(2).
20. 10 N.Y.C.R.R. § 763.11(c).
21. 10 N.Y.C.R.R. § 766.9(m)(2).
22. 10 N.Y.C.R.R. § 766.9(m)(3).
23. If an entity wishes to apply for Article 36 approval for operation of a certified home health agency, the requirements are enumerated at 10 N.Y.C.R.R. §§ 760.2 through 760.10 (application, requirements and general information), 10 N.Y.C.R.R. § 760.11 (non-profit corporation), 10 N.Y.C.R.R. § 760.12 (business corporation), 10 N.Y.C.R.R. § 760.13 (transfer of interest by persons or partnerships), 10 N.Y.C.R.R. § 760.14 (transfer of stock), 10 N.Y.C.R.R. § 760.15 (other acquisition of control not covered by §§ 760.13 and 760.14). For any of these arrangements, however, New York regulations require that the entity applying for approval demonstrate to the PHC that it is "of such character, competence, and standing in the community as to give reasonable assurance" of its ability to conduct its affairs in the best interests of the agency/applicant and "in the public interest" and to provide "proper care for those to be served by the certified home health agency." 10 N.Y.C.R.R. § 760.3(b).

    If an entity wishes to apply for Article 36 licensure for operation of a home care services agency, the provisions are enumerated at 10 N.Y.C.R.R. § 765-1.10 (non-profit corporation), 10 N.Y.C.R.R. § 765-1.12 (business corporation), N.Y.C.R.R. § 765-1.13 (transfer of stock), or § 765-1.14 (other arrangement). As with home health agencies, the regulations require similar standards for character, competence, and standing in the community. 10 N.Y.C.R.R. § 765-1.3(b).
24. *See* 15 U.S.C. § 18a. The first criterion is the "in-commerce" test, which requires that one of the parties to the transaction be engaged in interstate commerce or in an activity affecting interstate commerce. *See* 15 U.S.C. § 18a(a)(1); Jonathan Choslovsky, *Agency Review of Health Care Industry Mergers: Proper Procedure or Unnecessary Burden?*, 10 Admin. L.J. Am. U. 291, 300 (1996). The second criterion is the "size of the parties" test which requires one of the parties to have annual net sales or total assets of $100 million or more and the other party to have net sales or assets of $10 million or more. *See* 15 U.S.C. § 18a(a)(2)(A)-(C); *Id.*
25. *See* 15 U.S.C. § 18a(a)(3).
26. *See* 15 U.S.C. § 18a(c).

Francis J. Serbaroli is a partner in the 20-attorney Health Care Not-for-Profit Practice Group at Cadwalader, Wickersham & Taft, LLP in New York City. He writes a regular Health Law column for the *New York Law Journal*, and is the author of *The Corporate Practice of Medicine Prohibition in the Modern Era of Health Care*, published by BNA.

Aielleen Fajardo is a litigation associate at Cadwalader.

Disclaimer: Francis J. Serbaroli serves as a member and Vice Chairman of the New York State Public Health Council. The views expressed and any statutory and regulatory interpretations included in this article are the author's, and do not necessarily represent the views of the Public Health Council or the Department of Health.

Privacy/HIPAA Issues Faced by Orchard Health

By Anne Maltz

A. Introduction

If the application of HIPAA[1] to a single covered entity seemed complex and cumbersome, HIPAA's application to a health care system will seem absolutely Byzantine. The primary goals of the HIPAA regulations are to protect the individually identifiable health information of patients/protected health information ("PHI") by significantly restricting the manner in which covered entities use and disclose such information and to simplify the process of claims administration. The primary goals of a health care system are to facilitate long-term relationships with patients by offering a continuum of services and to increase efficiency and reduce expenses through centralization of administrative functions. The potential benefits of the health care system presuppose the ability to share PHI freely. If the health care system's HIPAA compliance effort is structured to take advantage of available definitions, within HIPAA, these conflicting approaches to sharing PHI can be reconciled such that both the health care system and HIPAA's goals can be met.

The HIPAA privacy regulations ("Privacy Regulations")[2] offer two organizational configurations that may be used in combination to effectuate the goals of HIPAA and support the sharing of information within a health care system ("HCS"): the affiliated covered entity ("ACE") and the organized health care arrangement ("OHCA").[3]

B. The Affiliated Covered Entity ("ACE")

According to the Privacy Regulations, legally separate covered entities may designate themselves as a single covered entity if all of the covered entities are under common ownership or control.[4] Such an entity is known as an affiliated covered entity ("ACE"). Common ownership is present if an entity or entities possess an ownership or equity interest of five percent or more in another entity.[5] Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.[6] The benefit of the ACE designation is that all covered entities within the HCS may use or share PHI within the ACE as if they are a single covered entity. The ACE structure permits maximum information exchange and is therefore better suited for use in a highly integrated health care system than the organized health care arrangement.

Orchard Health is composed of eight separate covered entities: Oak Medical Center, Oak Nursing Home, three primary care sites, Maplewood Nursing Home and Orchard Homecare ("Orchard Providers"), plus a corporate entity that does not provide health care services. The latter entity, the corporate parent, provides centralized administrative services to the covered entities.

The Orchard Providers are each covered entities,[7] because each is a health care provider that transmits health information in connection with an electronic transaction (electronic claims submission). The Orchard Providers are under the common control of Orchard Health. In fact, each Orchard Provider has the same board of directors as the parent Orchard Health. It is clear that the Orchard Providers fit within the ACE configuration. The status of Orchard Health itself as it relates to the ACE is more difficult.

Orchard Health is the corporate parent; it does not provide health care services. It does provide administrative services for the HCS. These centralized administrative services likely include utilization review, quality assurance, legal, accounting, and billing. Ideally it would be most convenient, for the flow of PHI, if Orchard Health could be part of the ACE. Whether or not this is permissible turns on whether it is a covered entity. It is already established that Orchard Health is not a health care provider, and based on the description in the hypothetical it is not a health plan. We must consider whether it fits the definition of health care clearinghouse. A health care clearinghouse means a public or private entity, including a billing service, that does either of the following functions:

> 1. Processes or facilitates processing of health information received from *another* entity in a nonstandard format . . . into standard data elements.
>
> 2. Receives a standard transaction from *another* entity and processes or facilitates the processing of health information into nonstandard format . . . for the receiving entity.[8]

If Orchard Health is part of the ACE and is providing HIPAA compliant billing services to the Orchard Providers, it is providing services to itself, not "another." Therefore it does not meet the definition of a health care clearinghouse and cannot be part of the ACE.

What status can Orchard Health take? It cannot be part of an organized health care arrangement ("OHCA") because OHCA membership presupposes covered entity status.[9] Its only viable choice is to be a

business associate of the ACE. The ACE will be required to issue a business associate agreement to Orchard Health. This document will identify all of the business associate's responsibilities and level of access to PHI, and must meet the requirements of the business associate agreement.[10] Orchard Health is a health care clearinghouse with respect to its claims administration function. It is thoroughly obligated to be a fully compliant covered entity. As a business associate, it must also be in compliance with HIPAA with respect to the other administrative services it performs for the ACE.

C. The Organized Health Care Arrangement ("OHCA")

The ACE should consider extending OHCA status to non-employee physicians, who are also covered entities, who hold privileges with the covered entities composing the ACE. To qualify as an OHCA, one of two scenarios must be present, either: 1) a clinically integrated setting in which individuals receive health care from more than one health care provider; or 2) an organized system of health care in which more than one covered entity participates and in which the participating covered entities "hold themselves out in a joint arrangement, and participate in joint action activities that include at least utilization review, quality assurance or financial risk sharing.[11]

One benefit of OHCA status is that the ACE and the privileged physicians can adopt a joint privacy notice for ACE related activities. This simplifies the notice of privacy practices ("Notice") process; such privileged physicians need not obtain a Notice each time they treat a new patient in the ACE. The privileged physician is required to issue a separate Notice reflecting the HIPAA compliance practices of his or her private office. Please note, in addition to the standard Notice requirement,[12] the OHCA Notice must identify which covered entities are to be included. A reference to non-employee, privileged physicians would be an adequate reference to the physicians. The Notice should also indicate that PHI will be shared among the members of the OHCA.

D. What does this HIPAA configuration mean for day-to-day operations of the ACE?

1. **Documentation**: The fact of the ACE designation must be documented; preferably in the board minutes of each ACE component as well as a central location. Such records must be maintained pursuant to the HIPAA record keeping requirements.[13]

2. **Privacy Officer**: The ACE is a single covered entity and must designate a single privacy officer with responsibility for development and implementation of HIPAA policies and procedures.[14] That being said, the manner in which the ACE implements HIPAA is flexible. Given the scope, size, and complexity of the HCS, a privacy team with representation from each component covered entity should be established. This should assure that the compliance manual and notice is relevant to all members of the ACE and will facilitate training, implementation, and audit. The ACE could delegate the privacy officer function to its business associate, Orchard Health. This choice has the virtue of centralizing the role and avoiding conflict among the ACE components.

3. **Privacy Notice**: The ACE will issue a single privacy notice that will remain valid when a patient transfers from one covered entity within the ACE to another.

4. **Implementation Strategy**: The ACE will have to determine the level of decentralization with which it is comfortable. The ACE will likely choose to develop ACE-wide policies and procedures including a single authorization and the patient's rights policies: right to inspect, amend, accounting, etc. While the design process may be centralized through the privacy committee, much of the implementation is likely to be locally administered. For example:

   - Medical records reside and are controlled at each covered entity. If a patient exercises his or her right to inspect at one covered entity, the request may be handled locally. If the patient was seen at more than one covered entity, the request may be handled centrally.

   - The notice must clearly identify an office to receive complaints. It is critical to handle a complaint quickly to avoid escalation to an external complaint. For this reason, a local complaint office that has an obligation to report centrally is an important feature of the ACE.

   - Training and audit could be decentralized with oversight. In order to achieve greater objectivity the component covered entities could audit each other.

5. **PHI "Use"**: The ACE's use[15] of PHI must comply with the minimum necessary rule.[16] In this regard, the relationship of each covered entity to its board of directors is of particular importance. There is rarely an instance where PHI may be properly shared with board members. Where, as here, the board members are also board members of a non-covered entity, albeit a business associate, the ACE should be particularly careful not to disclose PHI to board members. The board must of course receive HIPAA training.

6. **PHI "Disclosure"**: The ACE's disclosures[17] must comply with HIPAA. The ACE will have to assess its current disclosure pathways to determine how it will handle future disclosures. For example, it is likely that each covered entity will continue to make decisions logically regarding treatment, payment and health care operations, as well as routine public health, and JCAHO disclosures. The ACE may centralize government review and court-ordered or attorney-requested disclosures.

7. **Marketing and Fundraising**. To the very limited extent marketing[18] and fundraising[19] are permissible under HIPAA, the ACE could certainly develop a single marketing and fundraising plan and thereby send general newsletters to all patients of the ACE. While a single fundraising plan would be permissible, fundraisers usually focus on a more direct relationship between the entity and the patient. HIPAA does not permit fundraising by diagnosis but does permit fundraising to all covered entity current and former patients. The regulations are silent on whether components of an ACE may fundraise on a component basis. We would argue that since the regulations deem an entity-wide fundraising campaign permissible, because it was sufficiently non-patient specific and did not require the release of PHI, it is reasonable to conclude that it would still be a permissible activity for ACE components to conduct.

8. **Discipline**. It will be important to create a uniform policy for discipline of employees who violate HIPAA. If an employee or a privileged physician is disciplined, it must be centrally documented for HIPAA tracking purposes and locally documented in the disciplined individual's file. Such information should be considered if and when the individual is changing positions or seeking renewal of privileges.

9. **Research**. If possible, research should be centrally administered through one or two IRBs with the same standards. The IRB will need to address such issues as whether a researcher can choose candidates from the entire ACE and what level of access will researchers have to PHI prior to obtaining an executed authorization from the patient.

10. **Electronic Transactions and Code Sets Regulation**: The ACE business associate arrangement allows the ACE to submit electronic transactions[20] in non-standard format to Orchard Health. The ACE saves money by avoiding duplication in computerized enhancements to its legacy systems. In addition, by using a clearinghouse that is likely not seeking a profit, it is saving additional funds.

11. **Security Regulations**: In contrast to the privacy regulations that apply to PHI in any form, the Security Regulations,[21] with a compliance deadline of April 15, 2005, apply only to PHI transmitted or maintained in electronic media. The Security Regulations contain the same definitions of ACE, Hybrid, and OHCA as are present in the Privacy Regulations. Orchard Health and the Orchard Health Providers can centrally undertake the required risk analysis. The results of the analysis, which will include the variety of legacy systems, the level of risk and risk tolerance, and the amount of available funds, will dictate the level of centralized HIPAA compliance Orchard Health will be able to achieve.

Endnotes

1. The Administrative Simplification section of the Health Insurance Portability and Accounting Act of 1996, 42 U.S.C. § 1320d, has so far spawned three final regulations: the Privacy Regulation relating to the protection of medical information, electronic transactions and code sets regulation and the security regulations. Additional regulations are not in final form and will not be discussed herein.
2. 45 C.F.R. §§ 160, 164.
3. Another configuration, the hybrid entity, is not applicable to the Orchard Health fact pattern because it presupposes a single entity whose covered functions are not its primary function. 45 C.F.R. § 164.504(d). At Orchard Health, covered functions are the primary functions.
4. 45 C.F.R. § 164.504(d).
5. 45 C.F.R. § 164.504(a).
6. 45 C.F.R. § 164.504(a).
7. 45 C.F.R. § 160.103.
8. 45 C.F.R. § 160.103 (emphasis added).
9. 45 C.F.R. § 164.501.
10. 45 C.F.R. § 164.504(e).
11. 45 C.F.R. § 164.501.
12. 45 C.F.R. § 164.504(e).
13. 45 C.F.R. § 164.530(j).
14. 45 C.F.R. § 164.530.
15. 45 C.F.R. § 164.501.
16. 45 C.F.R. § 164.514(d).
17. 45 C.F.R. § 164.501.
18. 45 C.F.R. § 164.514(e).
19. 45 C.F.R. § 164.514(f).
20. 45 C.F.R. §§ 160, 162.
21. 45 C.F.R. §§ 160, 162, 164.

Anne Maltz is an attorney with Herrick Feinstein in New York City, and practices health care law. She has written and lectured extensively on HIPAA.

Medical Staff Issues Faced by Orchard Health

By Robert Wild, Leonard Rosenberg and Colleen McMahon

Introduction

The Orchard Health Care System includes two hospitals, two nursing homes and a home care agency. Oak Medical Center is a corporation comprised of two operating entities—a hospital (Oak Medical Center) and a nursing home (Oak Nursing Home). Birch Hospital and the other nursing home (Maplewood Nursing Home) are separate corporate entities.

An examination of the medical staff issues inherent in the Orchard Health System must start with the structure of the System and the structure of the medical staff of each of the components of the System.

Under New York law, a hospital is licensed under Article 28 of the Public Health Law and is issued an operating certificate[1] that specifies the types of services the hospital is authorized to provide. The term "hospital" includes a general (acute care) hospital, nursing homes, and various free-standing outpatient facilities, e.g., clinics and ambulatory surgery centers.[2] Assuming that the Oak Medical Center, Birch Hospital, Oak Nursing Home and Maplewood Nursing Home are separately "licensed" entities, each facility would be required to have a medical staff that meets the requirements for credentialing, re-credentialing, quality assurance, performance improvement and peer review (collectively Peer Review). Moreover, each hospital's licensing status is subject to the ongoing review of applicable state and federal agencies, including the state Health Department, CMS, and third-party accrediting bodies such as the Joint Commission on Accreditation of Health Care Organizations ("JCAHO").

To determine whether the component health facilities of Orchard Health can or should engage in System-wide medical staff activities, as opposed to individual medical staff activities, depends upon a legal analysis, economic considerations and the practicalities of carrying out these functions on a System versus an individual entity basis.

Credentialing

Recognizing that the two hospitals and the two nursing homes (we will omit the home care entity from this discussion) each has a medical staff, each facility thereby has the obligation to comply with legal requirements to conduct Peer Review.

Under Article 28 of the Public Health Law each independently licensed health facility in New York is required to have in place a system to determine the credentials of each member of the medical staff, and to determine the appropriate privileges to be granted to individual physicians based upon their training, experience and demonstrated competence.[3] In addition, ongoing review of a hospital's quality assurance programs, including physician credentialing, by accrediting agencies such as JCAHO, is a prerequisite to receipt of federal funds under Medicare and Medicaid.[4]

A "system wide" credentialing process may, in part, provide a means by which individual facilities can reduce the costs attendant to the credentialing process, but the legal requirements applicable to the individual licensee remain in full force and effect. Some systems use a centralized "primary source verification" process. Primary source verification refers to obtaining the basic information applicable to a practitioner to determine:

- Medical school education;
- Internships and residencies;
- Board eligibility and certification;
- Hospital affiliations;
- Malpractice insurance history and any reported matters to the National Practitioner Data Bank;
- Any matters reported to the Office of Professional Medical Conduct, New York State Department of Health.

While a health care system could utilize a centralized approach for primary source verification, the state Health Department has indicated its view that each individual facility must have a full "file" on each practitioner and that file must be readily available to the Health Department upon demand. Thus, while some centralized credentialing activities would be permitted by the Health Department, a central repository for the information to the exclusion of the maintenance of such information at each licensed facility would not be acceptable.

Although the issue will be discussed later, the use of any centralized system requires specific policies and agreements to be put in place to deal with the issues of confidentiality attendant to the credentialing process.[5] By developing an "agency" relationship between the centralized credentialing entity (presumably the System itself or a related entity) and the individual licensed facility, the confidentiality provided by the Education

Law, the Public Health Law and case law should be preserved.

Privileges

Privileges and credentialing are two different issues. A physician may be credentialed by verifying the individual's background, training and experience, but the question of what clinical privileges should be granted to that physician depends upon not only the individual's qualifications, but also the structure of the health care facility in question, as well as its needs.[6] Hospitals are generally set up along departmental lines (e.g., medicine, surgery, obstetrics and gynecology, pediatrics, radiology, pathology, etc.). Nursing homes tend to have a more limited structure.

Despite a centralized credentialing process, if any, privileges would normally be granted on an institution-by-institution basis (again, assuming individually licensed facilities which make up the System). Thus, a practitioner, even within the same System, might have varying privileges from one facility to another. This does not necessarily mean that the practitioner's skills are evaluated differently by the System components, although that is possible. Rather, the services offered by the facility and its internal structure may require different privileges from that of another facility within the System.

For example, if one System facility, such as Oak Medical Center, performs coronary-bypass surgery but another member of the System does not, a surgeon skilled in this field might have coronary bypass surgical privileges at the Medical Center but might have more limited surgical and vascular privileges at the sister hospital. By the same token, one member of the System might have an exclusive agreement for the provision of certain services (e.g., anesthesia) where another member of the System has an open staff. Thus, a member of the medical staff of one System facility would not get identical privileges at another System facility.

Privileging should be viewed on an institution-by-institution basis, although within a System inconsistencies should be avoided. The structure of a System may include a single group of individuals serving as the board for all System components or it may include a System board with individual boards at the institutional level. In either event, a limitation on a practitioner's privileges in one facility based upon training, experience or other demonstrated factors which is not then put into place at another System facility, could lead to a claim that either the individual is being treated unfairly or, in the context of a malpractice case, that the System does not enforce uniform quality standards. This, in turn, might allow claims against other than the institution involved where the System engages in System-wide quality programs.

The hallmark of a progressive, successful health care system is a single standard of quality, and thus, the failure to have a uniform approach to privileging where the practitioner holds privileges in more than one System facility does have the potential of negative public relations and perhaps a negative outcome with respect to liability claims.

Discipline

The discussion above regarding privileging spills over into the issue of physician discipline. Article 28 of the Public Health Law and related regulations provide that privileges, and medical staff membership itself, can be denied, modified or terminated on the basis of (i) character; and (ii) competence and; (iii) objectives of the institution.[7]

The Federal Health Care Quality Improvement Act,[8] and the JCAHO[9] employ similar principles with respect to physician discipline. Hospitals and nursing homes must follow their bylaws, and those bylaws must contain a reasonable system by which a practitioner who has been disciplined receives notice and is afforded an opportunity to be heard, thus ensuring "due process" to aggrieved physicians who wish to challenge adverse credentialing and/or privileges determinations.

While the bylaws of institutions can vary widely on how they approach this difficult issue, fundamentally, they do follow a consistent path. In the case of existing medical staff members, this usually includes an internal review by one or more departments, boards or committees, an informal approach to the practitioner regarding the outcome of that review and, if unresolved, a mechanism for referring charges against the practitioner, allowing the practitioner an evidentiary hearing and providing an avenue of appeal. The hearing process usually, but not necessarily, takes place within the medical staff structure while the appeal is usually made to the governing body.

The hearing process before the medical staff is essentially an evidentiary process which should involve notice of charges, provision of supporting information to the practitioner, a hearing before a body which has not previously considered the matter and which is not in economic competition with the practitioner, the right of the practitioner to be represented by counsel and to confront and cross-examine witnesses, and the right of the practitioner to present his or her own position. A record of the proceedings must be made and must be available for appellate review before the governing body or a committee thereof. Appellate review is not an evidentiary process but rather, a review of the record on appeal. Although oral presentations may be made, the taking of additional evidence is normally not permitted.

The complexity of the process described above—and the description is intentionally brief—emphasizes the need for each individual facility to have a hearing and appellate process in place and suggests that it may not be feasible to centralize this process. Because events that lead to a disciplinary process take place within a specific institution, it follows that the "peer review" aspect of that process requires an appropriate internal review and appeal process within that institution.

Where a practitioner holds privileges at more than one System facility, however, it is not unheard of that a reduction, suspension or loss of privileges at one facility is deemed to carry over to all System facilities. Although this is not a universal practice, it does occur. In addition to the obvious economic benefits, the application of a shared disciplinary response by System facilities would help to refute any contention that the System had failed to carry out its quality assessment and assurance function, which would be problematic if the System were to allow a practitioner who had been disciplined in one of its facilities to practice unrestricted in another facility. This assumes, of course, that the underlying discipline was based on a quality-of-care issue.

In the experience of the authors, there are few, if any, situations where a health system having multiple facilities uses a single disciplinary process. The one exception would be that rare instance where the multiple facilities have an identical medical staff. This is uncommon although we are familiar with at least one instance where this occurs. Where there are diverse medical staffs, a centralized disciplinary process is normally not employed.

However, systems can require that their component facilities' bylaws provide that reduction or loss of privileges at one facility has an automatic effect on the practitioner's status at another System facility, with or without due process. This is more common where there are overlapping or identical medical staffs, but if understood by practitioners to be the "rules of the road"—the bylaws and policies of each institution—may nevertheless be enforced in other situations. The granting of at least one "round" of due process may satisfy legal requirements where the bylaws, etc., so provide and where the action taken arises out of a single set of facts.

The Sharing of Protected Information

Although the privileging and disciplinary process usually is distinct among health system facilities, many systems have centralized quality programs which are used at the component facilities. The programs may differ in their application from facility to facility because of the nature of each facility (e.g., a teaching hospital versus a non-teaching hospital). Nevertheless, systems strive for a single standard of quality and therefore, often use a centralized quality approach. Thus, the centralizing or sharing of confidential information is not uncommon and the use of an "agency" relationship among or between various components of the System involved in the process may provide the necessary protection.

Endnotes

1. *See* N.Y. Pub. Health Law § 2805(1).
2. N.Y. Pub. Health Law § 2801.
3. *See* N.Y. Pub. Health Law § 2805-j(c) (requiring a system for reviewing physician credentials). The credentialing process is defined further at Part 405 of the governing regulations (the "Hospital Code") which requires a "biennial review of credentials, physical and mental capacity and competence in delivering health care services of all clinical staff." 10 N.Y.C.R.R. § 405.6(b)(7)(vi).
4. *See* 42 C.F.R. § 482.21.
5. Pursuant to section 2805-m of the Public Health Law and section 6527(3) of the Education Law, information obtained in, reports of, and statements made in the course of medical peer review proceedings are considered confidential, privileged and exempt from disclosure and, as such, are expressly excepted from disclosure otherwise required under Article 31 of the CPLR. *See Logue v. Velez*, 92 N.Y.2d 13, 17 (1998).
6. Under the New York Hospital Code, a hospital's governing body must ensure that members of the medical staff practice within the scope of privileges that have been granted by the hospital. *See* 10 N.Y.C.R.R. § 405.2(e)(11).
7. *See* N.Y. Pub. Health Law § 2801-b(1) (making it improper for a hospital to restrict a physician's privileges for reasons unrelated to "patient care, patient welfare, the objectives of the institution or the character or competency of the applicant"); N.Y. Pub. Health Law § 2805-j(1)(c) (requiring the periodic review of physician credentials); *see also* 10 N.Y.C.R.R. § 405.4(b)(4)-(5).
8. In 1986, Congress enacted the Health Care Quality Improvement Act ("HCQIA"), codified as 42 U.S.C. §§ 11101, *et seq*. In recognition of the "increasing occurrence of medical malpractice" and the importance of professional medical peer review, the statute requires health care entities to file reports to a national data bank about decisions that reduce, restrict, suspend or revoke physicians' medical staff privileges, and provides immunity from liability for peer review participants for such reports made in good faith.
9. Under standards promulgated by JCAHO, a hospital must ensure that its medical staff bylaws provide a process for granting or revising privileges. *See* JCAHO MS 4.20, 4.40 (2004). Medical Staff standard 4.50 requires that members of the medical staff be provided with a "fair hearing and appeal process for addressing adverse decisions" concerning their privileges. JCAHO MS 4.50.

Employment and Labor Law Issues Faced by Orchard Health

By Nicholas J. D'Ambrosio, Jr. and Christa J. Richer

Introduction

The complex relationships that exist within health care systems pose some unique labor and employment law concerns. This article first addresses overtime compensation concerns that may be raised when employees within a health care system are employed by more than one of its affiliates. This article will then address the issues that may need to be considered by health care systems in the event of a unionization campaign.

I. Overtime Pay Implications of Employees Working at Multiple Entities Within the System

The Fair Labor Standards Act ("FLSA") requires employers to pay employees at a rate of one and one-half times their regular rate for hours worked in excess of 40 in a workweek.[1] The FLSA permits hospital and residential care employers to enter into agreements with their employees under which the employees will be paid for overtime for hours worked in excess of eight hours in a workday and in excess of 80 hours in a fourteen-day period.[2]

Regardless of which method is used, employers within a health care system, such as Orchard Health, must review their relationship with other affiliates within the system in order to ensure that they are in compliance with the FLSA overtime requirements, particularly if employees are permitted or required to work in two or more entities within the health care system. What if an employee regularly employed by Oak Medical Center expresses an interest in working at the Oak Nursing Home, the Medical Center's subsidiary, or at Birch Hospital, on an occasional, "as-needed" basis? If a joint employment relationship exists between the employers—Oak Medical Center, Oak Nursing Home and/or Birch Hospital—the employee's work for these related entities is considered as one employment for FLSA purposes. Consequently, the hours worked in the multiple entities must be aggregated, likely resulting in an entitlement to overtime pay. Additionally, the two employers are held individually and jointly liable for complying with the overtime requirements.

The Ninth Circuit Court of Appeals recently held in *Chao v. A-One Medical Services, et al.*,[3] that two affiliated health care facilities, which were found to be joint employers, violated the FLSA when they failed to aggregate work performed by employees at both facilities for purposes of paying overtime. The two facilities, A-One Medical Services, Inc. ("A-One") and Alternative Rehabilitation Home Healthcare, Inc. ("Alternative"), were separate corporations owned by different individuals.[4] In 1996, the owner of A-One agreed to purchase Alternative. Several patients and employees were transferred from one facility to another and the operations of the facilities became closely coordinated in contemplation of the merger.[5] For example, A-One oversaw the patient care of Alternative, supervised Alternative's employees, contracted accounting services for Alternative, contracted vendors for Alternative, answered Alternative's telephone calls at the office that A-One shared with Alternative and oversaw Alternative's paperwork to comply with government requirements.[6] In addition, the two facilities shared a receptionist and A-One processed Alternative's payroll.[7] There was also common supervision and scheduling of the employees working at the two facilities. Although employees of one facility sometimes worked at the other facility, there was no formal arrangement for employee-sharing between the two facilities.[8] The application and hiring processes remained separate for both facilities, and employees received separate paychecks from the two facilities, depending on the facility for which they had performed services.[9] For many positions, the two facilities paid different hourly rates. Finally, employees were free to decline an assignment from either facility.[10]

At issue in the *Chao* case was whether A-One and Alternative were required to aggregate the time worked by employees at both facilities for the purpose of computing overtime. The facilities' practice had been to pay the employees for time worked at each facility separately. Under this practice, an employee working 30 hours at A-One and 25 hours at Alternative in a single workweek did not receive overtime, but was paid straight time for the hours worked at each facility.

The United States Department of Labor challenged this practice, arguing that the two facilities were joint employers under the FLSA regulations and were, therefore, required to count the time worked by employees at both facilities as if the work was performed for a single employer. That relevant FLSA regulation states, in relevant part:

> Where the employee performs work which simultaneously benefits two or more employers, or works for two or more employers at different times during the workweek, a joint employment relationship generally will be considered to exist in situations such as:

> (1) Where there is an arrangement between the employers to share the employee's services, as, for example, to interchange employees; or
>
> (2) Where one employer is acting directly or indirectly in the interest of the other employer (or employers) in relation to the employee; or
>
> (3) Where the employers are not completely disassociated with respect to the employment of a particular employee and may be deemed to share control of the employee, directly or indirectly, by reason of the fact that one employer controls, is controlled by, or is under common control with the other employer.[11]

The Ninth Circuit agreed with the Department of Labor, holding that "A-One and Alternative were joint employers that must aggregate, for purposes of FLSA compliance, the work done by their employees for both companies."[12] The Court, after finding that the employers' violations were willful,[13] awarded unpaid overtime wages for work performed during a one and one-half year period and an equal amount in liquidated damages.[14]

The *Chao* case demonstrates the potential liabilities that may arise from requiring or permitting employees to work in two or more facilities within the overall health care system. The determination regarding whether a joint employment relationship exists is, however, an extremely fact-intensive inquiry. Factors that will be determinative include: whether the positions at the two facilities are entirely distinct, whether the two employers will coordinate the employee's schedule, and whether the work performed by the employee benefits both employers simultaneously. Another factor is the extent to which employers act in concert with respect to the employment of a particular individual. For example, if the Oak Medical Center had an arrangement with the Oak Nursing Home in which it regularly transferred employees from one facility to another, as opposed to an individual employee pursing separate employment at the two facilities, a joint employment relationship is more likely to be found. Additionally, two corporations may be joint employers where they are commonly controlled.[15] For example, in the Orchard Health model, although each of the corporations may have their own distinct day-to-day administrators, the fact that the corporations share all twelve of the same Board members would be strong evidence of a joint employment relationship. In light of the potential for liquidated damages, employers must proceed with caution and give adequate consideration to the joint employer issue when interchanging employees between facilities within a larger health care system.[16]

II. Labor Relations Issues

A. Unionization Attempts and Bargaining Unit Implications

New York State has the highest rate of unionization and the health care industry is one of the industries with the greatest number of union members.[17] Health care systems, therefore, must be well versed in labor law issues and the health care regulations issued by the National Labor Relations Board (the "Board"). How should Orchard Health respond to a petition from a union to represent employees in one or more of the affiliates? Among many factors that would need to be considered is the composition of the bargaining unit proposed by the union. Because a union must be elected by a majority of votes cast by the employees of the proposed bargaining unit, the scope of the bargaining unit is a critical strategy issue for both employers and unions.[18] The union may not be able to establish majority support in a larger unit. If the union election is successful, the employer may still gain in having one or two larger units, as opposed to several small disassociated bargaining units. The relationship between the affiliates of the health care system may be used to expand or limit the petitioned-for bargaining unit.

Generally, employees who share a "community of interest" comprise an appropriate bargaining unit. Factors used by the Board to determine whether employees share a community of interest include similarity in wages, hours, and fringe benefits; common supervision; similar qualifications; similar working conditions and duties; frequent interchange or integration with other employees; and area practice.[19] The Board engages in a detailed factual analysis to determine the appropriate bargaining unit; no one factor is determinative.

An exception to the community of interest approach exists in the health care industry. In order to minimize labor disruptions that may interfere with patient care, the Board has issued regulations applicable to "acute care hospitals" that are used to determine the appropriate bargaining unit.[20] Nursing homes, psychiatric hospitals, rehabilitation hospitals, and other similar long-term facilities are excluded from the Board's regulations, and units in such facilities must be determined in the traditional manner by applying the community of interest analysis.[21] In rare cases, the Board, recognizing the complexity inherent in health care systems comprised of multiple affiliates, will not apply the Board's regulations, but will analyze whether the employees share a community of interests.

The Regional Director for the Third Region was recently faced with determining the appropriate bargaining unit in a complex health care system.[22] The employer, Albany Medical Center,[23] was the parent corporation of five legally separate corporations dedicated to health care services, medical education and medical research. The five affiliated corporations included two acute care hospitals, a medical college, a nonprofit foundation engaged in fundraising for all affiliates of the health care system, and a nonprofit organization providing daycare services for employees working in any of the affiliate facilities.[24] Albany Medical Center also operated thirty-seven satellite outpatient facilities.[25] All employees were employed by the parent corporation, but were budgeted to the various affiliates.[26] New York's Health & Human Service Union, 1199/SEIU, filed a petition to represent a bargaining unit comprised of all nonprofessionals employed by the parent corporation and budgeted to the two acute care hospitals, as well as two of the satellite facilities. The union's proposed unit excluded employees budgeted to the medical college, the fundraising foundation, the child care facility and the remaining thirty-five satellite facilities.[27]

The employer sought to expand the proposed bargaining unit to include over 600 workers employed by the other entities of the heath care system, including those employed at all 37 satellite outpatient facilities. The Regional Director declined to apply the Board's health care industry regulations, noting the unusual circumstances presented by Albany Medical Center's complex, integrated system.[28] Instead, the Regional Director engaged in an extremely fact-intensive community of interest analysis, looking primarily at the degree of integration between the affiliates. The Regional Director ultimately agreed, in part, with the employer that the bargaining unit proposed by the union was too narrow.

First, the Regional Director needed to determine whether the health care system, as a whole, constituted a single employer so that the representation of all of the proposed employees in one unit would be appropriate.[29] In concluding that Albany Medical Center and its five affiliate corporations constituted a single employer, the Regional Director considered the common ownership and financial control of the affiliates, and the substantial centralized control over labor relations.[30] Significantly, there was only one payroll system, one human resources department, and one set of personnel policies that governed all of the employees.[31]

The Regional Director then considered whether the employees in the employer's proposed unit shared a community of interest with the petitioned-for unit. The Regional Director added the nonprofessionals employed by the medical college to the unit, noting the close integration between the employees of the medical college and the hospital.[32] Employees at the hospital and the medical college worked together and even shared work space on the Medical Center's main campus, there was considerable overlap in job classifications and pay grades between the two affiliates, and the employees who worked at the hospital were interchanged with the medical college employees.[33] Further, the affiliates shared a substantial degree of integration of operations. For example, the medical teaching process took place in both the hospital and the medical college; the two affiliates had the same board of directors; and the affiliates shared central services, including human resources, housekeeping, computer, health and safety, laboratory, courier, receiving, distribution, and security.[34]

In contrast, the Regional Director concluded that the employees who worked at the fundraising foundation and at the child care facility did not share a community of interest with the other employees in the health care system. These employees had little interchange or meaningful contact with Albany Medical Center, its hospitals or the medical college.[35] Many positions at the fundraising foundation and child care facility did not exist in the other affiliates and these two affiliates did not share a common board of directors between themselves or with the remaining affiliates within the system.[36] Similarly, the Regional Director declined to include the employees who worked at the remaining satellite facilities into the petitioned-for unit. The Regional Director noted the absence of employee interchange and contact, the distance which physically separated the satellites from Albany Medical Center's main campus, the fact that the satellites were independently managed, and the fact that they did not rely on the central human resources department for hiring or discipline.[37]

Thus, due to the close relationship between the various affiliates of the health care system, the employer in the *Albany Medical Center* case was able significantly to expand the appropriate bargaining unit, thereby making it more difficult for the union to win the majority of votes in the union election. This case is instructive for other health care systems facing union campaigns and/or representation petitions. Assuming that the system is a single employer, the scope of the unit may be challenged by the employer to work in its favor. Of course, in some circumstances the employer will argue that the proposed bargaining unit is too large and will seek to limit it appropriately. As mentioned above, the factors that will be considered in determining whether employees share a community of interests, requiring that they be included in one bargaining unit, include: whether the employees share similar job classifications, similar working conditions, similar wages and hours,

whether the employees are interchanged (i.e., transferred from one affiliate to another), the physical proximity of the affiliates, whether there is common supervision of the employees and the degree of integration of operations between the affiliates (i.e., shared human resources, security, and payroll departments).

B. Shared Employees on Strike

Another labor issue that may arise if a union does represent one or more of the affiliates within a health care system is how to handle employees who go on strike. Clearly, strike activity raises a variety of legal issues. What if, as discussed in the FLSA topic above, employees are permitted or required to work for two or more affiliates within the overall system, but employees are in the course of a strike at one facility? Can the strikers be prohibited from working for another affiliate during the strike?

In a recent decision, an NLRB Administrative Law Judge held that, if a single or joint employment relationship exists between the two affiliates, shared employees who were on strike could be denied work by a second affiliate.[38] In that case, two hospitals that were affiliated under a nationwide umbrella corporation and many subordinate affiliated corporations were held to be single and joint employers as a result of a shared employment/transfer program, common management, centralized control of labor relations, and the fact that any shared employment had to be approved by the employee's home facility.[39] Shared employees received one paycheck from their home hospital for the work they did there as well as the work performed at a second affiliate hospital.[40] The ALJ held that because an employer is not required to subsidize the strike activities of its employees, the two hospitals were privileged to require shared employees, who were on strike from their home hospital, to work at their home hospital or not at all.[41] As a result, the strikers were denied the ability to withhold services from one entity while working at the secondary facility during the course of the strike.[42] Of course, within any health care system, such as the Orchard Health model, both the joint employer relationship and an employer's right to deny shared employees work during the course of a strike can only be determined by a very fact-intensive inquiry into all of the relevant factors.

Endnotes

1. 29 U.S.C. § 207(a).
2. *Id.* at 207(j).
3. 346 F.3d 908 (9th Cir. 2003), *cert. denied,* 124 S. Ct. 2095 (2004). Although the Ninth Circuit's opinion is not binding upon a court in New York, it would be persuasive in interpreting an employer's obligations under the FLSA.
4. *Id.* at 912.
5. *Id.* at 912–913.
6. *Id.*
7. *Id.*
8. *Id.*
9. *Id.* at 913.
10. *Id.*
11. 29 C.F.R. § 791.2(b).
12. *Chao,* 346 F.3d at 918.
13. A determination that a violation of the FLSA is willful expands the period of liability for overtime violations from two years to three years. *See* 29 U.S.C. § 255(a). In determining that the employers' violations were willful in *Chao*, the Court noted that one of the employers, A-One, had previously been found to be in violation of the FLSA. Although A-One's prior violations were different in kind, the Court found that the previous run-ins with the Labor Department put A-One on notice of other potential FLSA violations. *Id.* at 919.
14. *Id.* at 919–920. In awarding liquidated damages, the Court noted that the employers involved did not seek any legal advice from an attorney or the Department of Labor regarding the overtime obligations associated with the shared employees.
15. *See Chao,* 346 F.3d at 917; s*ee also Western Illinois Home Health Care, Inc. v. Herman*, 150 F.3d 659 (7th Cir. 1998) (holding that two home health care corporations that served different clientele and were miles apart were joint employers where the same two people were the corporations' sole shareholders, directors and officers).
16. Regulations issued by the Department of Labor under the FLSA permit three possible alternatives for calculating an employee's regular rate where the employee receives two or more rates of pay during the course of a work week: (1) Under the weighted average method, the employee's overtime compensation is calculated by dividing the employee's total compensation for the week by the total hours, including overtime hours, for the week and multiplying the resulting average by 0.5 for each overtime hour. 29 C.F.R. § 778.115; (2) The employer may pay time-and-one-half the established straight time rate for the particular work that the employee performs during overtime hours, i.e., ,the rate applicable to the type of work the employee performed in excess of 40 hours in the work week. In order to use this method, however, the employer and employee must agree in advance that this method will be used and the employer may not use this method in only those instances when this payment would produce a lower overtime payment. 29 C.F.R. § 778.419; or (3) If the employee regularly works approximately the same number of hours each week, the employer and employee may agree on an estimated rate that is substantially equivalent to the employee's average weighted hourly earnings. 29 C.F.R. § 548.306.
17. *See* U.S. Department of Labor, Bureau of Labor Statistics, 2003 Union Members Summary (January 21, 2004) (http:www.bls.gov/news.release/union2.nro.htm); *see also* Bureau of Labor Statistics, Union Affiliation Statistics by Occupation and Industry, Table 3 (http:www.bls.gov/news.release/union2.t03.htm); Barry T. Hirsh & David A. Macpherson, Union Membership, Coverage, Density and Employment by Industry, 2003 (2004) (http: www.trinity.edy/bhirsch/unionstats/Ind%20U%202003.htm).
18. If the employer challenges the composition of the proposed bargaining unit, the Regional Director of the National Labor Relations Board determines, after a hearing, whether the proposed unit is appropriate, and, if necessary, what changes to its composition must be made.
19. *See Washington Palm, Inc.,* 314 NLRB 1122 (1994); *Kalamazoo Paper Box Corp.,* 136 NLRB 134 (1962).

20. *See* 29 C.F.R. § 103.30. The regulation reads, in part: (a) This portion of the rule shall be applicable to acute care hospitals, as defined in paragraph (f) of this section: Except in extraordinary circumstances and in circumstances in which there are existing non-conforming units, the following shall be appropriate units, for petitions filed pursuant to section 9(c)(1)(AA)(i) or (9)(c)(1)(B) of the National Labor Relations Act, as amended, except that, if sought by labor organizations, various combinations of units may also be appropriate: (1) all registered nurses, (2) all physicians, (3) all professionals except for registered nurses and physicians, 4) all technical employees, 5) all skilled maintenance employees, 6) all business office clerical employees, 7) all guards, 8) all nonprofessional employees, business office clerical employees and guards, provided that a unit of five or fewer employees shall constitute an extraordinary circumstance. The regulation defines "acute care hospital" as either a "short term care hospital in which the average length of patient stay is less than thirty days, or as short term care hospital in which over 50% of all patients are admitted to units where the average length of stay is less than thirty days."
21. 29 C.F.R. § 103.30(d) & (g). *See Park Manor Care Ctr., Inc.,* 305 NLRB 872 (1991) (holding that the "acute care hospital" regulation does not apply to nursing homes); *see also Hebrew Home & Hosp.*, 311 NLRB 1400 (1993).
22. *See Albany Medical Center,* 3-RC-11168 (Sept. 5, 2002).
23. Albany Medical Center was created by Albany Medical Center Hospital and Albany Medical College by combining their governing boards, naming a common president and chief executive officer and forming a single management team.
24. *Albany Medical Center,* 3-RC-11168 (Sept. 5, 2002) at 2.
25. *Id.*
26. *Id.* at 3.
27. *Id.*
28. *Id.* at 27. In determining not to apply the health care regulation, the Regional Director relied upon the Board's decision in *Child's Hospital,* 307 NLRB 90 (1992). In *Child's Hospital*, the Board declined to apply the regulation due to the unusual character of the facility at issue, which included a nonprofit acute care hospital, a 120-bed residential nursing home, and the Samaritan Service corporation that provided the hospital and the nursing home with processing, security, and purchasing services. *Id.* at 92. The Board noted that the physical joinder of the nursing home and the hospital, the substantial nature of both operations, and the integrated support services provided to the hospital and nursing home evidenced extraordinary circumstances which made application of the regulation inappropriate. *Id.* Coincidentally, by the time of the *Albany Medical Center* case, Child's Hospital had become the South Campus of Albany Medical Center.
29. The absence of a single-employer finding does not necessarily preclude union representation, but where it is determined that the union is attempting to organize employees of several different employers (i.e., "multi-employer" bargaining), much more restrictive rules apply and the Board will not approve the creation of such a unit until the consent of all parties, the union and employers, is obtained. *See Artcraft Displays,* 262 NLRB 1233 (1982).
30. On the other hand, applying the traditional single-employer test, the Board concluded, in *Mercy General Health Partners*, 331 NLRB 783 (2000), that two health care corporations, which were corporate subsidiaries of a larger corporate parent, were not a singe employer. The Board noted that, despite their common ownership, there was no centralized control over labor relations. *Id.* at 785. Instead, the labor relations of the two entities were handled by different individuals. *Id.* Each entity had its own managers and supervisors, the entities applied different personnel policies and there was no common supervision between them. *Id.* Thus, the Board found that the employees of the two entities should have the option of being represented in separate units.
31. *Albany Medical Center,* 3-RC-11168 at 26.
32. *Id.* at 29–30.
33. *Id.*
34. *Id.* at 30–32.
35. *Id.* at 35–36.
36. *Id.*
37. *Id.* at 36–37.
38. *San Ramon Reg'l Medical Ctr.,* 2004 NLRB Lexis 327 (June 18, 2004).
39. *Id.* at *15–18.
40. *Id.* at *16.
41. *Id.* at *17–18.
42. *Id.*

Nicholas J. D'Ambrosio, Jr. is the Managing Attorney of the Albany Office of Bond, Schoeneck & King, PLLC and Christa J. Richer is an associate in the Syracuse Office of Bond, Schoeneck & King, PLLC. They both practice in the area of labor and employment law, representing numerous health care institutions.

"Closely Held Nonprofits": Corporate-Type Boards and the Gyroscope of Governance

By J. David Seay and David Weisberg

Gyroscopes are instruments used in navigation equipment, such as a heading indicator on an airplane or a ship, designed to keep it on a true course. Being made by humans, however, such devices are not perfect, and tend to spin slightly forward in a motion called precession. Because of that tendency, they need periodically to be calibrated to the magnetic compass to maintain their accuracy and ensure the vehicle's travel on its true course. Governing boards of nonprofit entities are charged with the responsibility of hewing to the mission of the organization. They are in many respects the conscience or gyroscope of the enterprise, responsible for keeping the organization on its true course. And like man-made gyroscopes, they need calibrating from time to time to ensure that they operate properly.

Introduction

Governmental payment cutbacks, increased demand for services, and competitive pressures from the for-profit and non-profit sectors have recently intensified, causing many nonprofit managers to scramble for survival and innovation. Such factors, among others, are converging on the vast nonprofit sector in the United States, propelling some nonprofit organizations to enter into new ventures and organizational forms. Many are doing so by adopting the ways of corporate enterprises, while abandoning traditional notions of the nonprofit order.

"Consolidation within the health care sector is having dramatic effects on both the delivery of health care services and the institutions providing the services."

Indeed, many nonprofits, in an effort to become more business-like, may have transformed into businesses, leaving observers and community members scratching their heads and wondering whether they truly are nonprofits and deserve the approbation and perquisites traditionally accorded charitable organizations. Perquisites include tax exemption, the ability to solicit and accept tax-deductible donations and grants, lower postage rates, and the like. It is reasonable to question whether such organizations have strayed from their missions and, if not, whether too much of the management's time and attention has been diverted elsewhere.[1] From museum shops to health clubs, from for-profit subsidiaries to affinity credit cards, from joint ventures with for-profit companies to advertising campaigns and incentive compensation arrangements, the rush to emulate the commercial world is dizzying. Some scholars have suggested that the nation's charities should be divided into two types, the commercial and the charitable, saying that only the charitable or "donative" nonprofits—those deriving most of their income from donations—are truly deserving of special status.[2]

Management experts are also on the scene preaching a number of new theories of management, organizational form, and governance. They have suggested that nonprofits adopt certain techniques from the for-profit sector such as their governance structures and functions.[3]

One particular area within the nonprofit world, health care—the largest single category of public charities in the country—has evidenced the aforementioned shift from non-profit to for-profit mentality, form and governance.[4] Consolidation within the health care sector is having dramatic effects on both the delivery of health care services and the institutions providing the services. Many forms of consolidation are being used, *inter alia*, loose affiliation agreements, memoranda of understanding, joint operating agreements, acquisitions, the use of subsidiaries and sole corporate member arrangements, parent holding companies, and full asset mergers. Undertaken to achieve structural and/or operational integration, these health care consolidations have involved all three classic types of integration under antitrust law: horizontal, vertical, and conglomerate integration.[5] Boards of directors within such organizations have fiduciary duties and responsibilities with respect to virtually all aspects of such transactions, including valuation and fair market value, due diligence and the use of timely and adequate information and data and the consideration of other potential alternative courses of action.[6]

Presently, this trend for some nonprofits to behave more like businesses is driven by the large cash flow, tight margins and the need for enormous infusions of capital that are often characteristic of larger organizations. Two percent of New York City's 19,500 nonprofits employ 75% of the sector's workforce,[7] and these are largely the hospitals and universities. There has been anecdotal evidence, however, that in a number of small-

er nonprofit organizations—in the arts and other areas—some of these trends have been seen. In any event, the apparent trend toward more corporate-like boards in the nonprofit sector, and its impact on "ownership" of the nonprofit entity, need careful examination.

This article reviews trends in the governance of nonprofit organizations and considers the impact of some of those trends on mission and accountability. It also suggests a reconsideration of the movement towards more "corporate" and less "community" governing boards, joining those voices calling for careful calibration of the gyroscope of nonprofit governance in an effort to keep the sector on a true course and headed in the right direction.

Corporate-Type Board Models: A Quasi-Hypothetical Example

In the late 1970s, two voluntary hospitals in New York City initiated a full asset merger, resulting in a unitary governing body.[8] Subsequently, other hospitals have consolidated, creating some fairly large systems of hospitals and affiliated institutions. For instance, a large Manhattan academic medical center chose to use the sole corporate member/parent-subsidiary model of acquiring mostly smaller hospitals. The acquired hospitals agreed to amend their bylaws to make themselves "membership corporations" under New York's Not-for-Profit Corporation Law (N-PCL), each with one corporate member, namely the acquiring hospital.[9] Vestigial boards of trustees often remained at the acquired hospitals, albeit with significantly limited governing powers or merely advisory powers. In any event, the trustees of the acquiring hospital appointed such boards. Essentially, the acquiring hospital's board of trustees became the ultimate legal governing body. Thus, one health "system" was created, replacing distinct and autonomous hospitals. Governing responsibility, in essence, was delegated upstream to one board of trustees.

Unlike the sole corporate member/parent-subsidiary model, another hospital utilized the holding company model of consolidation. A new parent corporation was created to govern subsidiary corporations, which had hitherto been independent. The parent's board of trustees controlled the major powers of the subsidiaries, including board election, thereby maintaining *de facto* control of the holding company's governing board. Each hospital remained "independent" by retaining a board of trustees, albeit with subordinated authorities, and kept its own operating certificate under Article 28 of the New York State Public Health Law.[10]

In the preceding examples, the governing boards differed in character and composition from the attributes of their predecessor hospital boards. The ultimate governing body in each case became more corporate or business-like. Directors were selected based upon criteria such as professional expertise rather than ability to represent the communities served by the hospitals. As such, boards became less diverse and smaller in size than the more traditional nonprofit hospital board. Inside directors—directors who are also employees of the corporation—dominated the boards. The architects behind these new models intended to minimize the response time necessary for decisions to be executed in order to keep up with the rapidly changing health care environment. They believed that a market-oriented approach required business-like governance.

If the two preceding health systems, which used different modes of consolidation, decided to merge, they would end up becoming subsidiaries of another company—a holding company. The holding company would create a board of directors consisting of three individuals—the new entity's president and chief executive officer (CEO), chief operating officer (COO), and chief financial officer (CFO)—each of whom had served in similar capacities with the larger and dominant of the two systems. The resemblance of this corporate governance structure to closely held proprietary corporations is striking.

New York's N-PCL and Public Health Law (PHL) do not prohibit the aforementioned structural arrangements. A rethinking of the laws governing these types of nonprofits might be in order, especially where traditional notions of autonomy, accountability, and checks-and-balances in the governance and operation of charitable nonprofit organizations are called into question.[11]

Surprisingly, there has been little public attention, regulation and enforcement of non-profit boards despite the fraud and malfeasance taking place in the corporate sector.[12] Harvey Goldschmid, a Commissioner of the United States Securities and Exchange Commission, has observed that "in contrast to the for-profit world, the law plays little role, other than aspirational, in assuring accountability in the nonprofit sector."[13]

Others have noticed that the laws of business corporations are being applied more frequently to nonprofit organizations, including the laws governing the duties and responsibilities of directors.[14] The Sarbanes-Oxley Act,[15] although not presently applicable to nonprofit corporations, provides some insight as to future regulation or guidance of hospital systems and other nonprofit corporations. Indeed, New York Attorney General Eliot Spitzer[16] has joined others in calling for reforms in the nonprofit sector.

Some common attributes of the "corporate" board model, which nonprofits are assuming, include: (1) professionalism, (2) compensation, (3) non-representation, (4) homogeneity, (5) inside directors and (6) small board size. Each will be addressed in turn as they relate to tra-

ditional notions of nonprofit "ownership," governance and accountability.

1. Professional Directors

For-profit corporate boards are frequently comprised of directors who are selected for their specific professional skill and expertise, whereas nonprofit boards have traditionally selected directors with varying backgrounds and expertise in order to ensure the representation of the community being served. Similar to large business corporations, larger and more complex nonprofits, such as hospitals and universities, are finding that a demanding set of decisions is required in the boardroom. Specific professional skills—law, accounting, investment, capital acquisition, strategic planning and management—are coming to the forefront as immediate governance needs.

Thus, directors of some of the emerging corporate-type nonprofit boards are being chosen for their narrowly defined individual professional skills. Sole-criterion selection often typifies board recruitment profiles and can lead to a board with some good professional talent—the "professional director." Some observers have questioned such directors' overall understanding or appreciation of the mission, stakeholders and long-term goals of the organization.[17]

In addition to their expertise, directors are required by law to bring sound judgment and an appreciation for and working knowledge of the organization's mission to the boardroom.[18] All too often, however, a critical attribute is overlooked or undervalued in nonprofit board selection and composition. That attribute is "a genuine understanding of the mission of the organization, combined with empathy and commitment."[19]

"[I]n constructing boards, there is a special need for members who are knowledgeable about the characteristic functions and problems of the particular enterprise in question."[20] Charitable directors are entrusted with the difficult task of ascertaining and evaluating the mission of the organization.[21] The business judgment rule may not shield directors from liability for breaching their fiduciary duties unless they actually exercise judgment.[22]

Charitable boards have the authority to delegate certain responsibilities and skills to outsiders and to rely on them for many of these talents.[23] Although board members may have specific technical and professional talents and skills, some decisions and actions require knowledge beyond its members' purview. In order to account for the professional shortcomings of its members, boards employ recruiting mechanisms. Responsible governance dictates this. Otherwise, the fear of liability remains a viable concern.

2. Compensated Directors

Corporate directors are generally compensated, in one form or another, for their board service. Nonprofit directors are rarely compensated. In most cases, there is no legal prohibition to compensating nonprofit directors. However, it is customary that directors of nonprofit organizations not be compensated for serving on nonprofit boards. There have been some exceptions to this general rule—mainly for directors of private foundations.

Some commentators suggest paying nonprofit directors in order to attract qualified professionals to serve on nonprofit boards.[24] Compensation, they state, would induce directors to devote the same amount of attention and professional judgment as they provide to their own businesses and their service on corporate boards. It has been observed that otherwise skilled and consummate businessmen and professionals too often behave quite differently on nonprofit boards than they do in their usual lines of business or professions.[25] For example, the board of the United Way of America, under the helm of William Aramony as CEO, was comprised of the best and brightest leaders of corporate America, and yet it seems as if they all checked their talent at the door of that boardroom.[26] The financial improprieties the board condoned made newspaper headlines all over the country. Some attributed this failure, in part, to the lack of compensation for services rendered, which led to a less rigorous and less accountable governance environment. Yet it is unclear to what extent the compensation issue had affected corporate governance at United Way of America.

The more traditional view is that nonprofit directors should not be paid. These are, by nature, voluntary, mission-driven organizations striving to serve the public good. It seems counterintuitive to pay a director for his or her service, only to turn around and solicit him or her for charitable contributions in support of the organization. The compensation of directors challenges the fundamental notion that the nonprofit sector should be voluntary and eleemosynary in nature.

Notably, at least one state prohibits the compensation of trustees of charitable corporations, whereas other states (i.e., New York) prohibit compensation of either members or directors of community mental health services and mental retardation services companies.[27]

3. Non-Representational Directors

Generally, for-profit corporate directors are not selected based upon their knowledge or representation of the community or market being served by the corporation, whereas nonprofit directors are chosen for these reasons. Nonprofit organizations' constituencies and

communities are usually represented on their boards. The problem is exacerbated when smaller boards are used. Since nonprofit hospitals and health care organizations and systems derive their exempt status on the basis of being community-benefit organizations, it logically follows that they need a board-level awareness of and understanding of the unique community needs served by the institution.

The concept of "moral ownership" has been used to describe the kind of allegiance a board should owe to the institution's mission and primary stakeholders, and it is a concept readily grasped by community leaders and residents.[28] There may be a sense of "ownership" and enhanced loyalty associated with community trustees and, thus, improved local accountability. Certainly, traditional notions of checks-and-balances and accountability of nonprofit organizations have included broadly representative governing boards. For example, voluntary hospital boards, historically, sought to protect and promote community interests by making sure that there was a broad range of representation on the board, including community and business leaders, patients or former patients, patients' families, medical staff, auxiliaries, local clergy and others.

The contrary view holds that a "community" board may actually hinder effective governance of a health care system, even though there are representatives from various communities on the governing board. The objective is to build a board of national health care experts, relying on vestigial local boards in advisory capacities. Some of these health systems have become so large, complex, and geographically diverse that governing boards have needed to adapt to a different set of demands than the supplanted local boards. New models are required for directors to adequately discharge their fiduciary responsibilities as well as to serve their respective institutions. Rethinking the way "community" is defined may be in order.

The contrary view also holds that the utility of a community-representative board is diminished by the modern circumstances of stiff competition and rapid consolidation on a grand scale. For instance, a case in point is the nonprofit health system, Catholic Health Initiatives (CHI), which is based in Denver, Colorado. CHI has a $7+ billion operating budget with over 100 hospitals and other health care facilities nationally. Representational concerns on a system or parent board level become more difficult to address. The Henry Ford Health System in Detroit, Michigan, is another example where the ultimate governing authority is now less community-representative than the precursor hospital boards of yore.[29] Often, the previously represented constituencies are fearful that the new monolithic systems will become less responsive and accountable to their needs; they sense an "ownership" transfer in the wrong direction.

4. Homogeneous Directors

Corporate boards tend to be more or less homogeneous in nature, as members are often selected for their individual skills and/or investment capability. Conversely, nonprofit boards strive for some level of diversity among directors in an effort to broadly reflect the community or communities served by the organization. The lack of diversity—race, ethnicity or creed—on contemporary nonprofit boards is probably an unintended consequence of modernization. On a broader level, diversity may also include representation among managers, practitioners such as physicians, employees, beneficiaries, donors and other interested parties. An egalitarian approach to nonprofit governance has been the exception rather than the rule, at least at hospitals, health systems and other larger organizations. Past social and class elitism of nonprofit boards is perhaps yielding to a form of commercial and business elitism.

Diversity in governance also includes tolerance of different viewpoints, opinions and perspectives among individual directors. Diversity allows organizations to benefit from this wealth of knowledge, while avoiding a myopic outlook too often damaging to corporate governance. That is, shortsightedness in pursuit of a corporate goal may cause mission opportunities to be missed. Diversity of opinions does not come without a price, however. It can spark litigation over the correct interpretation of mission as trustees exercise their judgment in ascertaining what the organization's mission requires at any given time.[30] Directors are increasingly burdened with ensuring that adequate information and reporting systems exist so that sound business judgment and decision-making is exercised.[31]

A number of states have adopted statutes to provide regulatory oversight over health care organizations that seek to convert from non-profit to for-profit entities. One such statutory provision requires boards of for-profit entities, which receive the charitable assets resulting from these conversions, to be "broadly based in and representative of the community."[32]

Thus, to the extent that diversity promotes accountability of nonprofit boards, care should be taken when board members are chosen. Homogeneous boards are more subject to the "group think" phenomenon, where lemming-like behavior can lead to erroneous and ill-conceived decisions and directions.

5. Inside Directors

For-profit corporate boards, unlike nonprofit boards, have been accustomed to inside directors—directors who are also senior officers employed by the

corporation—although public scrutiny has called for changes in directors' behavior. Inside directors have been classified as "interested directors,"[33] or "disqualified persons"[34] where they have a personal or other financial interest in a transaction being considered by their respective boards. Due to the inherent conflict of interest, they should be disqualified from participating in that decision. Common law has recognized that directors can have real, potential or apparent conflicts of interest. Sanctions have been imposed in cases of abuse.[35]

In extreme cases, portions of or entire boards of trustees have been replaced where the behavior has been egregious. There is a growing awareness and concern about nonprofit directors' abuses of authority and conflicts of interest.[36] Directors who commit fraud, self-deal, misappropriate corporate opportunities, improperly divert corporate assets and put personal interests before the welfare of the corporation, violate the duty of loyalty. Such neglect, mismanagement and improper decision-making are breaches of the directors' duty of care owed to the corporation.[37] The *Adelphi* case uncovered numerous examples of breaches of both the duty of care and the duty of loyalty.[38]

Historically, employees of nonprofit organizations have not served on their own boards as insiders, with the exception of the top paid individual, such as the executive director or president.[39] Voting privileges for such individuals were often discretionary by the board. Given their intimate knowledge of the organization and its field of operation, inside directors provide valuable information and insight to the whole board. The trade-off is that the law ascribes higher duties to them based on such information and knowledge.[40]

More recently, the number of insiders serving on health system boards has increased as hospital consolidations have proliferated. In some cases, three or more corporate officers, including the president/CEO, executive vice president/COO, and the vice president/CFO, serve on the governing board. The presence of physicians on hospital/holding company boards has also increased. Physicians who are not directly employed by the hospital on whose board they serve might still be deemed insiders, especially if they have hospital privileges as private attending physicians and/or contractual or other relationships with the hospital or system. As the board size continues to decrease, the problem is exacerbated.

There are a number of circumstances where employees or physicians acting as inside directors have more or less "built-in" or inherent conflicts of interest. One obvious conflict of interest arises when directors set their own executive compensation.[41] Actual and potential conflicts are pervasive due to inside directors' personal, professional and financial interest in the hospital, system or other nonprofit organization represented.

Receiving compensation from an organization can cloud a director's professional judgment and can dictate his/her actions, especially where incentive compensation arrangements based on bottom-line performance are used. Short and long-term strategic decisions about the future of the organization, including decisions to cut back services, reduce compensation, lay off employees or even to close the institution can all run counter to a paid director's own interests.

According to the Revised Model Nonprofit Corporation Act (the "Model Act"), "The object . . . is to ensure that a majority of the directors of public benefit corporations do not have a built-in conflict of interest. Directors who receive compensation from a corporation constantly make decisions which directly or indirectly affect their compensation or employment status. Thus, they are not completely free to decide dispassionately how to allocate a corporation's resources and what is in the corporation's best interest."[42]

To account for the actual/potential conflicts of interest, the Model Act suggests limiting the number of interested directors to 49%, thus maintaining a disinterested majority.[43] To date, only California has adopted the Model Act provision requiring a disinterested majority. [44] New York has largely remained silent on this issue, although as mentioned above, New York Attorney General Eliot Spitzer is recommending a series of reforms to the New York Not-For-Profit Corporation Law[45] modeled after the federal Sarbanes-Oxley Act.[46]

Article 28 of the PHL, which governs health systems, does not impose restrictions on the number of insiders who can serve on a board, although certain provisions contained therein prohibit directors with a financial interest from voting on any matters involving their interest.[47] The PHL defines financial interest as "an aggregate beneficial equity interest of 10 percent or more."[48] It has been noted that boards can act with greater independence if they have fewer insider directors. There is less likelihood of conflicts between self-interest and the best interests of the organization.[49]

Accordingly, composition of a board of directors can be very important when confronted with matters relating to conflicts of interest, self-dealing and other abuses of trust. In contrast to most large for-profit corporations, some nonprofit boards can be composed of token members controlled by in-house director employees.[50] Experts have observed that a weak nonprofit board is more likely "dominated by one or a small group of individuals who, as full-time officers and/or employees, have a financial interest in the organization

(even if limited to their salaries and related benefits). The board should consist predominantly of individuals who are financially disinterested."[51]

Considering the potential for abuse and the relative laxity of the law in many states (including New York) as an accountability vehicle, it seems only reasonable to call into question the continued reliance upon the existing statutory framework.[52] Perhaps the nonprofit sector and public would be better served by adopting stricter requirements regarding inside directors generally and interested directors specifically.

6. Small Board Size

Over the last several decades, there has been a downsizing trend in the size of for-profit corporate boards, whereas many nonprofit boards remain larger or even continue to expand in size. The dynamic and competitive nature of the nonprofit sector, especially in health care, has put pressure on nonprofit boards to make decisions quickly in order to respond effectively to market conditions. Some scholars believe that large nonprofit boards are just too cumbersome and unwieldy in their decision-making ability to function efficiently and effectively in this new environment.[53]

Nonprofit organizations are looking to emulate for-profit corporations by paring down the board to a "leaner and meaner" governing structure with fewer directors. In many states, such as New York, nonprofit boards may be as small as three,[54] although some states require a minimum of five directors.[55] The Model Act also sets the minimum at three.[56] One state even permits a "board" of one.[57]

Ironically, several consolidations have had the opposite effect—the size of the boards have increased. For instance, two hospitals in the New York metropolitan area post-consolidation have had over one hundred trustees each. Without wholesale delegation of duties to committees and management, effective operation and governance by such boards is unfathomable. As such, large boards are subject to being dominated by a small subset of individuals, often insiders.[58]

Clearly, a "just right" balance of inside directors versus independent directors is needed, even in the absence of agreement on what it should be.[59] At the least, states should reconsider the wisdom of allowing a three-director minimum, especially where no law exists disallowing any of them from being an inside director. A proper checks-and-balances system needs to be put into place.

Conclusion and Recommendations for Reform

The desire of nonprofit organizations to become more business-like—more efficient in terms of governance structure, composition, and operation—is understandable. The tendency to have a governing board that can formulate and execute decisions quickly in the rapidly evolving marketplace and amidst increasing competition is also comprehensible. Readjusting board size and composition and compensating nonprofit directors can be perceived as a rapid response to changing conditions. However, quick fixes to achieve efficiency can come at the expense of accountability, public understanding and political support. Nonprofit boards' hurried adoption of the characteristics of corporate boards has caused the gyroscope of governance to spin slightly off course. Some calibration through voluntary action or reforms in the laws and policies governing nonprofit organizations may be needed. Better accountability of nonprofit organizations to the public and its various constituencies can be achieved with such reforms.

Some of the attributes of the corporate-style boards are amenable to regulatory guidance and oversight. For instance, Ohio's prohibition of compensating trustees of charitable organizations should be adopted by other states.[60] Similarly, it is recommended that the statutory minimum number of directors, in New York and elsewhere where it is permissively low, be raised to at least five. Although the difference between three and five may not seem numerically significant, its impact can be substantial in the character, composition and conduct of a nonprofit governing board.

Additionally, the Model Act's optional section requiring that decisions be made by a disinterested majority of a nonprofit's governing board should be adopted by New York and other states. Short of banning inside directors outright, some consideration should be given to fixing a statutory maximum number or percentage of inside directors allowed on nonprofit boards. At a minimum, inside directors should be disqualified from participating in decisions where they have a personal or other financial interest in a transaction being considered by their respective boards. Stripping inside directors of their voting privileges altogether is another solution, although problematic for small boards with inside directors.

Other regulatory mechanisms include the "intermediate sanction" regulations, as defined in the Internal Revenue Code,[61] and the Sarbanes-Oxley Act.[62] The "intermediate sanctions" regulations were intended to penalize persons who used their influence over tax-exempt organizations in order to derive an impermissible benefit from an organization. Directors with conflicted interests were disqualified from participating in decisions relative to their interest. Under prior law, the only remedy for such transactions was revocation of the organization's tax exemption. The 1996 legislation provided an "intermediate" means of addressing improper

transactions by penalizing both the persons who benefited from such transactions and those organization managers who approved them.

The Sarbanes-Oxley Act was enacted by the United States Congress in July 2002 in response to the corporate and accounting scandals of Enron, Arthur Andersen and others, to rebuild trust in the corporate sector.[63] The law requires that publicly traded companies adhere to significant new governance standards that broaden board members' roles in overseeing financial transactions and auditing procedures. While it is still too early to know to what extent compliance will be achieved and director misconduct curbed in the corporate sector, the Sarbanes-Oxley Act does not apply to nonprofit corporations. However, some would like to see certain provisions of the Act made applicable to nonprofit corporations.

Other calls for reform within the nonprofit sector have included: (i) increasing the classes of person with standing to sue directors and officers of nonprofit organizations, (ii) using relators to enhance the role and reach of the attorneys general, (iii) increasing public involvement and letting "sunshine" into the affairs of nonprofits, (iv) lessening the complex dissolution and other arcane features in certain state regulatory schemes, and (v) using the Form 990 as a tool for enhanced disclosure and better oversight and accountability of nonprofits, among others. These are designed to make the nonprofit sector better and more accountable to its constituents and the community at-large.[64]

Ultimately, there is only so much change that can be achieved through involuntary external regulation and enforcement. Change must also come from within an organization. Voluntary and self-prescribed reforms are essential for the effective transformation of nonprofit governance. The increasing preference for more corporate-style boards among certain nonprofits, including hospitals and health care systems, must be reconsidered. It remains to be seen whether in the long run a move from community "ownership" toward a model more closely resembling the closely held corporation will be in the best interests of the nonprofit sector and society.

Endnotes

1. Ryan, William P., *The New Landscape for Nonprofits,* Harvard Business Review (Jan.-Feb. 1999).
2. Hansmann, Henry, *The Role of Nonprofit Enterprise*, 89 Yale L.J. 835 (1980); and Colombo, John D. & Hall, Mark A., The Charitable Tax Exemption (Westview Press, Inc. 1995).
3. Pointer, Dennis D. & Orlikoff, James E., Board Work: Governing Nonprofit Health Care Organizations (Jossey-Bass, San Francisco 1999).
4. Bowen, William G., et al., The Charitable Nonprofits 21 (Jossey-Bass, San Francisco 1994); *see also* Pointer & Orlikoff, *supra* note 3, at 1. (There are approximately 7,500 health system and hospital boards, and about 120,000 people sit on them).
5. Peters, Gerald R., Healthcare Integration: A Legal Manual for Constructing Integrated Organizations 3 *et seq.* (National Health Lawyers Association, Washington, D.C., 1995); and Pointer & Orlikoff, *supra* note 3, at 13.
6. Bryant, L. Edward, Jr., *Responsibilities of Directors of Not-for-Profit Corporations Faced with Sharing Control with Other Nonprofit Organizations in Health Industry Affiliations: A Commentary on Legal and Practical Realities,* 7 Annals of Health Law 139 (1998).
7. Nonprofit Coordinating Committee of New York, The Nonprofit Sector in New York City, at i (New York 1992).
8. The United Hospital Fund of New York provided a planning grant to study the feasibility of merging Saint Luke's Hospital Center and The Roosevelt Hospital in 1978. The merger was completed the following year.
9. N-PCL § 601.
10. N.Y. Public Health Law art. 28, and 10 N.Y.C.R.R. Part 405, *et seq*.
11. Ilchman, Warren F. & Burlingame, Dwight F., *Accountability in a Changing Philanthropic Environment,* in Philanthropy and the Nonprofit Sector in a Changing America (Clotfelter, Charles T. & Ehrlich, Thomas, eds., Indiana Univ. Press 1999).
12. Fishman, James J., *The Development of Nonprofit Corporation Law and an Agenda for Reform,* 34 Emory L.J., 617, 669 (1985).
13. Goldschmid, Harvey J., *The Fiduciary Duties of Nonprofit Directors and Officers: Paradoxes, Problems, and Proposed Reforms,* Journal of Corporation Law, Summer 1998, at 632, and presented at National Center on Philanthropy and the Law conference, New York, October 30–31, 1997; *see also* Kurtz, Daniel L., Board Liability: Guide for Nonprofit Directors 78 *et seq.* (The Association of the Bar of the City of New York, Moyer Bell Limited, Mt. Kisco, N.Y. 1988).
14. Dale, Harvey P., *Advising Directors and Trustees on Risks and Opportunities*, C875 ALI-ABA 57 (1993); *see also* Fremont-Smith, Marion R., *The Role of Government Regulation in the Creation and Operation of Conversion Foundations*, 23 EOTR 1, at 37 *et seq.*; Nat'l. Center on Philanthropy and the Law Symposium, *Enforceability and Sanctions in Governance of Nonprofit Organizations: Standards and Enforcement*, New York Univ. School of Law 1997.
15. Pub. Law No. 107-204, 116 Stat. 745.
16. Office of New York State Attorney General Eliot Spitzer, Press Release March 12, 2003; Draft Memorandum, Attorney General's Legislative Program, Program Bill No. 02-03; Legislative Drafting Comm. 06251-01-3; Senate Bill No. S.4836A (as amended June 10, 2003).
17. Pointer & Orlikoff, *supra* note 3, at 153.
18. *Todd v. Citizens Gas Co.,* 46 F.2d 855, 865 (7th Cir. 1931), *cert. denied*, 283 U.S. 852; *Eastern Kentucky Welfare Rights Organization v. Simon,* 506 F.2d 1278, 1288 (D.C. Cir. 1974); Clark, Carolyn C., *New York Healthcare Nonprofits: Regulation of the Merger and Conversion Process,* Conference on Health Care Conversion Foundations: Protecting the Public Interest, The State Capitol, Albany (draft dated April 20, 1999).
19. Bowen, William G., Inside the Boardroom: Governance by Directors and Trustees 51 (John Wiley & Sons, Inc., New York 1994).
20. Bowen, *supra* note 19, at 53.
21. *Queen of Angels Hospital v. Younger*, 136 Cal. Rptr. 36 (Cal. Ct. App. 1977), and Ono, Naomi, *Boards of Directors Under Fire: An Examination of Nonprofit Board Duties in the Health Care Environment,* 7 Annals of Health Law 107 (1998).

22. Brody, Evelyn, *The Limits of Charity Fiduciary Law,* 57 Md. L. Rev. 1400 (1998).

23. Kurtz, *supra* note 13, at 8 *et seq.*, and Goldschmid, *supra* note 13.

24. Millstein, Ira M., partner, Weil, Gotshal & Manges LLP, *Lessons from For-Profit Governance: Responsibilities in the Hospital Boardroom,* presentation at United Hospital Fund Trustee Leadership Briefing, New York, February 19, 1998; *see also* Kurtz, *supra* note 13, at 6.

25. Kurtz, *supra* note 13; *see also* Bowen, *supra* note 19.

26. Goldschmid, *supra* note 13.

27. Oleck, Howard L., Nonprofit Corporations, Organizations, and Associations, 4th ed. 619–20 (Prentice Hall, Inc., New Jersey 1980); and Ohio Rev. Code § 1713.30. *But see* N.Y. Mental Hygiene L. § 75.15; 27 N.Y.C.R.R. § 75.

28. Carver, John, Boards that Make a Difference: A New Design for Leadership in Nonprofit and Public Organizations 17 (Jossey-Bass, San Francisco 1990).

29. Warden, Gail L., CEO, Henry Ford Health System, *Creating Health Systems for the 21st Century: The Roles of Trustees, Management, and Physicians in Health Care Integration,* presentation at United Hospital Fund Trustee Leadership Briefing, New York, November 9, 1998.

30. *Commonwealth of Pennsylvania v. Barnes Foundation,* 398 Pa. 158, A.2d 500 (1960).

31. *In Re Caremark International, Inc. Derivative Litigation,* 698 A.2d 959 (1997), and Gruner, Richard S., *Director and Officer Liability for Defective Compliance Systems: Caremark and Beyond,* 995 PLI 57 (1997).

32. Fremont-Smith, *supra* note 14, at 48–49.

33. *See* Revised Model Nonprofit Corporation Act (RMNCA), The Committee on Nonprofit Corporations, Section of Corporation, Banking, and Business Law, American Bar Association, exposure draft, May 1986.

34. The term "disqualified persons" was adopted under the new intermediate sanctions regulations recently promulgated by the Internal Revenue Service. *See* Taxpayer Bill of Rights 2 (1996), Internal Revenue Code, 26 U.S.C. § 4958, REG-246256-96 (1998).

35. *Stern v. Lucy Webb Hayes National Training School,* 367 F. Supp. 536 (D.D.C. 1973), 381 F. Supp. 10003 (D.D.C. 1974); *Blankenship v. Boyle,* 329 F. Supp. 1089, *Fowle Memorial Hospital Co. v. Nicholson,* 189 N.C. 44, 126 S.E. 94 (1925).

36. *Committee to Save Adelphi, et al. v. Diamandopoulos, et al.*, Board of Regents of the Univ. of the State of N.Y. (Feb. 5, 1997); and Fishman, James J. & Stephen Schwartz, Cases and Materials on Nonprofit Organizations (re: the Adelphi University case) (Foundation Press 1995); *Trustees Ousted in Hawaii,* Chronicle of Philanthropy, Vol. XI, No. 15, May 20, 1999; *In re Estate of Beryl H. Buck, Deceased,* No. 23259 (August 15, 1986); Letter of Agreement between the Commonwealth of Massachusetts, Office of the Attorney General and Dr. G. B. Metcalf, Chairman and on behalf of Trustees of Boston University (November 16, 1993).

37. Goldschmid, *supra* note 13, at 646; Hopkins, Bruce R., The Law of Tax-Exempt Organizations, 6th ed. (1992).

38. *Committee to Save Adelphi*, *supra* note 36, and Goldschmid, *supra* note 13, at 647.

39. Bjorklund, Victoria, Fishman, James J. & Kurtz, Daniel L., New York Nonprofit Law and Practice: With Tax Analysis (Michie Law Publishers, Virginia 1997); *see also* Kurtz, *supra* note 13, at 6.

40. Kurtz, *supra* note 13, at 27.

41. *Boston Children's Heart Foundation, Inc. v. Nadal-Ginard*, 73 F.3d 429 (1st Cir. 1996); *Application of J. Stanley Baker v. Henry Glass & Co.*, 140 Misc. 2d 836, 531 N.Y.S.2d 746.

42. RMNCA § 8.13, Comments (1987).

43. RMNCA § 8.13.

44. Kurtz, *supra* note 13, at 7 n.11; Cal. Corp. Code § 5227.

45. *See* note 16.

46. *See* note 15.

47. 10 N.Y. ADC 610.4, 10 N.Y.C.R.R. § 610.4 (regarding the establishment of hospitals).

48. *See* note 43 *supra,* at sec. 610.4(a)(2).

49. Bjorklund et al., *supra* note 39, at 341.

50. Fishman, James J., *supra* note 12, at 674.

51. Kurtz, *supra* note 13, at 64, and Bjorklund et al., *supra* note 39, at 400.

52. Kurtz, *supra* note 13, at xi; Bjorklund et al., *supra* note 39, at 387; and Goldschmid, *supra* note 13, at 1.

53. Millstein, *supra* note 24, and Pointer & Orlikoff, *supra* note 3.

54. N-PCL § 702.

55. Oleck, *supra* note 27, at 597.

56. RMNCA § 8.03(a).

57. Cal. Corp. Code § 5151(a).

58. Oleck, *supra* note 27, and Taft., S., *Control of Foundations and Other Nonprofit Corporations,* 18 Clev. St. L. Rev. 478 (1969).

59. Pointer & Orlikoff, *supra* note 3, at 134.

60. *See* note 29, *supra*, p. 17. It should be noted, however, that given the deeply rooted tradition of compensating trustees of private foundations, a more practical recommendation may be to limit the prohibition to public charities and perhaps section 501(c)(4) organizations.

61. *See* Internal Revenue Code § 4958, enacted in 1996.

62. *See* note 15.

63. *See* note 15.

64. Fleishman, Joel L., *Public Trust in Not-for-Profit Organizations and the Need for Regulatory Reform,* ch. 8 in Philanthropy and the Nonprofit Sector in a Changing America, *supra* note 11; Goldschmid, *supra* note 13; Clark, *supra* note 18; Fishman, *supra* note 12; and Swords, Peter DeL., *The Form 990 as an Accountability Tool for 501(c)(3) Nonprofits,* 51 Tax Lawyer 571 (1998).

J. David Seay, Esq., is executive director of the National Alliance of the Mentally Ill of New York State. Previously, he was vice president, corporate secretary and general counsel of the United Hospital Fund. David Weisberg, Esq., is an attorney in private practice admitted in New York, New Jersey and Florida. Previously, he worked with Mr. Seay at the United Hospital Fund through an Albert Schweitzer Fellowship under the auspices of the Harvard University Medical School. An earlier version of this article was presented at the Nonprofit Forum.

Parent-Subsidiary Relationship of Not-for-Profit Corporations Raises Official Oversight Issues

By Robert P. Borsody

Given the increasing size and complexity of the not-for-profit sector of the economy,[1] it is important that attorneys who have contact with not-for-profit corporations understand the parent-subsidiary relationship that can exist between and among these types of organizations. This article examines the nature of this relationship and the applicable law—including some conflicting assertions of oversight authority by state agencies.

The Not-for-Profit Parent and Subsidiary, Generally

The term "parent-subsidiary relationship" has a well-understood meaning in the for-profit or business corporation sector. The parent controls one or more subsidiary corporations, usually through ownership of all or a majority of stock. Under the New York Business Corporation Law, ownership of such stock brings with it the right to elect directors. Directors control the corporation by the appointment of officers and the exercise of all other rights and powers over the subsidiary's corporate assets. However, and as will be seen below, the concept is less clear in the not-for-profit area, and cases interpreting the relationship and its implications are few.

In not-for-profits, the parent-subsidiary relationship is created by a provision in the by-laws (or certificate of incorporation) that contains language along the following lines: "[Subsidiary] shall be a membership corporation. [Parent] shall be the sole member of [subsidiary] corporation." To insure that the parent-subsidiary relationship cannot be changed by the subsidiary, the by-laws or certificate of incorporation will also contain a provision that these governing documents may not be changed or amended without the consent of the parent. To provide additional control by the parent entity, the by-laws may also permit the parent to remove directors without cause at any time, and to appoint replacements. A moment's reflection reveals that this combination of provisions gives considerable control to the parent.

Growing Use by Not-for-Profit Health Care Providers

To understand why the parent-subsidiary relationship has gained popularity among health care not-for-profit corporations, an initial overview of their organization and certain practical considerations is helpful.

New York not-for-profit corporations, as is the case with most such corporations in the United States, can be either membership corporations or non-member corporations. Non-member corporations, as the name implies, have no members, and the directors are elected by the directors themselves. If, for example, the by-laws provide that the terms of one-third of a board of nine directors shall expire every three years, then, at the end of three years when the term of three directors ends, the remaining six directors would nominate and elect three directors to replace those whose terms have expired. Similar provisions would exist for any "self-perpetuating" board of directors.

By contrast, a membership corporation will provide that the membership elects directors. These are fairly common for organizations such as soccer clubs, garden clubs, etc. Today, membership corporations are no longer the norm for entities such as hospitals, not-for-profit nursing homes and other not-for-profit health care providers.

At one time, it was common for the by-laws or certificate of incorporation of a hospital membership corporation to provide that the membership of the corporation would consist of those persons who assembled or met at a certain place on a certain date for the purpose of electing directors. The provisions were as simple as that. Others may have provided for membership based on payment of a nominal sum, or for residence in a certain area, or the additional qualification of being a recipient of the health care provider's services.

However, as hospital providers have become larger and more complex, with more complicated decisions to be made and heavier responsibilities to be shouldered by those in charge, these simple membership provisions have gradually been eliminated. One key reason is the desire to be more selective in the membership of the board of directors; there is a practical need for people with the business or professional skills and talents to make complicated decisions.

Political reasons exist for the elimination of these membership provisions as well. The writer was present at a membership meeting that demonstrated the potential problem that such provisions can cause for a hospital's management. A small upstate hospital had one of the "just show up" membership clauses described above. Its management became embroiled in a conflict with some members of its medical staff. On the appointed night of the annual membership meeting, those members of the medical staff assembled, with a

number of their friends and supporters and, in effect, "took over" the hospital.

A similar situation occurred in a downstate neighborhood health center. The health center found itself in a conflict with a major union. Members, their supporters and employees of that union assembled on the night of election for the board of directors. This did not result in the "takeover" of the not-for-profit membership corporation, but the simple membership provisions were eliminated from the by-laws shortly after the hotly contested election was resolved. The health center remained a membership corporation, but the by-laws were changed to provide for a single member. This was intended to create a "parent-subsidiary" relationship that, among other things, would eliminate the possibility that had nearly come to pass. Needless to say, the directors of the parent entity were elected by the "self-perpetuating board" process rather than by a membership from the community at large.[2]

Forms of Organization for Parent and Subsidiary Not-for-Profits

The most frequent configuration for a "parent-subsidiary" relationship occurs when a single hospital creates a parent entity. (In virtually all cases the hospital corporation, which is a New York not-for-profit corporation licensed under Article 28 of the New York Public Health Law, exists before the creation of the parent.) The parent entity is created by putting parent-subsidiary language into the by-laws of the hospital, giving the parent entity the right to elect or appoint the directors of the hospital. The parent entity is also a New York not-for-profit corporation and is usually a non-member corporation. The parent will often have additional subsidiaries. Frequently, one of those subsidiaries will be a fund-raising corporation, which will also have not-for-profit status. Another subsidiary or subsidiaries often are business corporations, such as real estate holding companies or corporations formed for joint ventures with for-profit professionals or professional entities, such as a doctor or doctor groups.

These sister subsidiaries of hospitals are usually formed for the purpose of insulation of liability and for avoiding regulatory control. They are given various popular names, such as Physician Hospital Organization (PHO) or Managed Care Organization (MCO). If the entity were a subsidiary controlled by the hospital, then the agency that regulates the hospital, the New York State Department of Health (DOH), could rightfully assert regulatory jurisdiction over the entity on the basis of such control. Because one of the reasons for creating the entity is to allow for freedom and flexibility, which the highly regulated health care system in New York does not enjoy, a "sister" subsidiary relationship is usually used.

Another minor variation is for the parent entity to be a trust instead of a New York not-for-profit corporation. A trust is quick and inexpensive to set up. The trust instrument—which is basically a contract between a donor and the trustees—contains language almost identical to the boiler-plate language found in most not-for-profit corporations, particularly those that intend to apply for federal tax exemption. Because it is essentially a "private" contractual form, it may be executed and come into existence instantly and at no cost, as compared to and contrasted with a not-for-profit certificate of corporation, which must be filed with the Department of State. It should be noted, however, that the creation of a not-for-profit corporation has been simplified and streamlined in recent years, because the consent of a Supreme Court justice is no longer required, as it was before the 1993 amendment to § 404 of the New York Not-for-Profit Corporation Law.[3]

Although created by an indenture requiring no filing with any agency, a trust is nonetheless a legal entity. It comes into being upon the execution of the trust instrument and the payment of the corpus of the trust from the donor to the trustees. This "corpus" can consist of any nominal amount, such as $10. The trust created by this process can own property, employ people, sue and be sued and, essentially, do everything that a not-for-profit corporation can do. Such a trust entity is legally identical to a testamentary or *inter vivos* trust set up by an individual to minimize estate taxes, or to provide for the support and protection of the individual's survivors. A "parent" trust, however, has a different purpose, which can generally be described as the support and direction of the subsidiary.

Returning to the more common corporate form, the certificate of incorporation of the parent not-for-profit corporation will not contain any provisions that require regulatory approval, or a consent from any regulatory agency such as the DOH or the Department of Education. This essentially means that the parent entities are "do nothing" corporations. The powers of the corporation must be drafted with care to avoid containing any phrases or words that would act as red flags to the reviewers in the Department of State, and cause them to reject the proposed certificate of incorporation on the ground that the corporation had to obtain a required approval or consent by one of the regulatory agencies before filing. Although a trust is not submitted to the Secretary of State, it should also not contain powers that would require consent, approval or license by any state agency.

Tax Considerations for Not-for-Profit Parent Organizations

Both the parent trust document and the parent not-for-profit corporation certificate of incorporation would

contain language in the purposes clause designed to assist in a successful application for tax exemption.

This language would contain all the basic boilerplate verbiage about no inurement to private parties, and would provide for appropriate disposition of assets in the event of dissolution. In addition to the basic and standard tax exemption language, however, the purposes clause must be drafted with care to set forth, on the one hand, tax exempt functions and, on the other, not to describe a function that will require licensing by some state agency.

A common approach here is simply to use "supporting organization" language that provides for the support of the tax-exempt subsidiary, usually by fundraising. If, as is usually the case, the supported subsidiary is an entity exempt under § 501(c)(3) of the Internal Revenue Code, then such a supporting organization parent will usually qualify under § 509(a)(3). It should be noted that if the parent entity is not tax exempt, a tax exempt subsidiary cannot "upstream" profits to the parent without risk to its own status, because such a transfer of profits would amount to an improper inurement from an exempt organization to a non-exempt one. At a minimum, it would trigger the application of some intermediate sanction under the 1996 "Intermediate Sanctions Law."[4]

It should be further noted that, if the purposes of a proposed New York not-for-profit corporation include support of an entity licensed under Article 28 of the New York Public Health Law, the approval of the Public Health Council is required.[5] A comprehensive discussion of the complexities of tax exemption is beyond the scope of this article, but the point to be made here is that both parent and subsidiary are almost always tax exempt, and the parent's exemption is usually dependent on or derivative from the subsidiary.

Organization of Multi-Hospital Systems

Multi-hospital systems are an interesting variant on the parent-subsidiary theme. A parent entity may be created to control several hospitals, a form that has become prevalent in downstate New York. In these multi-hospital systems, it is often the case that the "parent" is not the sole member of the subsidiary hospital, but rather exercises its influence through a number of different contractual and non-contractual relationships. These relationships can vary in nature and in importance, depending upon economic issues, the dynamics of power within and among the involved hospitals, and the history of the formation of the system.

Relationships can vary from an "affiliation agreement," providing for no more than the staffing of one hospital by another (certainly not a classic parent-subsidiary relationship), to one in which there are a transfer of assets, guarantees of debt and a "holding out" as a member of a system. The number and nature of these contractual relationships can be fluid. They wax and wane according to political and economic pressures, and are too numerous to describe in any detail here.

Other control relationships in a multi-hospital organization are more clear cut, however. For example, a management contract relationship, which alone would not create parent-subsidiary status, has sometimes been added to a more classic parent-subsidiary relationship to provide for additional control by the parent. Management contracts with an Article 28-licensed hospital are subject to specific and extensive regulation by the DOH.[6]

Another control provision is asset ownership by the parent. This could be accomplished by having the major assets of the subsidiary, such as real estate, transferred to the parent and then leased back to the subsidiary. Issues could arise here—such as the requirement of court approval for transfer of "all or substantially all" of the assets of a not-for-profit corporation,[7] and the restrictions on transfer of assets of a tax-exempt corporation that might result in an "inurement" to an entity that is not tax exempt. If, however, the parent entity is a not-for-profit corporation and tax exempt as well, these latter problems are minimized.

Special Issues for Religious Organizations Controlling Hospitals

The parent-subsidiary relationship is often created by religious organizations to control hospitals they have founded and continue to fund. Indeed, this is one of the most common and widespread contexts in which this form of relationship is utilized.

Most prominent in the downstate area is the Catholic Archdiocese of New York City, the parent entity for a number of its hospitals. Further, various orders of nuns within the diocese are parent entities for hospitals controlled by those orders. Again, and as is described above, this relationship is created by simply stating that the archdiocese or the order is the sole member of the membership corporation, the subsidiary hospital.

These religious organizations often have specific objectives that are sought to be achieved, or maintained, through the parent-subsidiary relationship. Common examples are based on the position the Catholic Church takes in the area of human reproduction, which would include restrictions on birth control, abortion and family planning. Compliance with the church's position might be achieved by specific wording in the by-laws of the subsidiary, and are often referred to as "reserved powers." This means that certain powers of the subsidiary are "reserved" for exercise by the parent or require consent, approval or some type of involvement by the parent. The obvious ques-

tion that arises is to what extent a parent may interfere with or control the operations of a hospital subsidiary without requiring some type of consent or approval by the New York State DOH under the provisions of Article 28 of the Public Health Law—which regulates all aspects of creation and operation of hospitals and nursing homes and other types of institutional providers.[8]

Article 28 Regulation and the *Fraidstern* Case

The first New York case examining the parent-subsidiary relationship was *Fraidstern v. Axelrod*.[9] In this case (unreported, unfortunately), the closing of St. Elizabeth's Hospital in northern Manhattan was challenged by a group of community residents, consumers of services and political personalities. The hospital had been transferred from one religious order to another, specifically, to the Missionary Sisters of the Sacred Heart (who also controlled Cabrini Hospital by means of the standard parent-subsidiary relationship) from the Franciscan Sisters of Allegany, who had controlled St. Elizabeth's Hospital through the same arrangement. The new controlling parent elected a new board and that board then proceeded, after proper notice to the DOH, to close St. Elizabeth's Hospital.

The plaintiff group challenged the closure and successfully secured a temporary restraining order to prevent it until a hearing could be had on the legal question raised. That question was whether the new board was properly and duly elected by the new parent, because the DOH's consent was not secured for either the transfer to the new parent or the election of the new board. The argument made by the plaintiffs was that a business corporation that owned and operated a New York hospital licensed under Article 28 was required to secure permission to transfer 10% or more of its stock; under that standard, they asserted, transfer of 10% or more of control of a not-for-profit corporation—and here it was 100%—should also require regulatory approval by the DOH.

The case aroused intense interest. Religious organizations did not want to have to secure regulatory consent for transfers of hospitals between religious orders—and, as it turned out, the DOH was even less willing to review them. The DOH official, who at that time was charged with reviewing Article 28 Certificate of Need applications, testified that the DOH had no jurisdiction over transfers of control of not-for-profit corporations, provided there was no change in the purposes or powers of the Article 28-licensed entity itself.[10]

The case had become a political "hot potato" because the plaintiffs consisted of a large group of concerned citizens and prominent politicians, and the defendants consisted of an order of nuns. It was heard by an upstate judge who was sitting in New York County by designation. The court ultimately found that there was no requirement for Article 28 review by the DOH in the case of transfers of control of not-for-profit hospital corporations. The court stated that the "regulations are devoid of any reference to required approvals for changes in the sponsorship of not-for-profit corporate hospitals operators" and dismissed the case.

After the *Fraidstern* case, regulations were promulgated that clarified when a parent entity has to secure "establishment approval" by the relevant New York State regulatory authorities, such as the Public Health Council or the State Hospital Review and Planning Council, if a transfer of control is to occur. In essence, the regulations provide that if the parent has certain operational authority over a subsidiary that is an Article 28-licensed entity, the parent has to apply to the DOH for "establishment" as a licensed Article 28 provider.[11]

The *Nathan Littauer* Case Limits Role of Attorney General

As described above, the DOH has plenary jurisdiction over certain types of parent-subsidiary relationships. Specifically, when the parent entity has certain operational powers over the Article 28-licensed hospital subsidiary, then the DOH has a right to require that the parent entity be "established," also under Article 28. Along with Article 28 establishment comes continuing regulatory authority by the DOH over the parent.

The New York Not-for-Profit Corporation Law also gives the attorney general the right to review certain activities of not-for-profit corporations. For example, if a not-for-profit corporation wishes to dispose of "all or substantially all of its assets," consent of a Supreme Court justice is required, upon notice to (or advance consent and waiver of the notice by) the attorney general.[12] The attorney general has broad authority to review the activities of not-for-profit corporations under the general *parens patrie* powers of the state. These powers are usually exercised over entities that are not otherwise specifically regulated as licensed organizations by other state agencies—for example, a general fund-raising entity, or a foundation that has been endowed through a grant or will for purposes of benefiting society in some particular manner. The attorney general has the power to act against waste, self-dealing and breaches of fiduciary duty by the trustees or directors of such foundations or entities.[13] That does not mean there never is controversy about the exercise of these powers, however, as indicated below.

In *Nathan Littauer Hospital Ass'n v. Spitzer*,[14] the attorney general was opposed by members of the health care industry regarding the scope of his right to review the actions of hospitals, most of which happen to be not-for-profit corporations.[15] The hospitals in that case had applied to the state regulatory agency, the DOH,

for a ruling that their proposed actions would require no regulatory approval, and this ruling was granted. The attorney general, however, was of the opinion that approval of the Supreme Court was required under the Not-for-Profit Corporation Law, including service on and a review by his office under that statute's procedure. The hospitals commenced a declaratory judgment action for a ruling that such approval was not required and the trial court agreed; the Appellate Division, Third Department affirmed.

"Health care providers strain beneath the weight of repeated legislative initiatives, which, though well-intentioned, often are expensive and onerous to administer—witness the new HIPAA statute."

The facts of the case were as follows: A community hospital, controlled by a parent, proposed a merger with a Catholic-sponsored hospital, also controlled by a Catholic-sponsored parent. It was proposed that the two hospitals combine by transferring control of both hospitals to a single parent. This new parent itself would be a subsidiary of the two entities that were formerly parents of the two hospitals. The proposed resulting structure would consist of the two former parent entities controlling the new single parent entity, which would then control the two hospitals. An issue raised in the case was that the new parent entity of the two hospitals would have certain "reserved powers" requiring that both of the hospitals comply with the Ethical and Religious Directives for Catholic Health Care. These directives would require the elimination of certain reproductive health services in both subsidiary hospitals. The original arrangement also had such reserved powers but only for the Catholic-sponsored hospital.

The attorney general, and a community-based entity that intervened as an *amicus*, argued before the trial court that this proposed reconfiguration constituted a change in corporate purposes, thereby requiring attorney general and court approval under the Charitable Trust Law.

The hospitals, on the other hand, argued that the proposed arrangement did not involve the transfer of assets or a statutory merger of the hospitals, and that those hospitals remained separate corporate entities. They also asserted that there was no change in the corporate purposes of either hospital but, simply, a change in membership. The ruling by the DOH that the new parent entity of the two hospitals did not need to be established under Article 28 of the Public Health Law, on the ground that it had no operational powers, was also cited in support of this argument.

The Hospital Trustees Association, as well as several of its state and regional hospital associations, as *amici*, argued that New York State already had a complex and comprehensive regulatory scheme over hospitals, with which the affiliating entities had complied, and that a further layer of regulation was not needed.

In ruling in favor of the plaintiffs, the trial court cited the statement of the New York State Hospital Association that the association has 234 members, 160 of which are members of hospital networks that exercise "some degree of corporate control over its members' hospitals," and adopted the association's position that the state Healthcare and Reform Act of 1996 reflected the legislature's intention of "reducing the role of regulation" over these health care organizations. Other "general legislative trends towards less regulation of hospitals, not more" were noted by the court, as had been argued by the association. The court also noted that the association's counsel, on oral argument, had stated that "200 similar transactions have occurred in the state without need for approval."

The court concluded that the attorney general had no role to play in the proposed transaction, stating that "the statutory scheme envisions DOH overseeing changes in the healthcare services of a hospital. That has been accomplished to their satisfaction in this case. The scheme does not include a role for the court or the attorney general in the proposed affiliation such as this one." As noted above, the lower court's decision was affirmed by the Appellate Division. Leave to appeal was denied by the Court of Appeals.

Conclusion

The New York health care system is already one of the most strictly and carefully regulated in the country. Health care providers strain beneath the weight of repeated legislative initiatives, which, though well-intentioned, often are expensive and onerous to administer—witness the new HIPAA statute.[16] Intended to protect patient privacy, it has instead primarily benefitted consultants, who sell expensive packages and hold seminars and publish books on how to comply with its numerous, complex provisions—among which is the prominently featured possibility of a $250,000 penalty for each violation. Under these circumstances, intervention in the New York health care system by the attorney general (who has certainly shown commendable leadership in other areas) to provide an additional layer of oversight is unnecessary.

The cost of regulatory compliance has been recognized; state and federal laws now come with regulatory impact statements, which attempt to assess the cost of compliance by those entities affected by a new pro-

posed law or regulation. But there is no such required regulatory impact assessment if a state agency or official such as the attorney general begins to assert a quasi-regulatory role in an area where there has not been one before. The New York State DOH and the Office of the New York State Attorney General should come to an understanding that in the area of not-for-profit organizations, especially health care providers, current practices and existing regulatory authority is sufficient to protect the public.

Endnotes

1. *The New Equation for Charities: More Money, Less Oversight*, N.Y. Times, Nov. 17, 2003, at F1, col 1. The non-profit service sector accounts for 22% of all private sector jobs in New York. 19 Crain's N.Y. Bus. 1, Dec. 8, 2003, 2003 WL 9129409.
2. The provisions of membership corporations providing for election of the directors by members chosen from the community at large is similar to the requirements of federal regulations for federally funded Neighborhood Health Centers funded under § 330 of the U.S. Public Health Law. Regulations under this section require that the board of the directors of a Neighborhood Health Center contain a majority of users from the area served by the center. Formerly, there was no requirement or specification as to how those directors were to be elected, and as in this example they were able to be appointed by a parent entity or elected by a "self perpetuating board," so long as they actually and ultimately complied with the regulatory requirement. This changed in 1997 when the Division of Community and Migrant Health of the Bureau of Primary Health of the Health Resources and Services Administration of the U.S. Dept. of Health and Human Services promulgated Policy Information Notice 97-27, dated July 22, 1997, which provided that a section 330-funded Neighborhood Health Center could not be controlled by another entity. Affiliation Agreements of Community and Migrant Health Centers, *available at* <ftp://ftp.hrsa.gov/bphc/docs/1997PINS/97-27.PDF>.
3. 1993 N.Y. Laws ch. 139, § 1, eff. Aug. 20 1993.
4. 26 U.S.C. § 4958.
5. *See* Not-for-Profit Corp. Law § 404(o), (t).
6. *See* 10 N.Y.C.R.R. § 405.3(f).
7. *See* Not-for-Profit Corp. Law § 510(a)(3). See also the prohibition against payment of distributions or dividends to the membership of a not-for-profit corporation. Not-for-Profit Corp. Law §§ 508, 515.
8. This issue is intended to be addressed by the following regulation in 10 N.Y.C.R.R. § 405.1(d), which provides as follows:

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

9. Index No. 7414/81 (Sup. Ct., N.Y. Co. July 16, 1981).
10. This official was asked by the attorney for the plaintiffs if he wouldn't want to examine the character and competence—one of the requirements of Article 28 Certificate of Need review—of the membership of an Article 28-licensed hospital if that new member was proposed to be the American Nazi Party or the Ku Klux Klan. He replied that he would have no power to do so.
11. The regulations, found at 10 N.Y.C.R.R. § 405.1(c), provide that:

    > (c) Any person, partnership, stockholder, corporation or other entity with the authority to operate a hospital must be approved for establishment by the Public Health Council unless otherwise permitted to operate by the Public Health Law or as provided for by section 405.3 of this Part. For the purposes of this Part, a person, partnership, stockholder, corporation or other entity is an operator of a hospital if it has the decision-making authority over any of the following:
    >
    > (1) appointment or dismissal of hospital management level employees and medical staff, except the election or removal of corporate officers by the members of a not-for-profit corporation;
    >
    > (2) approval of hospital operating and capital budgets;
    >
    > (3) adoption or approval of hospital operating policies and procedures;
    >
    > (4) approval of certificate of need applications filed by or on behalf of the hospital;
    >
    > (5) approval of hospital debt necessary to finance the cost of compliance with operational or physical plant standards required by law;
    >
    > (6) approval of hospital contracts for management or for clinical services; and
    >
    > (7) approval of settlements of administrative proceedings or litigation to which the hospital is party, except approval by the members of a not-for-profit corporation of settlements of litigation that exceed insurance coverage or any applicable self-insurance fund.

12. Not-for-Profit Corp. Law §§ 510(a)(3), 511(a), (b).
13. Not-for-Profit Corp. Law § 112(a) lists nine situations where the attorney general may bring actions to enforce these powers.
14. 287 A.D.2d 202, 734 N.Y.S.2d 671 (3d Dep't 2001), *leave to appeal denied*, 98 N.Y.2d 602, 774 N.Y.S.2d 762 (2002).
15. A recent article written by the author noted that there were only three hospitals in the state that were not owned by not-for-profit corporations. Robert P. Borsody, *Institutional Licensing in New York State: Ownership by Public Companies*, 8 Health L.J. 26 (Winter 2003). One of the three has since closed.
16. Health Insurance Portability and Accountability Act of 1966, 42 U.S.C. §§ 201 *et seq.*

Robert P. Borsody serves of counsel to Fischbein, Badillo, Wagner, Harding in Manhattan. He directed a federally funded project for health and law research and test case litigation in the 1970s, and served as chair of the Public Health Committee of the NYSBA for four years. He received both his undergraduate degree and his law degree from the University of Virginia.

This article originally appeared in the May 2004 issue of the New York State Bar Association *Journal*.

Supreme Court Rules that ERISA Preempts State Law Claims Challenging Utilization Review by HMO

By Beverly Cohen

Eagerly Awaited Decision on HMO Liability

On June 21, 2004, the United States Supreme Court ruled that members of ERISA health plans cannot sue their plan administrators for consequential damages for injuries the members suffered allegedly due to the administrators' coverage decisions. The *Aetna Health Inc. v. Davila*[1] ruling confirmed the historical view that ERISA plan participants and beneficiaries are limited to the civil remedies set forth in section 502(a) of ERISA.[2] Section 502(a) allows suits for benefits due under the plan and equitable relief, but no consequential or punitive damages. The *Aetna* decision squelched several theories advanced by lower courts that had found that such claims for consequential or punitive damages did not fall within ERISA § 502(a), and therefore were not preempted by ERISA.[3] While the *Aetna* Court's ruling limits potential liability of ERISA plans and helps to control their costs, it also leaves members who allegedly suffer physical injury from negligent utilization review largely without a remedy.

Background—Facts in the *Aetna* Case and the District Courts' Decisions

The *Aetna* case consolidated two Texas cases, both of which presented the same issue of whether ERISA claimants can obtain damages for personal injury allegedly caused by faulty utilization review decisions by health plan administrators. One of the plaintiffs, Juan Davila, received Aetna HMO coverage through his employer's health plan. He is a post-polio patient who suffers from diabetes and arthritis, and was prescribed Vioxx by his treating physician to remedy his arthritis pain. Studies reportedly have shown that Vioxx has less tendency to cause gastrointestinal bleeding, ulceration, or perforation than other drugs on Aetna's formulary. Before covering the Vioxx, however, Aetna required Davila to participate in its "step program," whereby Davila would first have to try two other (less expensive) medications to determine if they would be successful. After three weeks of taking Naprosyn, the first alternate drug required by Aetna, Davila was rushed to the emergency room with bleeding ulcers, which in turn caused a near heart attack and internal bleeding. Davila was kept in intensive care for five days, and received seven units of blood. As a result of his severe reaction to the Naprosyn, Davila can no longer take any pain medication that is absorbed through the stomach.[4]

The second plaintiff, Ruby Calad, was a beneficiary of CIGNA HealthCare of Texas, Inc., through her husband's employer. She underwent a hysterectomy with rectal, bladder, and vaginal repair, performed by a CIGNA physician. Despite her doctor's recommendation for a longer post-surgery hospital stay, CIGNA's hospital discharge nurse decided that the standard one-day hospital stay was sufficient, and refused to cover additional days of inpatient care. A few days after her release, Calad suffered complications that forced her to return to the hospital. Calad blamed the complications on her early release.[5]

Davila and Calad sued their respective HMOs in state court under the Texas Health Care Liability Act (THCLA), asserting that the HMOs' refusals to cover the treatments sought by plaintiffs' treating physicians violated the HMOs' duty imposed by the THCLA "to exercise ordinary care when making health care treatment decisions." The HMOs removed the cases to federal district court, asserting that Davila's and Calad's claims fit within the scope of ERISA's civil remedies, and therefore were preempted by ERISA. The district courts agreed, and when the claimants refused to amend their complaints to bring ERISA claims, the district courts dismissed the complaints with prejudice.[6]

Background—The Fifth Circuit's Decision Reinstating the State Law Causes of Action

When Davila and Calad appealed the dismissals of their complaints, the Fifth Circuit Court of Appeals reversed the district courts' decisions, ruling that the THCLA claims were not preempted by ERISA. The Fifth Circuit found that the plaintiffs' state law claims did not fall within the scope of ERISA, as there were no civil remedial provisions in ERISA that covered plaintiffs' tort claims. The Fifth Circuit declared that ERISA's only arguably relevant remedial sections were sections 502(a)(1)(B), 502(a)(2), and 502(a)(3). As to section 502(a)(3), the court reasoned that it was inapplicable to Davila's and Calad's claims for money damages because it affords only equitable relief. The court next considered section 502(a)(2), which allows relief for fiduciary breaches. Relying on the Supreme Court's holding in *Pegram v. Herdrich*,[7] the Fifth Circuit declared that the utilization review decisions challenged by Davila and Calad were "mixed treatment and eligibility decisions," as they combined components of coverage determinations and medical judgment as to appropriate treatment.[8] The *Pegram* court had found that such mixed treatment and eligibility decisions, albeit when made by a treating physician, were not fiduciary in nature. Based on this finding, the Fifth Circuit concluded that the mixed treatment and eligibility decisions made with regard to Davila and Calad could

not be the basis of a section 502(a)(2) claim for fiduciary breach.[9]

This left only ERISA § 502(a)(1)(B) as a possible source of preemption of the Texas state law claims. Section 502(a(1)(B) allows plan participants or beneficiaries to sue "to recover benefits due . . . under the terms of [an ERISA] plan." But the Fifth Circuit observed that Davila and Calad had raised tort claims, not contract claims for reimbursement for the plan benefits that allegedly had been wrongfully denied. Moreover, plaintiffs were asserting claims that existed independent of their health plans, i.e., a breach of the duty of "ordinary care" imposed by the THCLA, which protected the claims from preemption. Further, relying on the Supreme Court's decision in *Rush Prudential HMO, Inc. v. Moran*,[10] the Fifth Circuit held that ERISA's remedies preempted state law causes of action only when the state claims duplicated the causes of action expressly set forth in ERISA § 502(a). As Davila's and Calad's claims did not fit within any of the section 502(a) remedies, the Fifth Circuit ruled that the THCLA claims were not preempted by ERISA.[11]

Background—Other Venues That Had Allowed Consequential Damages to ERISA Plan Members

In reinstating Davila's and Calad's claims for consequential damages, the Fifth Circuit joined a small but growing group of courts and states that had permitted claimants injured by utilization review decisions made by ERISA health plans to pursue non-ERISA claims for damages. In 2003, the Second Circuit Court of Appeals in *Cicio v. Vytra Healthcare*[12] held that a medical malpractice claim challenging Vytra's medical decision making in the course of its utilization review as administrator of Cicio's ERISA plan was not preempted by ERISA. The Second Circuit relied chiefly on the Supreme Court's recognition of mixed treatment and eligibility decisions in *Pegram* to find that the plaintiff could challenge the treatment component of the utilization review decision as not meeting the state's standards for medical care.[13]

Five months after the Second Circuit decided *Cicio*, the Eleventh Circuit Court of Appeals held in *Land v. CIGNA Healthcare of Florida*[14] that Land's claims against CIGNA for negligent medical judgment in the course of CIGNA's utilization review as administrator of Land's ERISA plan was not preempted by ERISA. The Eleventh Circuit, again relying upon *Pegram*, characterized CIGNA's utilization review determinations as mixed treatment and eligibility decisions. Since Land was challenging the treatment component under state law malpractice standards, and was not seeking to recover benefits due under the plan, the Eleventh Circuit held that his claims did not fall within the civil enforcement provisions of ERISA § 502(a), and thus were not preempted.[15]

Outside of the health care context, several district courts have utilized another theory to allow ERISA plan members to maintain state law claims for extracontractual damages against their ERISA plans. In *Rosenbaum v. UNUM Life Ins. Co. of America*,[16] the District Court for the Eastern District of Pennsylvania ruled that a plaintiff's challenge to a denial of ERISA disability plan benefits under Pennsylvania's bad faith statute for insurance claims was not preempted by ERISA. The *Rosenbaum* court relied on the express language of ERISA's savings clause, which exempts from preemption "any law of any State which regulates insurance."[17] The *Rosenbaum* court reasoned that the savings clause's express exemption overrode any implied intent of Congress to prohibit punitive damages. The court therefore held that Pennsylvania's bad faith insurance statute was saved even though it allowed punitive damages, which are not permitted by section 502(a) of ERISA.[18] Under the reasoning of *Rosenbaum*, states could promulgate insurance laws authorizing consequential or punitive damages for ERISA members, and such laws would be saved from preemption by virtue of ERISA's savings clause.

As the *Aetna* and *Rosenbaum* cases illustrate, state legislatures have struggled with the need to provide meaningful relief to ERISA claimants allegedly injured by their plans' negligent or bad faith coverage decisions. Nine other states, in addition to Texas, have passed laws similar to the THCLA, whereby ERISA health plan members may receive consequential damages for personal injuries caused by faulty plan utilization review decisions.[19]

The Supreme Court's Reversal in *Aetna* of the Fifth Circuit's Decision

The Supreme Court in *Aetna* gave a clue to its ultimate holding by declaring at the outset of its opinion that ERISA's "integrated enforcement mechanism" was meant to achieve a uniform, comprehensive regulation of employee benefit plans. The Court stated that ERISA's remedial scheme represents a deliberate balancing of the need for prompt and fair claims decisions against the desire to encourage employers to voluntarily provide health benefits to their employees. Thus, any state law claim that "duplicates, supplements, or supplants" the remedies set forth in ERISA disrupts ERISA's comprehensive remedial scheme and potentially upsets this balance.[20]

Under the doctrine of "complete preemption," any claims that can be brought under ERISA's civil remedy provisions, and where there is no other independent legal duty breached by the defendant, are completely preempted by ERISA.[21] Although Davila's and Calad's claims were styled as challenges to the poor quality of the medical judgments made by the HMOs, the Supreme Court found that the crux of Davila's complaint was that Aetna had refused to approve immediate coverage for Vioxx. Similarly, the action complained of by Calad was CIGNA's failure to approve an extended hospital stay. The Court held that these, in effect, are standard chal-

lenges to denials or limits on coverage that fall within ERISA § 502(a)(1)(b), claims for benefits due under the respective ERISA plans.[22]

Further, the Supreme Court disagreed with the Fifth Circuit's finding that the THCLA constituted an independent standard of care that could be enforced outside of ERISA. The Court reasoned that the terms of the ERISA plans themselves were the grounds for the denials, placing the plans themselves at the center of the controversies. Since resolution of the THCLA claims would necessarily require an interpretation of the terms of coverage of the plans, the Supreme Court concluded that the THCLA claims were not independent of the plans.[23]

While the Fifth Circuit had determined that Davila's and Calad's tort claims for damages did not fall within ERISA's § 502(a) contractual and equitable remedies, the Supreme Court held that preemption should not hinge upon whether the plaintiffs labeled their claims as "contract" or "tort." Basing preemption upon such labels would "elevate form over substance" and would permit an easy evasion of ERISA preemption.[24] Although the Fifth Circuit had found, citing to *Rush v. Prudential*, that a state cause of action was preempted only when it exactly duplicated an ERISA remedy, the Supreme Court stated that this was a misreading of *Rush*, and that preemption is not limited to just those situations where the state cause of action exactly duplicates an ERISA cause of action. Rather, a state claim can be preempted by ERISA even when it does not exactly duplicate an ERISA claim, if it changes or adds to ERISA's exclusive civil remedies.[25]

One of the most significant aspects of the Supreme Court's holding in *Aetna* is its discussion of how the Fifth Circuit misapplied the *Pegram* holding. *Pegram*'s discussion of "mixed treatment and eligibility decisions" made by HMOs has led lower courts to conclude that such decisions constitute, at least in part, medical treatment that may be challenged under state quality-of-care laws.[26] The *Aetna* Court explained, however, that *Pegram* stands only for the limited principle that an eligibility decision made by the treating physician is so intertwined with treatment (a mixed treatment and eligibility decision) that it cannot be characterized as a fiduciary act under ERISA. Rather, such a mixed decision can be challenged as medical malpractice under state law, and the state law claim is not preempted by ERISA's fiduciary remedies. In contrast to *Pegram*, the *Aetna* Court observed that Davila's and Calad's benefit determinations were made by their plan administrators, not by their treating physicians or the physicians' employers. Even though these coverage decisions necessarily involved medical judgments, the Court held that these administrative coverage determinations by non-treating entities were "pure eligibility decisions" that were clearly preempted by ERISA's exclusive remedial provisions.[27]

Finally, the *Aetna* Court settled the issue of whether state laws such as the THCLA which allow remedies for ERISA claimants that are not permitted by ERISA itself nevertheless could be saved as the regulation of insurance (i.e., the *Rosenbaum* theory). Here, the Court declared that ERISA's savings clause must be "informed by the legislative intent concerning the civil enforcement provisions provided by ERISA." Because the remedial scheme of ERISA could be "completely undermined" by such saved state laws that permit remedies in addition to those set forth in ERISA, the Court ruled that the THCLA was not saved from preemption.[28]

Reactions to the *Aetna* Decision

Reported reactions to the *Aetna* decision demonstrate how polarized the views are on this issue. Health care payors, including HMOs, health insurers, and employer groups, applauded the decision for placing limits on costly litigation and holding down expenses for employee health benefit plans.[29] Payors were understandably concerned at the prospect of virtually unlimited liability for their utilization review decisions, with the possibility of being sued for every adverse medical outcome following a coverage denial or limitation.[30]

At the other end of the spectrum, many ERISA health plan members and their doctors tend to see the limits on ERISA health plan liability as allowing the plans to make careless or even bad-faith coverage denials without redress. Their concern is that the *Aetna* decision fails to provide any meaningful relief to plan members who may suffer grievous bodily injury at the hands of utilization reviewers who might be more interested in shaving costs than in ensuring quality care to plan members.[31]

Renewed Debate Over Patients' Rights Legislation

The day following release of the *Aetna* decision, a bipartisan group of senators held a news conference urging reconsideration of the issue of patients' rights legislation, which Congress failed to pass in 2001.[32] At that time, the House and Senate had passed separate patients' rights bills, but were unable to agree on a final version.[33] Immediately following announcement of the *Aetna* decision, Rep. John Dingell (D-Mich.) introduced patients' rights legislation identical to the bill that the Senate passed in 2001.[34] The bill allows patients to file personal injury suits in federal court against their ERISA health plans' agents or fiduciaries for unlimited economic damages, unlimited damages for pain and suffering, and up to $5 million in punitive damages.[35]

During the presidential campaign, Sen. John Kerry (Mass.) reportedly criticized President Bush for ping-ponging on the patients' rights issue. Bush initially vetoed the Texas law at issue in the *Aetna* case when he served as governor of the state, but ultimately allowed it to pass without his signature. However, when campaigning for president, he referred to the law as one of his

achievements. Then during the *Aetna* appeal, he sided with the insurance industry against the law.[36]

Aides to Kerry reportedly stated that Kerry would make patients' rights legislation "an increasing focus" of his health care agenda.[37] Kerry is reported to have said that a patients' rights bill "could become law tomorrow if the Bush administration was not standing in the way."[38] His running mate, Sen. John Edwards (D-N.C.), declared, "At a time when the Bush administration is pushing millions of seniors on Medicare into HMOs, it is more important than ever to put health care decisions back in the hands of patients and their doctors."[39]

ERISA's "Regulatory Vacuum"—The Concurring Opinion in *Aetna*

One of the most important benefits of the *Aetna* decision is that it has finally clarified that extra-ERISA damages are preempted for ERISA health plan members who sue their plans alleging that they have been physically injured by delayed or negligent utilization review decisions. Prior to *Aetna*, there was growing uncertainty over this serious issue, with courts utilizing various creative theories to find a way to avoid ERISA preemption in these cases. The language of "mixed treatment and eligibility decisions" in *Pegram*, in particular, had raised a lot of questions over the extent to which such mixed decisions might be challenged as medical malpractice under state law, in view of the *Pegram* Court's recognition that these decisions necessarily involved medical judgment and affected members' medical treatment.

An equally important benefit of the *Aetna* decision, however, is that it focuses the spotlight on what ERISA fails to do: It fails to provide any meaningful remedy to ERISA plan members who are physically injured by utilization review decisions that may be unjustifiably delayed, carelessly made, or deliberately made in bad faith.

The cases of Davila and Calad are perfect examples. Davila now suffers from permanent injury from the bleeding ulcers that he developed as a result of Aetna's insistence that he try an alternate drug to the Vioxx that his doctor prescribed before Aetna would consider covering the Vioxx. Davila's injury makes him unable to take any drug for his arthritis pain (or any other ailment he may develop) that is absorbed through his stomach. This injury cannot be reversed. If Davila had asserted an ERISA claim against Aetna, the most that ERISA could have given him would have been coverage for the Vioxx that he sought in the first place, which he can no longer ingest due to his injury.

Calad suffered from serious complications from her surgery, that possibly could have been prevented if CIGNA had agreed to cover additional days of inpatient hospitalization. While ERISA gave her appeal rights for the denial, it is probably unrealistic to suppose that, a day after serious surgery, she could have mounted an appeal to obtain the hospitalization she sought. Moreover, she apparently was unwilling to assume the risk of remaining hospitalized and potentially incurring substantial costs that her insurance would not cover. There is no ERISA remedy for the physical injury that Calad suffered, or for the risk of harm in which CIGNA's denial may have placed her.

While approving the unanimous *Aetna* decision for its consistency with governing case law, Justice Ginsburg (joined by Justice Breyer) wrote a concurring opinion to echo the pleas from several lower courts for a legislative solution to this ERISA dilemma. Justice Ginsburg referred to ERISA's apparent inability to give make-whole relief as a "regulatory vacuum," where ERISA forecloses states from authorizing non-ERISA remedies for negligent utilization review decisions that lead to personal injury, but does not itself offer appropriate remedies.[40] To address the "host of situations in which persons adversely affected by ERISA-proscribed wrongdoing cannot gain make-whole relief," Justice Ginsburg called for "fresh consideration of the availability of consequential damages" under ERISA's remedial scheme.[41]

To this end, Justice Ginsburg suggested that consequential damages might be available under ERISA § 502(a)(3), which allows a plan member to obtain "other appropriate equitable relief." She noted that some forms of make-whole relief were historically available in equity courts. However, because Davila and Calad refused to amend their complaints to state ERISA claims, this issue was not considered on appeal.[42]

The availability of a section 502(a)(3) option may be quite limited, however, despite Justice Ginsburg's characterization of it as a theory that injured ERISA claimants might "fruitfully pursue."[43] On at least three occasions, the Supreme Court has already rejected the notion that the term "equitable relief" as used in ERISA includes consequential damages.[44] Therefore, if, as Justice Ginsburg predicts, there will one day be redress for injured ERISA health plan claimants,[45] it is more likely that the remedy will come from Congress, not the Supreme Court.

Endnotes

1. 124 S. Ct. 2488 (June 21, 2004) (hereinafter "*Aetna*").
2. 29 U.S.C. § 1132(a).
3. *E.g.*, *Land v. CIGNA Healthcare of Florida*, 339 F.3d 1286 (11th Cir. 2003); *Cicio v. Vytra Healthcare*, 321 F.3d 83 (2d Cir. 2003). Both these decisions were vacated by the Supreme Court on June 28 in light of the *Aetna* ruling (*Land*, 124 S. Ct. 2903; *Cicio* 124 S. Ct. 2902), whereupon the respective circuits reinstated the lower courts' findings that plaintiffs' claims were preempted by ERISA (*Land*, 381 F.3d 1274; *Cicio*, 2004 U.S. App. LEXIS 20049).
4. *Aetna*, 124 S. Ct. at 2493; *Roark v. Humana, Inc.*, 307 F.3d 298, 303 (5th Cir. 2002) (hereinafter "*Roark*"). We note that on Sept. 30, Merck voluntarily withdrew Vioxx from the market due to findings that it could induce heart attacks and strokes. Eric J. Topel, *Good Riddance to a Bad Drug*, N.Y. Times, Oct. 2, 2004, *available at* LEXIS, Health Library, NYT File.

5. *Aetna*, 124 S. Ct. at 2493; *Roark*, 307 F.3d at 302.
6. *Aetna*, 124 S. Ct. 2493.
7. 530 U.S. 211 (2000).
8. *See id.* at 228–229.
9. *Roark*, 307 F.3d at 305–308.
10. 498 U.S. 133 (1990).
11. *Roark*, 307 F.3d at 308–311.
12. 321 F.3d 83.
13. *Id.* at 100–104.
14. *Land*, 339 F.3d 1286.
15. *Id.* at 1290–1294.
16. 2003 U.S. Dist. LEXIS 15652.
17. 29 U.S.C. § 1144(b)(2).
18. *Rosenbaum*, 2003 U.S. Dist. LEXIS 15652, *19–24 (E.D. Pa. 2003). *But see Morales-Ceballos v. First UNUM Life Ins. Co. of Am.*, 2003 U.S. Dist. LEXIS 9801 (E.D. Pa. 2003); *McGuigan v. Reliance Standard Life Ins. Co.*, 256 F. Supp. 2d 345 (E.D. Pa. 2003) (finding that the Pennsylvania bad-faith statute at issue in *Rosenbaum* did not constitute a law that regulates insurance for purposes of exemption from preemption under ERISA's savings clause, and that in any event, the statute would be preempted because it expands ERISA's exclusive remedies by providing punitive damages against the insurer).
19. Arizona, California, Georgia, Maine, New Jersey, North Carolina, Oklahoma, Washington, and West Virginia are reported to have similar laws. Charles Lane, *Justices Limit Suits Against HMOs; State Patients' Rights Laws Struck Down,* Wash. Post, June 22, 2004, *available at* LEXIS, NEWS Library, WPOST File.
20. *Aetna*, 124 S. Ct. at 2495.
21. *Id.* at 2495–96.
22. *Id.* at 2496–97.
23. *Id.* at 2497–98.
24. *Id.* at 2498–99.
25. *Id.* at 2499–2500.
26. *See supra* note 3.
27. *Aetna*, 124 S. Ct. at 2500–2502. We note, however, that the Supreme Court's discussion in *Aetna* of its *Pegram* holding is not completely consistent with *Pegram* itself. In *Pegram*, the Court states that a utilization review decision is a mixed treatment and eligibility decision not just because it is made by a treating physician, but also because it is a medical judgment about the particular patient's medical needs intertwined with a coverage decision. 530 U.S. at 228–229. In *Aetna*, however, the Court indicates that an essential element of a mixed decision is that it is made by someone providing medical treatment. 124 S. Ct. at 2502. This seems to indicate that a utilization review decision must be made by a treating entity before it could be classified as a mixed treatment and eligibility decision.
28. *Id.* at 2500.
29. Officials from Aetna and CIGNA approved the decision as "affirming the role of ERISA in keeping employers' health care costs down [so that] workers will continue to receive affordable insurance through their jobs." *SUPREME COURT: Decision Limits Lawsuits Against HMOs in State Courts* (hereinafter "*Decision Limits Lawsuits*"), American Health Line, June 22, 2004, citing to Hous. Chronicle, June 22, 2004, *available at* LEXIS, HEALTH Library, HLTLNE File.
30. A spokesperson for America's Health Insurance Plans stated that the decision "puts the brakes on efforts by trial lawyers to turn every question about the scope of an individual's coverage into a costly lawsuit." Linda Greenhouse, *Justices Limit Ability to Sue Health Plans,* N.Y. Times, June 22, 2004, *available at* LEXIS, HEALTH Library, NYT File. James A. Klein, president of the American Benefits Council, which represents the employee-benefits industry, praised the decision, saying that it "is critical employers feel confident that ordinary benefits decisions will not subject them to the extreme costs associated with often unlimited remedies under many state laws." Lane, *supra* note 19.
31. Calad criticized the Court for "look[ing] the other way on the issue of HMO abuse. With this ruling, the HMOs can simply walk away from their responsibilities while Mr. Davila and I and millions of other Americans are left with the consequences." *Decision Limits Lawsuits, supra* note 29, citing to Baltimore Sun, June 22, 2004. The American Medical Association issued a statement that "managed-care plans can now practice medicine without a license, and without the same accountability that physicians face every day." Greenhouse, *supra* note 30. Carlton Carl, a spokesperson for the Association of Trial Lawyers of America, stated that the decision "insulates HMOs from any responsibility for delaying or denying care that injures patients and shifts responsibility unfairly to doctors and others . . . who are told what medical care they can give by the HMOs." *Decision Limits Lawsuits, supra* note 29, citing to Flandez, Wash. Post, June 22, 2004.
32. *Patients' Rights: Decision to Renew Debate Over Legislation* (hereinafter "*Decision to Renew Debate*"), American Health Line, June 23, 2004, citing to AP/San Francisco Chronicle, June 22, 2004, *available at* LEXIS, HEALTH Library, HLTLNE File.
33. *Id.*
34. *Decision Limits Lawsuits*, supra note 19, citing to Heil, CongressDaily, June 22, 2004.
35. 2001 S. 283 § 302.
36. *Patients' Rights: Kerry, Bush Campaigns Address Issue* (hereinafter "*Kerry, Bush*"), American Health Line, June 24, 2004, citing to Wilgoren, N.Y. Times, June 24, 2004, *available at* LEXIS, HEALTH Library, HLTLNE File. In a brief filed by the Justice Department in the *Aetna* appeal, the Bush administration said that state laws should not allow additional remedies "where . . . the HMO and its representatives are not treating the patient, but are making benefits determinations." *Decision Limits Lawsuits, supra* note 29, citing to Wash. Times, June 22, 2004. White House press secretary Scott McClellan has stated that Bush is in favor of patients' rights legislation, but that he has "not commit[ted] to renewing an effort to pass" such a bill. *Decision to Renew Debate, supra* note 32, citing to CongressDaily, June 22, 2004.
37. *Kerry, Bush, supra* note 36, citing to N.Y. Times, June 24, 2004.
38. Bruce Japsen, *Justices Protect HMOs From Big Damage Awards*, Chi. Trib., June 22, 2004, *available at* LEXIS, NEWS Library, CHTRIB File.
39. *Decision to Renew Debate, supra* note 32, citing to AP/San Francisco Chronicle, June 22, 2004.
40. *Aetna*, 124 S. Ct. at 2503, quoting from *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 453 (3d Cir. 2003) (Becker, J., concurring), and citing to John H. Langbein, *What ERISA Means by "Equitable": The Supreme Court's Trail of Error in Russell, Mertens, and Great-West*, 103 Colum. L. Rev. 1317 (2003) (arguing that in keeping with traditional trust remedies, make-whole relief should be available under the equitable relief provisions of ERISA § 502(a)(3)).
41. *Aetna*, 124 S. Ct. at 2503.
42. *Id.* at 2504.
43. *Id.*
44. *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204 (2002); *Mertens v. Hewitt Assocs.*, 508 U.S. 248 (1993); *Massachusetts Mut. Life Ins. Co. v. Russell*, 473 U.S. 134 (1985).
45. *Aetna*, 124 S. Ct. at 2503.

Beverly Cohen is a Professor of Law at Albany Law School, where she teaches health care courses on finance, fraud and abuse, privacy and security, and antitrust.

In the Matter of K. L. (Anonymous), Appellant. Glenn Martin, &c., Respondent, Attorney General of the State of New York, Intervenor-Respondent.

February 17, 2004

Dennis B. Feld, for appellant.
Sachin S. Pandya, for intervenor-respondent.
Stephen J. McGrath, for respondent.
New York Lawyers For The Public Interest, Inc., et al., amici curiae.

KAYE, CHIEF JUDGE:

On January 3, 1999, Kendra Webdale was pushed to her death before an oncoming subway train by a man diagnosed with paranoid schizophrenia who had neglected to take his prescribed medication. Responding to this tragedy, the Legislature enacted Mental Hygiene Law § 9.60 (Kendra's Law) (L 1999, ch 408), thereby joining nearly 40 other states in adopting a system of assisted outpatient treatment (AOT) pursuant to which psychiatric patients unlikely to survive safely in the community without supervision may avoid hospitalization by complying with court- ordered mental health treatment.

In enacting the law, the Legislature found that "there are mentally ill persons who are capable of living in the community with the help of family, friends and mental health professionals, but who, without routine care and treatment, may relapse and become violent or suicidal, or require hospitalization" (L 1999, ch 408, § 2). And in mandating that certain patients comply with essential treatment pursuant to a court-ordered written treatment plan, the Legislature further found that "there are mentally ill persons who can function well in the community with supervision and treatment, but who without such assistance, will relapse and require long periods of hospitalization. * * * [S]ome mentally ill persons, because of their illness, have great difficulty taking responsibility for their own care, and often reject the outpatient treatment offered to them on a voluntary basis. Family members and caregivers often must stand by helplessly and watch their loved ones and patients decompensate" (*id.*).

Studies undertaken in other jurisdictions with AOT laws have found that outpatients subject to court orders had fewer psychiatric admissions, spent fewer days in the hospital and had fewer incidents of violence than outpatients without court orders (*see* Mem of Off of Atty Gen, Bill Jacket, L 1999, ch 408, at 13, citing Marvin S. Swartz et al., *Can Involuntary Outpatient Commitment Reduce Hospital Recidivism?: Findings From a Randomized Trial With Severely Mentally Ill Individuals*, 156 Am J Psychiatry 1968 [1999]). Kendra's Law was thus adopted in an effort to "restore patients' dignity * * * [and] enable mentally ill persons to lead more productive and satisfying lives" (*id.*), while at the same time reducing the risk of violence posed by mentally ill patients who refuse to comply with necessary treatment.

In October 2000, a petition was filed seeking an order authorizing assisted outpatient treatment for respondent K.L. Respondent suffered from schizoaffective disorder, bipolar type, and had a history of psychiatric hospitalization and noncompliance with prescribed medication and treatment, as well as aggressiveness toward family members during periods of decompensation. The treatment prescribed in the proposed order included a regimen of psychiatric outpatient care, case management, blood testing, individual therapy and medication. Pursuant to the plan, respondent was required in the first instance to orally self-administer Zyprexa. If, however, he was "non-compliant with above," the plan required that he instead voluntarily submit himself to the administration of Haldol Decanoate by medical personnel.

Respondent opposed the petition, challenging the constitutionality of Kendra's Law in a number of respects. Supreme Court and the Appellate Division rejected each of respondent's constitutional arguments, as do we.

I.

Before a court may issue an order for assisted outpatient treatment, the statute requires that a hearing be held at which a number of criteria must be established, each by clear and convincing evidence. The court must find that (1) the patient is at least 18 years of age; (2) the patient suffers from a mental illness; (3) the patient is unlikely to survive safely in the community without supervision, based on a clinical determination; (4) the patient has a history of lack of compliance with treatment for mental illness that has either (a) at least twice within the last 36 months been a significant factor in necessitating hospitalization, or receipt of services in a forensic or other mental health unit of a correctional facility or a local correctional facility, not including any period during which the person was hospitalized or incarcerated immediately preceding the filing of the petition, or (b) resulted in one or more acts of serious violent behavior toward self or others or threats of, or attempts at, serious physical harm to self or others within the last 48 months, not including any period in

which the person was hospitalized or incarcerated immediately preceding the filing of the petition; (5) the patient is, as a result of his or her mental illness, unlikely to voluntarily participate in the recommended treatment pursuant to the treatment plan; (6) in view of the patient's treatment history and current behavior, the patient is in need of assisted outpatient treatment in order to prevent a relapse or deterioration which would be likely to result in serious harm to the patient or others; and (7) it is likely that the patient will benefit from assisted outpatient treatment (*see* Mental Hygiene Law § 9.60 [c]). The court must also find by clear and convincing evidence that the assisted outpatient treatment sought is the least restrictive treatment appropriate and feasible for the patient (*see* Mental Hygiene Law § 9.60 [j] [2]).

If an assisted outpatient later fails or refuses to comply with treatment as ordered by the court; if efforts to solicit voluntary compliance are made without success; and if in the clinical judgment of a physician, the patient may be in need of either involuntary admission to a hospital or immediate observation, care and treatment pursuant to standards set forth in the Mental Hygiene Law,[1] then the physician can seek the patient's temporary removal to a hospital for examination to determine whether hospitalization is required (*see* Mental Hygiene Law § 9.60 [n]).

II.

Respondent contends that the statute violates due process because it does not require a finding of incapacity before a psychiatric patient may be ordered to comply with assisted outpatient treatment. He asks that we read such a requirement into the law in order to preserve its constitutionality.

In *Rivers v Katz* (67 NY2d 485 [1986]), we held that a judicial finding of incapacity to make a reasoned decision as to one's own treatment is required before an involuntarily committed patient may be forcibly medicated with psychotropic drugs against his or her will. Mental Hygiene Law § 9.60, however, neither authorizes forcible medical treatment in the first instance nor permits it as a consequence of noncompliance with court-ordered AOT.[2]

Nevertheless, respondent urges that, under *Rivers*, a showing of incapacity is required before a psychiatric patient may be ordered by a court to comply with any assisted outpatient treatment. Although respondent—in asking us to read a requirement of incapacity into the statute—disclaims any effort to strike down the law, such a reading would have the effect of eviscerating the legislation, inasmuch as the statute presumes that assisted outpatients are capable of actively participating in the development of their written treatment plans, and specifically requires that they be afforded an opportunity to do so (*see* Mental Hygiene Law § 9.60 [i] [1]). Indeed, the law makes explicit that "[t]he determination by a court that a patient is in need of assisted outpatient treatment shall not be construed as or deemed to be a determination that such patient is incapacitated pursuant to article eighty-one" of the Mental Hygiene Law [governing guardianship proceedings] (Mental Hygiene Law § 9.60 [o]).

Respondent concedes that a large number of patients potentially subject to court-ordered assisted outpatient treatment would be ineligible for the program if a finding of incapacity were required. In enacting Kendra's Law, the Legislature determined that certain patients capable of participating in their own treatment plans could remain safely in the community if released subject to the structure and supervision provided by a court-ordered assisted treatment plan. Such a plan may enable patients who might otherwise require involuntary hospitalization to live and work freely and productively through compliance with necessary treatment.

Since Mental Hygiene Law § 9.60 does not permit forced medical treatment, a showing of incapacity is not required. Rather, if the statute's existing criteria satisfy due process—as in this case we conclude they do—then even psychiatric patients capable of making decisions about their treatment may be constitutionally subject to its mandate.

While "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body" (*Schloendorff v Socy. of New York Hosp.*, 211 NY 125, 129 [1914]) and to "control the course of his medical treatment" (*Matter of Storar v Dillon*, 52 NY2d 363, 376 [1981]), these rights are not absolute. As we made clear in *Rivers*, the fundamental right of mentally ill persons to refuse treatment may have to yield to compelling state interests (67 2 at 495). The state "has authority under its police power to protect the community from the dangerous tendencies of some who are mentally ill" (*Addington v Texas*, 441 US 418, 426 [1979]). Accordingly, where a patient presents a danger to self or others, the state may be warranted, in the exercise of its police power interest in preventing violence and maintaining order, in mandating treatment over the patient's objection. Additionally, the state may rely on its *parens patriae* power to provide care to its citizens who are unable to care for themselves because of mental illness (*see Rivers*, 67 NY2d at 495).

The restriction on a patient's freedom effected by a court order authorizing assisted outpatient treatment is minimal, inasmuch as the coercive force of the order lies solely in the compulsion generally felt by law-abiding citizens to comply with court directives. For although the Legislature has determined that the existence of such an order and its attendant supervision increases the likelihood of voluntary compliance with

necessary treatment, a violation of the order, standing alone, ultimately carries no sanction. Rather, the violation, when coupled with a failure of efforts to solicit the assisted outpatient's compliance, simply triggers heightened scrutiny on the part of the physician, who must then determine whether the patient may be in need of involuntary hospitalization.

Of course, whenever a physician determines that a patient is in need of involuntary commitment—whether such a determination came to be made after an assisted outpatient failed to comply with treatment or was reached in the absence of any AOT order at all—the patient may be hospitalized only if the standards for such commitment contained in the Mental Hygiene Law are satisfied. These standards themselves satisfy due process (*see Project Release v Prevost*, 722 F2d 960 [2d Cir 1983]). If, however, the noncompliant patient is not found to be in need of hospitalization, the inquiry will be at an end and the patient will suffer no adverse consequence. For as the statute explicitly provides, "Failure to comply with an order of assisted outpatient treatment shall not be grounds for involuntary civil commitment or a finding of contempt of court" (Mental Hygiene Law § 9.60 [n]). Moreover, any restriction on an assisted outpatient's liberty interest felt as a result of the legal obligation to comply with an AOT order is far less onerous than the complete deprivation of freedom that might have been necessary if the patient were to be or remain involuntarily committed in lieu of being released on condition of compliance with treatment.

In any event, the assisted outpatient's right to refuse treatment is outweighed by the state's compelling interests in both its police and *parens patriae* powers. Inasmuch as an AOT order requires a specific finding by clear and convincing evidence that the patient is in need of assisted outpatient treatment in order to prevent a relapse or deterioration which would be likely to result in serious harm to self or others, the state's police power justifies the minimal restriction on the right to refuse treatment inherent in an order that the patient comply as directed. Moreover, the state's interest in the exercise of its police power is greater here than in *Rivers*, where the inpatient's confinement in a hospital under close supervision reduced the risk of danger he posed to the community.

In addition, the state's *parens patriae* interest in providing care to its citizens who are unable to care for themselves because of mental illness is properly invoked since an AOT order requires findings that the patient is unlikely to survive safely in the community without supervision; the patient has a history of lack of compliance with treatment that has either necessitated hospitalization or resulted in acts of serious violent behavior or threats of, or attempts at, serious physical harm; the patient is unlikely to voluntarily participate in the recommended treatment plan; the patient is in need of assisted outpatient treatment in order to prevent a relapse or deterioration which would be likely to result in serious harm to the patient or others; and it is likely that the patient will benefit from assisted outpatient treatment.

In requiring that these findings be made by clear and convincing evidence and that the assisted outpatient treatment be the least restrictive alternative, the statute's procedure for obtaining an AOT order provides all the process that is constitutionally due.

Nor does Mental Hygiene Law § 9.60 violate equal protection by failing to require a finding of incapacity before a patient can be subjected to an AOT order. Although persons subject to guardianship proceedings and involuntarily committed psychiatric patients must be found incapacitated before they can be forcibly medicated against their will, a court-ordered assisted outpatient treatment plan simply does not authorize forcible medical treatment—nor, of course, could it, absent incapacity. The statute thus in no way treats similarly situated persons differently (*see City of Cleburne v Cleburne Living Ctr., Inc.*, 473 US 432, 439 [1985]).

III.

Respondent next challenges the detention provisions of Kendra's Law, contending that the failure of the statute to provide for notice and a hearing prior to the temporary removal of a noncompliant patient to a hospital violates due process.

Under Mental Hygiene Law § 9.60 (n), when an assisted outpatient who persists in the failure or refusal to comply with court-ordered treatment may, in the clinical judgment of a physician, be in need of involuntary hospitalization, the physician may seek the removal of the patient to a hospital for an examination to determine whether hospitalization is indeed necessary. If the assisted outpatient refuses to take medication—or refuses to take or fails a blood test, urinalysis, or alcohol or drug test—as required by the court order, the physician may consider this refusal or failure when determining whether such an examination is needed. A noncompliant patient thus removed under Kendra's Law may then be retained in the hospital for observation, care and treatment, and further examination, for up to 72 hours, in order to permit a physician to determine whether the patient has a mental illness and is in need of involuntary hospital care and treatment pursuant to the provisions of the Mental Hygiene Law. A patient who at any time during the 72-hour period is determined not to meet the standards for involuntary admission and retention and does not consent to remain must be immediately released.

When the state seeks to deprive an individual of liberty, it must provide effective procedures to guard against an erroneous deprivation. A determination of

the process that is constitutionally due thus requires a weighing of three factors: the private interest affected; the risk of erroneous deprivation through the procedures used and the probable value of other procedural safeguards; and the government's interest (*see Mathews v Eldridge*, 424 US 319, 335 [1976]).

While we disagree with the Appellate Division's determination that the involuntary detention of a psychiatric patient for up to 72 hours does not constitute a substantial deprivation of liberty, we nevertheless conclude that the patient's significant liberty interest is outweighed by the other *Mathews* factors. In the context of the entire statutory scheme, the risk of an erroneous deprivation pending the limited period during which an examination must be undertaken to determine whether a persistently noncompliant patient is in need of involuntary care and treatment is minimal. For before a court order authorizing an AOT plan is issued, there must already have been judicial findings by clear and convincing evidence that the patient is unlikely to survive safely in the community without supervision; has a history of noncompliance resulting in violence or necessitating hospitalization; and is in need of assisted outpatient treatment in order to prevent a relapse or deterioration which would be likely to result in serious harm. Nor is a court better situated than a physician to determine whether the grounds for detention—persistent noncompliance and the need for involuntary commitment—have been met. A pre-removal hearing would therefore not reduce the risk of erroneous deprivation.

In addition, the state's interest in immediately removing from the streets noncompliant patients previously found to be, as a result of their noncompliance, at risk of a relapse or deterioration likely to result in serious harm to themselves or others is quite strong. The state has a further interest in warding off the longer periods of hospitalization that, as the Legislature has found, tend to accompany relapse or deterioration. The statute advances this goal by enabling a physician to personally examine the patient at a hospital so as to determine whether the patient, through noncompliance, has created a need for inpatient treatment that the patient cannot himself or herself comprehend. A pre-removal judicial hearing would significantly reduce the speed with which the patient can be evaluated and then receive the care and treatment which physicians have reason to believe that the patient may need. Indeed, absent removal, there is no mechanism by which to force a noncompliant patient to attend a judicial hearing in the first place.

Respondent contends that a comprehensive psychiatric examination can be easily performed in less than 72 hours after removal. But since the temporary detention permitted by the statute comports with due process, it is not for us to determine whether the 72-hour limit is ideal, or necessary, or wise. As long as the time period satisfies constitutional requirements—which it does—it is not for this Court to substitute its judgment for that of the Legislature.

Finally, we find no violation of the constitutional prohibition against unreasonable searches and seizures (*see* US Const, 4th Amend; NY Const, art I, § 12) in the statute's failure to specify that a physician must have probable cause or reasonable grounds to believe that a noncompliant assisted outpatient is in need of involuntary hospitalization before he or she may seek the patient's removal. It is readily apparent that the requirement that a determination that a patient may need care and treatment must be reached in the "clinical judgment" of a physician necessarily contemplates that the determination will be based on the physician's reasonable belief that the patient is in need of such care.

Accordingly, the order of the Appellate Division should be affirmed, without costs.

Order affirmed, without costs. Opinion by Chief Judge Kaye. Judges George Smith, Ciparick, Rosenblatt, Graffeo and Read concur. Judge Robert Smith took no part.

Decided February 17, 2004

Footnotes

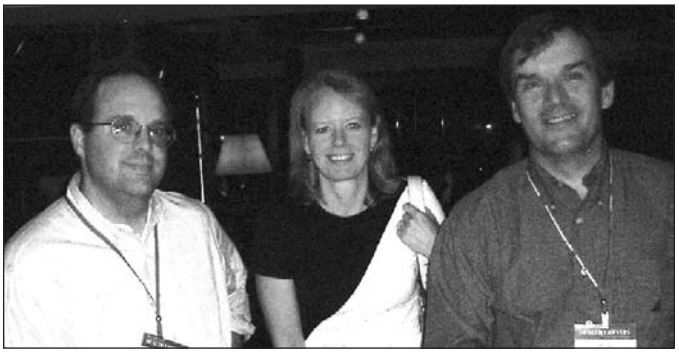
1. Under Mental Hygiene Law § 9.27, a person may be involuntarily admitted to a hospital upon the certification of two physicians when he or she is in need of involuntary care and treatment, defined as having "a mental illness for which care and treatment as a patient in a hospital is essential to such person's welfare and whose judgment is so impaired that he is unable to understand the need for such care and treatment" (Mental Hygiene Law § 9.01). Under Mental Hygiene Law §§ 9.39 and 9.40, persons in need of immediate observation, care and treatment may be admitted to a hospital on an emergency basis when they have a mental illness which is likely to result in serious harm to themselves or others, defined as a "substantial risk of physical harm to himself as manifested by threats of or attempts at suicide or serious bodily harm or other conduct demonstrating that he is dangerous to himself, or * * * a substantial risk of physical harm to other persons as manifested by homicidal or other violent behavior by which others are placed in reasonable fear of serious physical harm" (Mental Hygiene Law § 9.39 [1], [2]).
2. Inasmuch as the statute does not—and could not, absent a showing of incapacity—authorize the forcible administration of psychotropic drugs, any AOT order purporting to contain such a direction would exceed the authority of the law. Respondent's treatment plan contained no such illegal direction. Any persistent refusal to comply with the directive that he voluntarily submit to the administration of Haldol would not have resulted in his being forcibly medicated. Rather, the sole consequence would have been that a physician might then have determined that respondent may have been in need of involuntary hospitalization. In that event, respondent could have been temporarily removed to a hospital for examination (*see* Mental Hygiene Law § 9.60 [n]).

Section Participates in AHLA Annual Meeting

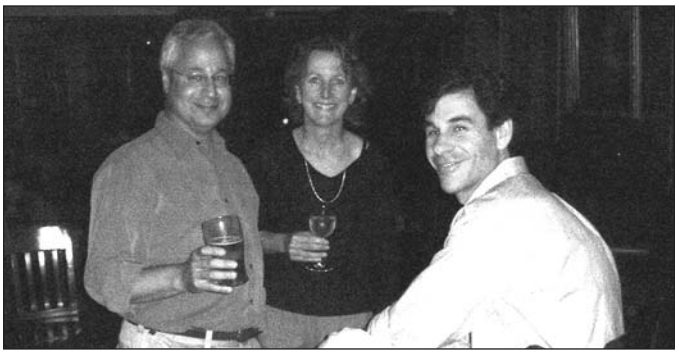
In late June, the American Health Lawyers Association held its annual meeting at the New York Marriott Marquis. It was the AHLA's first annual meeting in New York City, and as a result, a large number of NYSBA Health Law Section members were in attendance. New York State Attorney General Eliot Spitzer gave the keynote speech.

The Section sponsored a well-attended breakfast program, at which Joseph Baker, Chief of the Attorney General's Health Care Bureau, described the activities of the Bureau. He explained that while the Bureau had focused primarily on the activities of managed care plans, it is expanding its attention to other matters, such as problematic marketing and research-related practices of drug companies.

During the conference, a number of Section members got together socially at a nearby pub.



Scott Carroll, Marcia Smith, Jim Lytle



Robert Swidler, Carol Hyde, Philip Rosenberg

ABA Health Care Summit

The NYSBA Health Law Section is co-sponsoring the 2nd Annual ABA Health Care Summit on December 6–7, 2004. The Summit will be at the Ritz-Carlton Pentagon City in Arlington, Virginia. Numerous senior federal officials will offer their insights, including Senator Max Baucus, CMS Administrator Mark McClellan, HHS General Counsel Alex Azar and OIG Chief Counsel Lew Morris. A brochure can be found at www.wrf.com/db30/cgi-bin/pubs/WHS.pdf.

NEWS flash

What's Happening in the Section

Upcoming Program on Provider Transactions

The Section recently held a program entitled Health Care Provider Transactions: Practical Issues and Skills. The program was offered in New York City (October 15), Albany (October 28) and Rochester (November 5). It covered, among other topics, federal and state regulatory issues, deal structure, tax and financing issues, asset purchase agreements, ambulatory surgery centers, securities transactions and commercial arbitration. The overall planning co-chairs were Ari J. Markenson of Epstein Becker, Claudia Hinrichsen of Nixon Peabody, and Michele Masucci of Nixon Peabody.

Annual Chat with U.S. Attorneys

On October 26, the Section sponsored the third annual "chat" with U.S. Attorneys from the Southern and Eastern Districts. The chat provides an opportunity for Section members to meet and hear from and talk with the U.S. Attorneys in charge of the civil and criminal fraud and abuse units of both districts. In addition, David Kelly, the U.S. Attorney for the Southern District, was the luncheon speaker. Robert Borsody organized the chat, which was held at the Princeton Club in New York City.

Section's Annual Meeting Topics Are Not-for-Profit Governance and Compliance

The Health Law Section's Annual Meeting in January 2005 will have two programs: a morning program on Not-for-Profit Governance, and an afternoon program on Compliance.

The morning program, chaired by Edward Kornreich of Proskauer Rose, is expected to address, among other issues: board member obligations, best practices, the Attorney General's proposed changes; health care system issues; and ethics for lawyers in non-profit systems.

The afternoon compliance program is chaired by Anne Maltz of Herrick Feinstein, LLP. In addition to covering the latest developments in compliance, anti-kickback, Stark, and fraud and abuse, the program will address the evolution of compliance; handling internal and external investigations; compliance effectiveness reviews; and conflicts of interest.

Section Committees and Chairs

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

Biotechnology and the Law
Sally T. True (Chair)
True Walsh & Miller, LLP
202 East State Street, 7th Floor
Ithaca, NY 14850
(607) 272-4234
Fax: (607) 272-6694
e-mail: stt@twmlaw.com

Consumer/Patient Rights
Randye S. Retkin (Chair)
NY Legal Assistance Group
40 West 33rd Street, 11th Floor
New York, NY 10001
(212) 613-5080
Fax: (212) 750-0820
e-mail: rretkin@nylag.org

Ethical Issues in the Provision of Health Care
Kathleen M. Burke (Co-Chair)
New York Presbyterian Hospital
525 East 68th Street, Room W-109
New York, NY 10021
(212) 746-4075
Fax: (212) 746-8994
e-mail: kburke@nyp.org

Fraud, Abuse and Compliance
Marcia B. Smith (Chair)
Iseman Cunningham Riester & Hyde, LLP
9 Thurlow Terrace
Albany, NY 12203
(518) 462-3000
Fax: (518) 462-4199
e-mail: msmith@icrh.com

Health Care Providers
Edward S. Kornreich (Chair)
Proskauer Rose LLP
1585 Broadway, 19th Floor
New York, NY 10036
(212) 969-3395
Fax: (212) 969-2900
e-mail: ekornreich@proskauer.com

In-house Counsel
Karen I. Gallinari (Chair)
Administrative Offices
600 East 233rd Street
Bronx, NY 10466
(718) 920-9241
Fax: (718) 920-9245
e-mail: kgallinari@chcsnet.org

Long-Term Care
Ari J. Markenson (Chair)
Epstein Becker & Green, P.C.
250 Park Avenue, 14th Floor
New York, NY 10177
(212) 351-4709
Fax: (212) 878-8709
e-mail: amarkenson@ebglaw.com

Managed Care
Robert P. Borsody (Co-Chair)
Law Office of Robert P. Borsody
909 3rd Avenue, 17th Floor
New York, NY 10022
(212) 453-2727
Fax: (212) 644-7485
e-mail: rborsody@fbwhlaw.com

Harold N. Iselin (Co-Chair)
Greenberg Traurig, LLP
54 State Street
Albany, NY 12207
(518) 689-1400
Fax: (518) 689-3499
e-mail: iselinh@gtlaw.com

Membership
Patrick Formato (Co-Chair)
Abrams Fensterman et al.
1111 Marcus Avenue, Suite 107
Lake Success, NY 11042
(516) 328-2300
Fax: (516) 328-6638
e-mail: pformato@abramslaw.com

Hon. James F. Horan (Co-Chair)
NYS Health Department
433 River Street, 5th Floor, Suite 330
Troy, NY 12180
(518) 402-0748
Fax: (518) 402-0751
e-mail: jfh01@health.state.ny.us

Mental Health Issues
Henry A. Dlugacz (Co-Chair)
740 Broadway, 5th Floor
New York, NY 10003
(212) 254-6470
Fax: (212) 254-0857
e-mail: hdlugacz@gis.net

J. David Seay (Co-Chair)
National Alliance of the Mentally Ill of New York State
260 Washington Avenue
Albany, NY 12210
(518) 462-2000, x207
Fax: (518) 462-3811
e-mail: dseay@naminys.org

Nominating
James D. Horwitz (Chair)
Glens Falls Hospital
100 Park Street
Glens Falls, NY 12801
(518) 926-1981
Fax: (518) 926-1988
e-mail: jhorwitz@glensfallshosp.org

Professional Discipline
Kenneth R. Larywon (Co-Chair)
Martin Clearwater & Bell, LLP
220 East 42nd Street
New York, NY 10017
(212) 916-0918
Fax: (212) 949-7054
e-mail: larywk@mcblaw.com

Carolyn Shearer (Co-Chair)
Bond, Schoeneck & King, PLLC
111 Washington Avenue
Albany, NY 12210
(518) 533-3000
Fax: (518) 533-3299
e-mail: cshearer@bsk.com

Public Health
Arthur J. Fried (Chair)
Staten Island University Hospital
500 Seaview Avenue
Staten Island, NY 10305
(718) 226-9990
Fax: (718) 226-8692
e-mail: afried@siuh.edu

Announcing

Health Law Section

Committee Assignment Request

Please designate the Committee in which you are interested.

____ Biotechnology and the Law

____ Consumer/Patient Rights

____ Ethical Issues in the Provision of Health Care

____ Fraud, Abuse and Compliance

____ Health Care Providers

____ In-house Counsel

____ Long-Term Care

____ Managed Care

____ Membership

____ Mental Health Issues

____ Nominating

____ Professional Discipline

____ Public Health

Name_____

Office _____

Office Address _____

Home Address _____

E-mail Address _____

Office Phone No. _____ Office Fax No. _____

Home Phone No. _____

Please return this form to:

New York State Bar Association
One Elk Street
Albany, New York 12207
Attn: Cindy O'Brien
Fax: 518-487-5517

Publication and Editorial Policy

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

Publication Policy: All articles should be submitted to either:

Assoc. Dean Dale L. Moore
Albany Law School
80 New Scotland Avenue
Albany, NY 12208
(518) 445-2343
e-mail: dmoor@mail.als.edu

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

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

For ease of publication, articles should be submitted on a 3 1/2" floppy disk. Please also submit one hard copy on 8 1/2" x 11" paper, double spaced.

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

HEALTH LAW JOURNAL

ISSN 1530-3926

Health Law Section
New York State Bar Association
One Elk Street
Albany, NY 12207-1002

ADDRESS SERVICE REQUESTED

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