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Inside

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

in cooperation with

ALBANY LAW SCHOOL

A Message from the Section Chair

I have just been informed by the editor of this publication that this column will be my last as Chair of the New York State Bar Association Health Law Section. No, I'm not the victim of some misguided coup. My one-year term has nearly expired.

While millions of faithful readers are now audibly breathing a sigh of relief, I must confess I have some regrets. I have enjoyed the responsibility of chairing this dynamic and challenging Section of health law attorneys and the support of so many talented and dedicated members of this Bar Association.

We had a very successful year, due to a number of factors well outside my control. CLE programs that had been in the planning stages during my predecessor's term and that were quarterbacked by talented Section members addressed issues like professional discipline, HIPAA, fraud and abuse, and long-term care. An Annual Meeting that earned high marks focused on the intersection of health care law and health care quality, thanks to the great work of a team led by Jim Horwitz. New efforts to bring the benefits of health law expertise to persons confronting chronic illness were spearheaded by the Section's committees on Consumer Rights and AIDS. And, joined by our late founding chair's wife, Sherry Gold, we awarded the Barry Gold Legal Writing award to an Albany Law School student who wrote a penetrating analysis of Medicare prescription drug policy.

But, we have no time to celebrate these achievements of the Section or to rest on our laurels. We have, as the poet put it, "promises to keep . . . and miles to go before we sleep." In the time remaining and in the years to come, here is what I think we need to do:

- ***Strengthen our legislative and regulatory advocacy:*** We have made strides in this area: at the initiation of David Seay and the Mental Health Committee, we advanced a position on behalf of the Section in favor of "Timothy's Law" that would bring parity to mental health coverage; with Carl Coleman's leadership, the Section continued to support and lobby for the Family Health Care Decisions Act; perhaps of greatest long term benefit, soon-to-be Chair-Elect Lynn Stansel helped us craft a process by which the Section can take positions on important health care issues, recognizing that unanimity among any group of intelligent people is difficult and, among lawyers, impossible. But we should be doing more: The expertise of this Section should be generating ten to fifteen reports per legislative session on the most complex health care legal issues. And we should be examining the policies of the health care regulatory agencies and making recommendations to improve the lives of our clients and the patients they serve.

"I have enjoyed the responsibility of chairing this dynamic and challenging Section of health law attorneys and the support of so many talented and dedicated members of this Bar Association."

- ***Expand the Section's public interest mission:*** While the work of the Consumer Rights and AIDS committees were noteworthy, we should continue to identify means by which health care lawyers can make a contribution to their communities: by educating seniors about how to protect their autonomy by executing health care proxies; by advising young people about their health care rights and responsibilities; by assisting community organizations in improving access to and the quality of health care services.
- ***Enhance the camaraderie of the Section:*** We may be the all-work-and-no-play Section of the New York State Bar Association. I was recently asked by the Chair of another section if it would be all right if our members were solicited to attend their summer meeting on a quasi-health care related subject at a prominent Northeastern casino. He apologized: This year's location was less appealing perhaps than Newport, London, or the Napa Valley—all places where prior meetings had been convened. We've never had a summer (or a spring or fall) meeting at any location. And the only gambling associated with our meetings is whether the Marriott's elevators are operating. Planning is now underway for a social event associated with the American Health Lawyers Association Annual Meeting in New York City this June (please stay tuned to your e-mail for further announcements) and preliminary discussions are underway to plan for a summer event. But we have

much ground to cover before we even come close to the social opportunities afforded by the other NYSBA sections.

- ***Celebrate the achievements of our colleagues:*** Perhaps because of the field we have chosen, health care lawyers make significant contributions to their communities: through pro bono efforts, through educational commitments, through just good solid citizenship. At a time when our profession continues to be demonized, we should occasionally reflect upon and honor those among us who have made extraordinary contributions to their profession, to the improvement of the law and to their communities. I will be looking to our Executive Committee to help define the criteria and the manner in which we might, either regularly or occasionally, recognize someone who represents the best of what a health lawyer can be.

On second thought, after reflecting on all that remains to be done, I will admit that a one-year term doesn't seem like a bad idea, after all.

I would be remiss, in closing, if I didn't thank the committee chairs and my fellow officers—Phil Rosenberg, Lynn Stansel, Mark Barnes and Peter Millock—for their great efforts during the past year. To my predecessors, and particularly, to Sal Russo, Past-Chair, we've done our best to try to follow in your imposing footsteps. To Robert Swidler and Professor Dale Moore, thanks for your hard work in keeping this *Journal* at the top of its game. And to Lisa Bataille, Kathy Plog and the rest of the Bar Association staff, it can truly be said that it couldn't be done without you.

James W. Lytle

In the New York State Courts

By Leonard M. Rosenberg

Hospital May Terminate Physicians for Threatening to "Stop Taking Call"

Priovolos v. St. Barnabas Hospital, 766 N.Y.S.2d 435 (1st Dep't 2003). The Appellate Division, First Department, recently held that a hospital may terminate employed attending surgeons for suggesting to hospital administrators that they would stop taking emergency call.

The surgeons involved in the case were at-will employees of St. Barnabas Hospital in the Bronx. St. Barnabas had assigned the surgeons to provide services at Lincoln Medical and Mental Health Center, a hospital operated by the New York City Health and Hospitals Corporation, for which St. Barnabas had contracted to provide physician services.

During the course of an employment dispute with St. Barnabas, the surgeons had "intimated" to hospital administrators that, unless the dispute was resolved, they would stop taking emergency call at Lincoln. In response to this demand, St. Barnabas terminated the surgeons' employment.

The surgeons responded to their termination by commencing a lawsuit in the Supreme Court, Bronx County. Among other things, the surgeons sought damages for breach of contract and wrongful termination. St. Barnabas counterclaimed, contending that the surgeons breached the duty of loyalty that they owed their employer when they threatened to stop taking emergency call.

After the Supreme Court granted St. Barnabas' summary judgment motion seeking dismissal of the surgeons' claims—and denied the surgeons' cross-motion seeking summary judgment dismissal of St. Barnabas' counterclaims—the surgeons appealed to the Appellate Division, which unanimously affirmed the Supreme Court's decision.

In reaching its decision, the Appellate Division explained that, because the surgeons were at-will employees, under New York law St. Barnabas could terminate them for any non-discriminatory reason. The Appellate Division then concluded that there was sufficient record evidence to establish that St. Barnabas terminated the surgeons for a non-discriminatory reason: their threats to stop taking emergency call. Accordingly, the court held that no rational juror could find that St. Barnabas terminated the surgeons for discriminatory reasons, and dismissed the surgeons' claims.

With respect to St. Barnabas' counterclaim contending that the surgeons breached the duty of loyalty that they owed the hospital, New York law prohibits an employee from acting in a manner inconsistent with the employer's interest and requires an employee to exercise the "utmost good faith and loyalty" in the performance of his or her duties. Concluding that the surgeons' threats regarding the refusal to take emergency call raised triable issues of fact regarding their loyalty to St. Barnabas, the Appellate Division affirmed the Supreme Court's refusal to grant the surgeons' summary judgment dismissal of the hospital's counterclaims.

Court Finds That On-Call and Clinical Rotations Are Not Hospital Privileges That Rise to the Level of Constitutionally Protected Property Interest

Rafiy v. Nassau County Medical Center, 218 F. Supp. 2d 295 (E.D.N.Y. 2002). Plaintiffs, father and son physicians of Persian descent specializing in orthopedic surgery, sued Nassau County Medical Center. The suit alleged that actions taken by the Medical Center to relieve them of "on-call" assignments at the Medical Center's Emergency Room, and of assignments to supervise resident physicians at the Medical Center's orthopedic outpatient clinic, deprived plaintiffs of property without due process. In addition, Plaintiffs asserted claims for racial discrimination and retaliation for the exercise of free speech.

The action revolved around a rift between Plaintiffs and the Chairman of the orthopedic department, another named defendant. According to Plaintiffs, the Chairman "had it in for them" because of their Persian descent. Arguments over patient care led one of the Plaintiffs to write letters complaining about the Chairman. In addition, Plaintiffs complained that the Chairman made racially insensitive comments. Defendants ultimately removed Plaintiffs from the on-call and clinical schedules.

Defendants asserted that they exercised the lawful discretion vested in them to take away "but a fraction of the privileges those doctors enjoyed at the Medical Center." Defendants cited a host of unprofessional and careless activities that caused the removal of Plaintiffs from the on-call and clinical schedules.

With respect to Plaintiffs' procedural due process claim, the Eastern District found that on-call and clinical privileges are not protected property interests under the Due Process Clause of the Fourteenth Amendment. The Court stated, "[i]n New York, then, whether a particular feature or perquisite of medical practice at a hospital rises to the level of a constitutionally protected property interest under the Due Process Clause depends on whether a particular hospital chooses to put that feature in writing as part of its state-mandated delineation of privileges." The Court found that Plaintiffs did not have a "clear entitlement" to the on-call and clinical schedules, because they were not delineated as privileges by the Medical Center.

The Court found that, even if the on-call and clinical rotations were constitutionally protected privileges, plaintiffs' claim would be dismissed because they failed to seek redress under state law. The Court stated that the Plaintiffs should have either complained to the New York Public Health Council, or proceeded under Article 78.

The Court rejected Plaintiffs' remaining claims. Plaintiffs were not able to "marshal evidence tending to show that they were singled out on the basis of their race, skin color, or country of origin, and subjected to unequal treatment on that basis." With respect to the retaliation against exercise of free speech claim, the Court found that Plaintiff's letters complaining about the Chairman were not protected by the First Amendment because "when a public employee speaks not as a citizen upon matters of public concern, but instead as an employee upon matters only of personal interest, absent the most unusual circumstances, a federal court is not the appropriate forum in which to review the wisdom of a personnel decision taken by a public agency allegedly in reaction to the employee's behavior."

Upon Dissolution, Former Partner of Dental Practice Has No Ownership Interest in Medical Charts of Patients Treated by Other Partners of the Practice

Lewis v. Clement, 766 N.Y.S.2d 296 (Sup. Ct., Monroe County 2003). In connection with dissolution proceedings, the former partner of a dental partnership brought an action seeking the medical records for all patients treated by the partnership. The Court determined that patient medical records belong to the individual physician with whom the patient developed a physician-patient relationship, and not to the partnership as a whole. Citing a Second Department case standing for the same proposition, the Court held that "a corporate entity that provides medical and dental services has no patients of its own and therefore no interest in Patient [sic] records." Accordingly, the departing physician is entitled only to those medical records pertaining to patients with whom he had established a patient-physician relationship, i.e., those he actually treated.

Further, the Court held that the federal statute, the Health Insurance Portability and Accountability Act ("HIPAA"), cited by both parties here as a law either allowing or prohibiting disclosure of patient records, cannot be used "as a sword or a shield in disputes between partners as it relates to the sharing of patient records." The Court acknowledged that the statute permits entities within the scope of the statute to share "protected health information" under certain circumstances. However, "[i]f the physician (the covered entity) has a relationship with the patient, the remaining partners may not refuse to provide files by virtue of HIPAA. On the other hand, nothing in HIPAA requires partners to share records with former partners where there is no patient relationship." To put it succinctly, "a patient-physician relationship is required to trigger the right to patient records and the obligation to provide the patient records."

Court Upholds Physician Discipline for Refusal to Comply with CMR Order, but Indefinite Suspension of License Is Not a Permissible Penalty

Ostad v. New York State Department of Health, 766 N.Y.S.2d 441 (3d Dep't 2003). After the death of a patient, a physician became the subject of an investigation by the Office of Professional Medical Conduct ("OPMC"). Four months after OPMC's initial interview with the physician, an investigative committee of the Board of Professional Medical Conduct ("BPMC") was convened. The committee did not issue any charges of misconduct against the physician, but ordered a comprehensive medical review ("CMR") of his patient and office records. Three months later, a second investigative committee was convened due to a procedural defect with the first committee's paperwork supporting the CMR order. The second committee also ordered a CMR of the physician's patient and office records. However, the physician refused to comply with the CMR order, and upon investigation, a third investigative committee charged him with misconduct relating to the patient who had died in his care, and for refusing to comply with the CMR order.

After a hearing, the third committee's charges of misconduct were rejected by BPMC based on its finding that an investigative committee was not timely convened within 90 days of the physician's initial OPMC interview, as required by Public Health Law § 230(10)(a)(iii) ("PHL"). Upon review, the Administrative Review Board for Professional Medical Conduct ("ARB") disagreed with BPMC's finding of untimeliness, but found no evidence of misconduct

relating to patient care. The ARB did, however, find the physician guilty of misconduct for failing to comply with the CMR order, and suspended the physician's license until he complied with the CMR order. The physician then brought this Article 78 proceeding challenging the suspension of his license.

The Court rejected the argument that the investigative committee lacked authority to order a CMR because it was convened more then 90 days after his initial OPMC interview. Instead, the Court held that the physician failed to show any prejudice or infringement of his due process rights as a result of the delay. Moreover, the physician could have enforced the PHL's time limitations by commencing a CPLR Article 78 proceeding to dismiss the charges—an express statutory remedy under PHL § 230(10)(j). Because the physician failed to avail himself of the statutory remedy and failed to show any prejudice, the Court found the physician guilty of misconduct for failing to comply with the CMR order.

The Court also rejected the physician's argument that it was improper for BPMC to convene a second investigative committee after the first committee declined to issue any charges of misconduct. To the contrary, the Court found that there is no statute, regulation, or case law prohibiting a second investigative committee being convened to correct a procedural error. The Court also noted that OPMC may, but is not required to, apply for a court order compelling compliance with a CMR order. The Court did, however, find that the ARB's indefinite suspension of the physician's license was inappropriate, as it is not a permissible penalty under PHL § 230. Thus, the Court remitted the matter to the ARB for a determination of an appropriate penalty.

Medical School May Not Require Non-Employed Physicians to Share Practice Income

Odrich v. Trustees of Columbia University, 193 Misc. 2d 120, 747 N.Y.S.2d 342 (Sup. Ct., New York County 2002); *aff'd*, 308 A.D.2d 405, 764 N.Y.S.2d 448 (1st Dep't 2003). In this case, the Appellate Division ruled that a medical school may not require unpaid faculty members to pay to the medical school a percentage of the income generated from their private practice. Both courts determined that such payments constitute an illegal "fee-splitting" arrangement under New York State's Education Law, because the medical school did not employ the physicians through its faculty practice corporation.

Plaintiffs are New York State licensed ophthalmologists who held part-time faculty appointments at Columbia University's College of Physicians and Surgeons (the "Medical School") while maintaining private practices. Initially, the plaintiffs were not required to share their private practice income with the Medical School. In June 1998, they joined the Medical School's full-time faculty. Each became an Assistant Professor with concomitant teaching, research, and administrative duties, and each had responsibility for performing clinical services.

As full-time faculty members, the plaintiffs gave up their private practice of medicine and began rendering professional services to patients as salaried employees, eventually becoming part of the Medical School's newly formed faculty practice corporation. All income derived from their professional services was billed through, and collected by, Columbia University according to its own fee schedule. As part of their employment arrangement, the plaintiffs were required to pay the Medical School a so-called "Dean's Tax"—namely, 10% of the gross revenues generated from the professional services personally rendered by them. The Dean's Tax revenues were paid to and shared equally by the Dean's Office and the Department of Opthalmology.

Thereafter the plaintiffs resigned from the faculty practice corporation to resume the private practice of medicine. At that time, they also expressed a desire to continue their affiliation with the Medical School and their privileges at New York Presbyterian Hospital (the "Hospital"). The Medical School responded that "[a]s an exception to University policy," their full-time appointments would be changed to part-time appointments and they would have access to "outpatient faculty practice space assigned to the Department," but only if they agreed to subject all of their private practice income to the 10% Dean's Tax. When the plaintiffs refused to agree, the Medical School terminated their faculty appointments and did not forward their renewal applications to the Hospital, resulting in a denial of their Hospital privileges. Plaintiffs sued.

In response, the Medical School asserted that the proposed arrangement was legal because "a hospital run by a medical school is organized for the provision of medical care and treatment to patients and . . . sharing of fees with a medical school is exempt from the prohibitions of the Education Law." Although the Court acknowledged that the Education Law permits "fee-splitting" arrangements by physicians in a university faculty practice corporation, it stressed that once the plaintiffs left their full-time appointments, such an arrangement no longer existed. In addition, the Court rejected the Medical School's contention that an earlier Court of Appeals decision permits "fee-sharing" arrangements with

medical schools, even where the services provided and the income generated have no connection to the school or its clinical practice. The Court ruled that the Court of Appeals decision merely stands for the proposition that physicians may collectively practice medicine through a clinic run by a medical school.

The Court ultimately concluded that one could not interpret previous case law to permit health care providers to share fees "when they are neither affiliated in a partnership, corporation, or similar organization, nor sharing in the care of the patient—merely because one is a medical school which grants hospital privileges to the physician." Nonetheless, the Court added that "the [Medical] School and the Hospital are free to negotiate a fee or price with [the Odrichs] for their use of, or access to, the facilities on whatever terms they may find acceptable." The Court also noted that "the [medical] school is free to create economic incentives and disincentives, including any form of legal contractual arrangement to keep faculty at the school."

On appeal, the Appellate Division ruled that the motion Court had "correctly held that [the plaintiffs'] payment of the Dean's Tax would constitute illegal fee-splitting in violation of Education Law §§ 6530(19) and 6531, where [the plaintiffs] are no longer employees of the faculty practice corporation, and [the Medical School] is no longer providing [them] with salary, employee benefits, facilities, supplies, staff or malpractice insurance."

DOH Correspondence and Hospital Applications Exempt From Disclosure in Medical Malpractice Action

Brandes v. North Shore University Hospital, 767 N.Y.S.2d 668; *Brandes v. North Shore University Hospital*, 767 N.Y.S.2d 666, (2d Dep't 2003). The Appellate Division held that New York State law prevents the plaintiff in a medical malpractice action from obtaining correspondence from the New York State Department of Health ("DOH") relating to the performance and disciplinary history of a defendant physician. The Court also ruled that a malpractice plaintiff may not obtain a defendant physician's initial applications for hospital privileges or subsequent renewal applications from hospitals where the physician was on the medical staff. In both instances, the Court ruled that the confidentiality of the documents was protected because the documents were related to the performance of a medical or quality review function.

Pamela Brandes sued North Shore University Hospital and I. Michael Leitman, M.D. ("Physician") for medical malpractice and wrongful death following the death of her husband. In her suit, the plaintiff alleged that her husband suffered, and eventually died from, complications arising during an operation to remove his gall bladder.

During the lawsuit, plaintiff sought to obtain correspondence that DOH had sent to the physician, as well as the physician's initial applications and subsequent renewal applications for hospital privileges. The motion Court denied both motions on the grounds of privilege, and the Appellate Division for the Second Department affirmed.

Although the Court acknowledged that Public Health Law § 2805-l, which applies to incident reports, does not protect the state Health Department's correspondence with physicians, it held that Education Law § 6527 generally protects from disclosure such correspondence when it relates to a medical or quality review function. The Court went on to explain that, except in very limited circumstances, under Education Law § 6527, the proceedings and records prepared for purposes of medical or quality review are not subject to disclosure in civil litigation.

As to the medical staff applications and reappointment information, the Court ruled that "those records are exempt from disclosure pursuant to [both] Education Law § 6527 and Public Health Law article 28" because Public Health Law § 2805-m, like the Education Law, protects the records of proceedings related to hospital privileging, credentialing and quality assurance activities.

Malpractice Plaintiff Employs FOIL but Is Entitled Only to DOH Statement of Deficiencies

Smith v. Delago et al., 770 N.Y.S.2d 445 (3d Dep't 2003). Through the Freedom of Information Law ("FOIL"), plaintiff obtained the results of DOH's investigation into a complaint regarding his care, and subsequently commenced a medical malpractice action against his treating physician and the medical college, hospital and medical center. The documents contained redacted interviews with defendants' medical staff, as well as DOH's independent review of the medical care provided. Defendants moved for a protective order to prohibit plaintiff's use of the FOIL documents on the basis that they were confidential under Education Law § 6527(3) and Public Health Law article 28. Plaintiff cross-moved to obtain additional information related to the DOH investigation. The Supreme Court found the documents to be privileged, releasing to plaintiff only the names and contact details of the physicians who cared for him.

On appeal, the higher Court held that defendants met the burden of establishing that the interviews and other documents made available to DOH were entitled to statutory confidentiality as they were "in furtherance of its internal quality assurance review obligations." However, the Court found no basis to hold back

the DOH's Statement of Deficiencies, upon redaction of the conclusions of law and the opinions of the DOH. The court found the Education Law inapplicable as the records were obtained through FOIL, and not pursuant to CPLR article 31.

County Hospitals Commission Must Give Corrections Commission "Root Cause Analysis" of Inmate's Death

Croce v. Bhattacharyya, 767 N.Y.S.2d 564 (Sup. Ct., Albany County 2003). An inmate of Rockland County Jail died in Nyack Hospital. JCAHO standards required the Rockland County Commissioner of Hospitals to complete a review of the cause and background behind the death of the inmate—a "root cause analysis." Croce, in his capacity as Chairman and Commissioner of the New York State Commission of Correction, is required under Correction Law § 47(1)(a) to similarly investigate the death of any inmate of a correctional facility.

Petitioner Croce requested that the Commissioner of Hospitals produce the root cause analysis to the Corrections Commission. Respondent argued that petitioner's request should be denied because the material requested is privileged and confidential under Public Health Law § 2805-m because the material was collected pursuant to section 2805-j, and because Education Law § 6527(3) prevents disclosure of the root cause analysis.

Noting that the Correction Commissioner's obligation to investigate and review the cause of death of inmates under Corrections Law § 47 was in direct conflict with the statutory privilege of non-disclosure, the Court nonetheless held that the root cause analysis must be provided to the Commission. The Court relied in part on the Corrections Commission's authority to request and receive assistance, information and data from the County Hospitals Commission in order to properly carry out its duties under Corrections Law § 44(4).

Provision of Mental Hygiene Law Allowing for Waiver of Rules of Evidence Held Inapplicable to Contested Guardianship Proceedings; Medical Records of AIP Protected by Doctor-Patient Privilege

In re Rosa B.-S., 767 N.Y.S.2d 33 (2d Dep't 2003). A proceeding was brought pursuant to Mental Hygiene Law Article 81 for the appointment of a guardian for Rosa B.-S., the alleged incapacitated person ("AIP"), which was contested by her. At the ensuing jury trial, the trial court admitted the medical records of the AIP, and the jury determined that the AIP was an incapacitated person and appointed a guardian.

The Appellate Division, Second Department ruled that it was error to admit the AIP's medical records. Noting that, pursuant to the Mental Hygiene Law, a court may waive the rules of evidence at guardianship where "good cause" is shown, the Court added that the waiver provision was applicable only in uncontested proceedings where there is consent to the appointment of a guardian. The Court continued by remarking that the trial court was mandated to adhere to the rules of evidence, including the doctor-patient privilege, because the AIP had not consented to the appointment of a guardian. The Court also declared that, although an AIP's medical and mental condition is in issue at a guardianship proceeding, the AIP does not waive the doctor-patient privilege unless he or she affirmatively places his or her medical condition in issue.

In this case, in the absence of a waiver of the privilege by the AIP or the AIP affirmatively asserting her medical condition at the guardianship trial, the Appellate Division ruled that it was error for the trial court to allow testimony from the AIP's former physician concerning his treatment of her.

The Court concluded, however, that the error did not warrant a new trial, because the testimony of the AIP's children established her inability to care for her medical, personal or financial needs. As the Court further opined, Article 81 of the Mental Hygiene Law does not require medical testimony in a guardianship proceeding.

Leonard Rosenberg is a partner of Garfunkel, Wild and Travis, P.C. The firm represents health care clients in New York and beyond.

In the New York State Agencies

By Francis J. Serbaroli

Health Department

Personal Care Services Reimbursement

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend 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 and institute a 30-day advance notification of January personal care rates. *See* N.Y. Register, November 19, 2003.

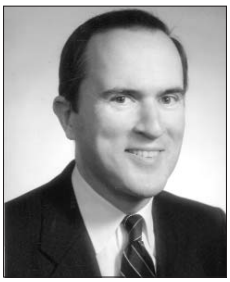
Smallpox Vaccine

Notice of adoption. The Department of Health amended sections 2.1 and 2.2 of Title 10 N.Y.C.R.R. to enable the Department to monitor for complications associated with smallpox vaccination and to request vaccinia immune globulin on a timely basis from the Centers for Disease Control, which is used to treat adverse reactions to the smallpox vaccine. Filing date: December 2, 2003. Effective date: December 17, 2003. *See* N.Y. Register, December 17, 2003.

Newborn Screening

Notice of adoption. The Department of Health amended section 69-1.2 of Title 10 N.Y.C.R.R. to add three disorders to the current New York State newborn screening panel, including: (1) cystic fibrosis; (2) congenital adrenal hyperplasia; and (3) medium-chain acyl-CoA dehydrogenase deficiency. Filing date: December 2, 2003. Effective date: December 17, 2003. *See* N.Y. Register, December 17, 2003.

Physician Profiling



Notice of adoption. The Department of Health added Part 1000 to Title 10 N.Y.C.R.R. to implement the Patient Health Information and Quality Improvement Act of 2000, which requires the Department to collect information and create individual profiles on physicians that will be available for dissemination to the public. Information to be disseminated about the physicians includes criminal convictions and medical malpractice information. Filing date: December 5, 2003. Effective date: December 24, 2003. *See* N.Y. Register, December 24, 2003.

Environmental Laboratory Standards

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: December 11, 2003. Effective date: December 11, 2003. *See* N.Y. Register, December 31, 2003.

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 controlled substance diversion. Filing date: December 24, 2003. Effective date: December 24, 2003. *See* N.Y. Register, January 14, 2004.

Communicable Disease-Arboviral Infection Reporting

Notice of emergency rulemaking. The Department of Health amended section 2.1 of Title 10 N.Y.C.R.R. to add arboviral infection to the list of communicable diseases that health care providers are required to report to the Department. Filing date: January 12, 2004. Effective date: January 12, 2004. *See* N.Y. Register, January 28, 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: January 15, 2004. Effective date: January 15, 2004. *See* N.Y. Register, February 4, 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: January 20, 2004. Effective date: January 20, 2004. *See* N.Y. Register, February 4, 2004.

Criminal History Record Check of Certain Non-Licensed Nursing Home and Home Care Staff

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend sections 763.13 and 766.11 and add section 400.23 to Title 10 N.Y.C.R.R. and to

amend section 505.14 of Title 18 N.Y.C.R.R. to protect nursing home residents and home care clients by requiring non-licensed nursing home and home care staff who provide direct care or supervision to undergo criminal history checks. *See* N.Y. Register, February 18, 2004.

Live Adult Liver Donation and Transplantation

Notice of adoption. The Department of Health amended section 405.22 of Title 10 N.Y.C.R.R. to establish minimum standards for live adult liver donation and transplant services at hospitals approved to provide such services. Filing date: February 10, 2004. Effective date: February 25, 2004. *See* N.Y. Register, February 25, 2004.

Smoking Cessation Products

Notice of adoption. The Department of Health added section 85.21(t) to Title 10 N.Y.C.R.R. and amended section 505.3(f)(3) of Title 18 N.Y.C.R.R. to add over-the-counter smoking cessation products to the list of Medicaid reimbursable products. Filing date: February 10, 2004. Effective date: February 25, 2004. *See* N.Y. Register, February 25, 2004.

Severe Acute Respiratory Disease (SARS)

Notice of adoption. The Department of Health amended sections 2.1 and 2.5 of Title 10 N.Y.C.R.R. to add Severe Acute Respiratory Disease (SARS) to the list of communicable diseases that health care providers are required to report to the Department. Filing date: February 10, 2004. Effective date: February 25, 2004. *See* N.Y. Register, February 25, 2004.

Monkeypox

Notice of adoption. The Department of Health amended sections 2.1 and 2.5 of Title 10 N.Y.C.R.R. to designate monkeypox as a communicable disease that health care providers are required to report to the Department. Filing date: February 10, 2004. Effective date: February 25, 2004. *See* N.Y. Register, February 25, 2004.

Adult Day Health Care Regulations

Notice of emergency rulemaking. The Department of Health repealed Parts 425 through 427 of Title 10 N.Y.C.R.R. and added a new Part 425 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 13, 2004. Effective date: February 13, 2004. *See* N.Y. Register, March 3, 2004.

Expedite 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: February 11, 2004. Effective Date: February 11, 2004. *See* N.Y. Register, March 3, 2004.

Insurance Department

Healthy New York Program

Notice of adoption. The Department of Insurance amended sections 362-2.3 and 362-4.3 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. Filing date: January 23, 2004. Effective date: February 11, 2004. *See* N.Y. Register, February 11, 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: February 4, 2004. Effective date: February 4, 2004. *See* N.Y. Register, February 25, 2004.

Claim Submission Guidelines

Notice of emergency rulemaking. The Department of Insurance added Part 230 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: February 4, 2004. Effective date: February 4, 2004. *See* N.Y. Register, February 25, 2004.

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For Your Information

By Claudia O. Torrey

The following information highlights two federal governmental actions under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") that took place during the first quarter of 2004:

1. On January 16, 2004, the Department of Health and Human Services ("HHS") posted on its website new guidance information regarding the HIPAA Privacy Rule and research databases that utilize medical records. This "new guidance" is a response to those who complained that the HIPAA Privacy Rule is too burdensome in its attempt to de-identify protected health information ("PHI") for research purposes.

   Under the HIPAA Privacy Rule, a covered entity (health care: plans, providers, and/or clearinghouses) *must* remove eighteen identifiers[1] in order to get out from under the Privacy Rule, and must not have actual knowledge that could subsequently identify the research subject(s). A covered entity can also achieve the goal of de-identified data by having a person, with the appropriate knowledge of and experience with statistical and scientific methods, document that the risk of re-identifying the research subject(s) is very small.[2] While research PHI requires an authorization under HIPAA, de-identified research PHI is not protected by the Privacy Rule, and can be used and disclosed without restriction!

   The HHS posted guidance reiterates that a limited data set ("LDS") excludes direct identifiers, but is still considered PHI because of the identifying potential of the non-direct identifiers.[3] Thus, an authorization is needed, except for research, public health, or health care operations.[4] These three exceptions would require the covered entity and the LDS recipient to enter into a data use agreement. Of course, a data use agreement would not be necessary if the disclosed information qualified as an exception to the Privacy Rule.[5]

2. On January 23, 2004, HHS published the final rule for the National Provider Identifier ("NPI") under HIPAA.[6] Health care providers may apply for the NPI no earlier than May 23, 2005. Covered entities will need to implement NPIs for filing and processing health care claims by May 23, 2007 (to be codified at 45 C.F.R. § 162.404). The goal is to streamline the many different identifying numbers a provider may acquire due to data destination.

   The NPI final rule commentary clearly states that obtaining an NPI does not confer covered entity status on a health care provider. A health care provider that is assigned an NPI, but is not a covered entity performing a covered function under HIPAA, DOES NOT magically become a covered entity as a result of NPI assignment![7]

Endnotes

1. *See* 45 C.F.R. § 164.514(b)(2).
2. *See* 45 C.F.R. § 164.514(b)(1).
3. *See* 45 C.F.R. § 164.514(e)(2).
4. *See* 45 C.F.R. § 164.514(e)(3).
5. *See* 45 C.F.R. § 164.512(b).
6. *See* 69 Fed. Reg. 3434–3469.
7. *See* 69 Fed. Reg. 3437–3438.

Claudia O. Torrey, Esq. chaired the 1998 year-long Study Group project that produced "Who Wants To Know?—The Search for a Balance Between Health Information Privacy and Confidentiality." The project was the catalyst for the current Special Committee on Medical Information. Ms. Torrey is a member of the American Bar Association, the American Health Lawyers Association, and the New York State Bar Association (Sustaining Member).

IRB and Institutional Roles and Remedies in Managing Conflicts of Interest in Industry-sponsored Academic Research

By Patrick L. Taylor

IRBs and academic investigators are in the crosshairs of two conflicting imperatives: the necessity and promise of industry collaboration, and escalating pressure to protect human subjects from resulting conflicts of interest. The purpose of this paper is to distinguish the roles of institutions and IRBs in addressing such conflicts, and to recommend specific IRB strategies in doing so.

Because of academic creativity, the speculative nature of biotechnology, financial stakes, and competition for new drugs, companies pursue academic scientists as fruitful sources of discovery. In forging relationships with them, companies naturally attempt to bring scientists within their own corporate culture, compensation structure, and control, using equity, options, and other devices to incentivize a scientist's commitment and performance. Cash-poor start-ups, often built around scientists' own inventions, routinely offer academic institutions equity over cash, arguing that this also offers scientists their only chance to share in wealth created by the discovery.

By requiring academic scientists to share in company revenue from licensed discoveries, the federal Bayh-Dole Act ("Bayh-Dole")[1] necessarily promotes conflicts of interest for scientists who collaborate with such companies in related research. Even scientists unmotivated by personal wealth face conflicts in translating their discoveries into breakthroughs: As commercially held patents and biological materials necessary for academic inquiry increasingly dominate biomedical research—it is now almost impossible to conduct research covered by a patent without its owner's permission[2]—scientists necessarily grapple with the terms companies demand for collaboration, including terms that violate conventional academic standards of independence and objectivity.

While such conflicts grow, the media ask whether commercial values and methods corrupt biomedical research. Informally surveyed, concerns revolve around (a) the high financial and media profile of biotech, characterized by inflated and premature expectations of medical breakthroughs; (b) ambivalence about investigators' potential financial gain; (c) the effects of commercially driven biotechnology on health care quality, humanity and costs, especially at end-of-life; (d) biotech's pivotal reliance on disinterested scientists generating objective results amidst the market's monetary drives; (e) whether laws protecting commerce are misapplied to medical research (e.g., patenting genes); and (f) public suspicion that the moral boundaries of research (and researchers) are too elastic, emphasizing ends over any means (e.g., stem cell and therapeutic cloning debates).

"IRBs and academic investigators are in the crosshairs of two conflicting imperatives: the necessity and promise of industry collaboration, and escalating pressure to protect human subjects from resulting conflicts of interest."

Recent court cases question the morality of research linked to biotech.[3] Complaints in these contested cases assert that researchers placed financial or academic interests above law and human dignity. In some cases, the combination of financial interest plus adverse event has fostered a presumption of institutional and scientist guilt. Unlike traditional medical malpractice cases, these class actions seek enormous damages; allege fraud and ethical lapses as well as clinical errors; and name, as high-profile defendants, IRB members and institutional leaders.[4]

Government agencies, academic groups, and courts proclaim that industry norms concerning collaboration and incentive compensation, if not circumscribed, will impair research objectivity, academic freedom, ethical judgment, public trust, and patient care. There is growing consensus that historical mechanisms for managing conflicts—institutional oversight and federal regulations—are insufficient. This leaves IRBs and institutions grappling with how to address conflicts.

Why Do IRBs Need to Address Conflicts of Interest?

The United States has no comprehensive approach to conflicts, and no regulations specifying IRBs' role or obligations. Six of the eight major federal extramural research-funding agencies do not require academic grantees to identify and manage research conflicts of interest.[5] Public Health Service regulations[6] and professional association guidelines[7] endorse institutional management, requiring grantee institutions to establish a conflicts policy, disclosure to the institution and funding agency of investigators' (but not institutions') conflicts, review of "all significant financial interests," and require institutional findings that conflicts have been managed, reduced or eliminated. Generally, under these analyses, conflicts consist of investigator financial interests or relationships (such as equity or consulting arrangements) that may be affected by the research, or with entities whose own financial interests may be affected.

Association guidelines and government guidance[8] suggest reviewer questions to assess whether a conflict might impart bias, drive inappropriate resource use, and facilitate self-dealing. Historically, guidelines were not addressed to subject protection. Later guidelines and literature suggest that institutions segregate technology licensing, investment management, and research administration; limit institutional officials from holding related financial interests or corporate positions; scrutinize gifts and procurement from sponsors; and recognize a presumption, rebuttable in "compelling" circumstances, that scientists should not engage in clinical research sponsored or involving any company or invention in which there is a financial interest.[9] However, association guidelines stop short of specifying IRB management strategies.

Recent literature[10] and government agency reports[11] criticize institutional management. Collectively, these sources point to institutional variability; lack of diligence and accountability; unclear and inconsistent policies; failure to report conflicts and corrective actions to IRBs and funding agencies; ineffective or absent measurement of effectiveness; limited or absent intra-institutional sharing or consolidation of financial information; and limited understanding of NIH regulations. IRBs should therefore question whether institutional management will adequately protect human subjects without additional IRB steps.

Institutions face internal conflicts; unless resolved, independent management of conflicts is questionable. Institutions share the concern that research be objective, research subjects be protected, public trust in academic research continue, and academic independence be preserved. However, under Bayh-Dole, institutions own discoveries from federally funded research, provided they diligently license them to companies and share proceeds with inventors. Institutions have an incentive to maximize revenue even before a discovery is validated by further research, to accept equity if necessary to secure a license, and—as mandated by Bayh-Dole—to provide the very financial return to a scientist that may create a conflict with further related research, given the terms of the license (such as equity or milestone payments shared with the inventor). Apart from licensing, institutions' promotion of research leads them to walk a tightrope among competing objectives: preserving academic independence, maximizing research funding, and facilitating collaborations with industry representatives who, unsympathetic with conflicts rules, may seek aggressive terms.

These factors compel IRBs to avoid relying entirely on institutions' management of conflicts.

Nor can IRBs depend on Food and Drug Administration regulations[12] to prevent conflicts. Those regulations do require applicants for marketing approval of a device, drug, or biological product to certify the

TABLE I

Comparing Institutional and IRB Concerns in Evaluating Conflicts of Interest (COI)

	Institutional COI process	**IRB**
Concerns:	Research objectivity	Protecting subjects
	Academic independence • publication • board and other entanglements • resource allocation • resource dependence	
	Conflicting institutional roles (e.g., enforcing license terms while also being an equity holder)	
	Protecting trainees	
	Reviewing "export" of new developments to private sector • effect on institutional research strategy • effect on investigator's academic career • Bayh-Dole obligations	
	Insider trading, or appearance of it	
	Conflicts with investigators over equity • management of institutional holdings • sale • distributions	

absence of certain financial interests of clinical investigators or disclose the interests and any steps taken to minimize the potential for bias. Conflicts, here, mean investigator interests that could be affected by study outcome; a proprietary interest in the tested product (including patent, trademark, copyright or licensing agreement), an equity interest in the study sponsor, or certain "significant payments of other sorts" by a sponsor to the investigator or to the institution to investigator activities.

However, FDA conflicts rules do not target protecting subjects: FDA review will occur after trial data is submitted with a marketing application; historically, FDA conflicts remedies address objectivity and data validity, rather than subject protection; and FDA rules govern "investigators," excluding some conflicted parties (such as physicians enrolling their patients).

Moreover, commercial sponsorship is correlated with positive published trial results[13]—even in trials subject to FDA rules—and this correlation is apparently not due to editors' publication choices.[14] While manuscript standards have been revised, they are still inadequate to detect or deter conflicts among nonauthors. FDA rules, previous manuscript standards, and institutional management have been insufficient to ensure objectivity in research, let alone subject protection.

In short, IRBs cannot rely on general institutional conflict of interest committees and policies, or on the patchwork of federal regulations, to protect human subjects. IRBs must therefore assess institutional policies and, working with institutions, take steps to ensure that the conflict of interest process as a whole adequately protects subjects.

Recommended Steps

The first step is to understand the intended and actual effect of institutional policies on human subject protection. Most likely, institutional policies are aimed at different issues (see Table I) but will indirectly affect subject protection by prohibiting certain conflicts. Institutional procedures to manage conflicts (see Table II) are not targeted at subject protection. The IRB should create a policy—reasonably integrated with institutional procedures—that focuses on protecting subjects, understanding that institutional remedies may achieve much but not all of what is required, and that redundant review and meaningless burdens should be avoided. While institutions' and IRBs' concerns are *distinct*, their procedures for disclosure and evaluating their impact can be *interrelated*, and their remedies may be *overlapping*, although certain issues and remedies will inevitably be for an IRB to determine.

The best approach is inclusive: an interdisciplinary working group representing the offices of research finance, sponsored programs, technology transfer, and general counsel; IRB members; and investigators. Cited guidance will be helpful to start, but should be adapted and sharpened to meet recurring investigator and institutional conflicts revealed by the interdisciplinary process.

Institutions frequently require disclosure only above certain thresholds that define a prohibited conflict. IRBs will be better served by broad disclosure of interests and relationships, which can then be addressed in IRB review. Disclosure forms should ask about any interests that may be affected by the research, the FDA regulatory categories described above, and specific recurring examples, such as equity interests, licensed and unlicensed inventorship interests, "free" equipment, and consulting and other agreements relevant to the study, in particular special commitments concerning exclusivity, noncompetition, authorship, resource commitments, publication limitations, or confidentiality provisions that may impair independent investigator judgment.

Table II

Institutional Remedies for Conflicts of Interest

- Requiring disclosure of conflict in advance to institutional committees, peers, journals
- Divestiture or termination of relevant personal interest (often a financial threshold)
- Outright prohibitions on certain financial interests (e.g., principal investigator holding equity greater than X)
- Outright prohibition on certain corporate fiduciary relationships (e.g., board memberships, executive positions)
- Requiring investigator recusal from a study
- In case of equity:
  - imposing a bar on insider trading, or
  - requiring the transfer of securities to an independent financial manager or blind trust, or
  - limiting the timing of sales or proceeds distributions in relation to peer review or publication of results
- Independent review of data and other retrospective reviews for bias, objectivity, comprehensiveness of reporting (versus withholding data)
- Require revision or withdrawal of manuscript or publications; require journal letters clarifying misstatement or omission
- Repetition of study

The policy should ensure that IRB review is informed by the potential effects of a conflict. For example, investigator representations that might otherwise be taken at face value—such as those concerning alternatives, risks and benefits—may require reconfirmation. While other factors are specified in Table III, generally IRB reviewers should think systematically about potential impacts on human subjects and potential remedies from beginning to end of proposed research, including study design; the informed consent form (particularly its representations of risks, benefits and alternatives); the clinical burdens on a subject (e.g., frequency and relatedness of sample collection); data collection and event reporting; and all aspects of the conduct of the trial. Reviewers must assess the conflict's potential effect on eligibility determinations, application of inclusion and exclusion criteria, endpoints, choice of control, consent, related clinical determinations (e.g., dose modifications, patient withdrawal, related care), the determination and reporting of protocol deviations and adverse events, and data submitted for continuing review.

Conflicts should be disclosed to institutional conflict committees and patients, but also to sponsors, monitors, DSMBs, scientific reviewers, and clinical departments. IRBs should consider requiring institutional and industrial research and clinical participants to clarify how they will address conflicts in meeting their responsibilities. IRBs should ask if monitors and clinical departments can mitigate conflicts' effects. Hospital clinical departments can undertake special medical peer review and IRB reporting of clinical incidents, whether or not they are "adverse events" for FDA purposes. Monitors can report protocol deviations implicating clinical care. Sponsors can disqualify conflicted investigators from DSMBs reviewing the study. If sponsors, monitors, institutions and IRBs see managing a conflict as a shared interest, they will take these steps.

The policy should allow IRBs to require independent, proactive, and concurrent or retrospective monitoring of study procedures that could be affected, including consent, exclusion, adverse incidents and subject withdrawal. For clinician researchers enrolling patients, the IRB should consider specifically testing for impacts on physician-researchers' primary clinical obligations, and consider independent review of clinical care.

The policy should require investigator recusal from parts of a study where other remedies are inappropriate or insufficient, and require some functions to be independently performed (e.g., other clinicians performing clinical assessments related to continuing participation, or incident assessment).

The policy should be the first but not the last step in educating investigators concerning conflicts. Education should also embrace others in the research community, including administrators and staff from the offices represented in policy formulation.

Through these steps, IRBs can avoid relying on institutional procedures to protect human subjects without having understood or assessed those procedures, and work effectively to protect subjects, investigators, the public and IRBs' own role in industry-academic clinical research.

Table III

Points of Emphasis in IRB Review of a Study Involving an Investigator Conflict of Interest

- Assess scientific merit with COI in mind (not necessarily by IRB itself). Be especially alert to studies with weak statistical power and limited societal benefit.
- Verify PI representations relevant to risks and benefits of materials, procedures, interventions, test articles and study as a whole (particularly if researcher or department is sponsor, and researcher is testing an invention). Verify literature.
- Consider whether the study will adequately reveal and document any effects of the conflict. For example, are subject interaction windows defined so broadly that they will mask related protocol deviations? Would required reporting of additional clinical or research events or data that do not qualify as SAEs be helpful?
- Look closely at whether burdens are minimized and benefits to subject are appropriate. If there is a conflict, resolve gray areas against investigator design.
- Design: Evaluate inclusion and exclusion criteria, and endpoints: Could these have been shaped by conflict?
- Compensation of investigator: Is it outcome-dependent directly or indirectly?
- Evaluate possible use of different designs which could mitigate COI (e.g., single-site vs. multi-site, placebo versus other comparators, use of random, double-blind design).
- Assess make-up of DSMB (eliminate members with COI), and DSM plan.
- Assess degree to which subject safety depends solely on clinical judgments by an investigator with a conflict, and consequences from conflict affecting clinician researcher's clinical duties to subject as patient (e.g., possibility researcher will inadvertently reinforce therapeutic misconception during recruitment; exercise of clinical judgment in exclusion, subject withdrawal, or event reporting).

Endnotes

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3. *Gelsinger v. University of Pennsylvania* (Pa. C., No. 001885, complaint filed September 18, 2000); *Grimes v. Kennedy-Krieger Institute*, 782 A.2d 807 (Ct. App. Md. 2001); *Greenberg et al. v. Miami Children's Hospital Research Institute, Inc. et al.*, 2003 WL 21246347 (S.D. Fla. 2003).

4. Mello, M.M., Studdert, D.M., & Brennan, T.A., *The Rise of Litigation in Human Subjects Research*, Ann. Intern. Med., 2003, 139:40–45.

5. General Accounting Office, University Research—Most Federal Agencies Need to Better Protect Against Financial Conflicts of Interest, GAO-04-31, November 2003.

6. 42 C.F.R. Part 50, Subpart F.

7. Association of American Medical Colleges, Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research (1990); Council on Scientific Affairs and the Council on Ethical and Judicial Affairs, American Medical Association, *Conflicts of Interest in Medical Center/Industry Research Relationships*, JAMA 1990, 263:2790–3; Association of American Universities, Framework Document on Managing Financial Conflicts of Interest (1993); Association of American Medical Colleges, Protecting Subjects, Preserving Trust, Promoting Progress I: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research (2001).

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10. McCrary, S., Anderson, C., Jakovljevic, J., et al., *A National Survey of Policies on Disclosure of Conflicts of Interest in Biomedical Research*, NEJM 2000, 343:1621–6; Lo, B., Wolf, L.E., & Berkeley, A., *Conflict-of-Interest Policies for Investigators in Clinical Trials*, NEJM 2000, 343:1616-20; Cho, M.K., Shohara, R., Schissel, A., et al., *Policies on Faculty Conflicts of Interest at U.S. Universities*, JAMA 2000, 284:2203–08.

11. National Institutes of Health, Office of Extramural Research, Financial Conflict of Interest: Objectivity in Research (2002); Gen. Accounting Office, Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest (2001).

12. 21 C.F.R. part 54.

13. Djulbegovic, B., Lacevic, M., Cantor, A., et al., *The uncertainty principle in industry-sponsored research*, Lancet 2000, Aug. 19, 356 (9230):635–8.

14. Olson, C.M., Rennie, D., Cook, D., et al., *Publication bias in editorial decision-making*, JAMA 2002, 287(21):2825–8.

The Federal False Claims Act as a Remedy for the Failure of Care to a Resident of a Nursing Home

By Robert Trusiak

I. Summary

The False Claims Act, 31 U.S.C. §§ 3729, et seq., is the primary statute used by the United States to civilly prosecute the failure of nursing home care. The proceeding discussion will set forth the liability predicate for a False Claims Act prosecution of a nursing home due to failure of care. The theory of civil prosecution involves the following tripartite analysis: first, a discussion of federal and state regulations that set forth the minimum level of nursing home care; second, the quality-of-care issues that dominate the prosecutorial focus; and third, the False Claims Act theory of liability in a failure-of-care case. The understanding by provider counsel of the foregoing regulatory, clinical, and legal areas will permit the opportunity for an assessment of potential client liability and the institution of voluntary remedial measures to reduce litigation exposure.

II. Regulatory Authority that Governs the Minimum Level of Nursing Home Care

On October 1, 1990, the Nursing Home Reform Act ("Act") took effect and mandated that nursing facilities comply with federal requirements relating to the provision of services.[1] Specifically, in terms of the quality of life for residents of nursing facilities, the Act states, "a nursing facility must care for its residents in such a manner and in such an environment as will *promote maintenance or enhancement* of the quality of life of each resident."[2] Stated otherwise, *do no harm.*

Additionally, the Act mandates that a nursing facility "provide services and Activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care which—(A) describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met . . ."[3]

The Act places a legal duty on the nursing facility to fulfill the residents' care plans by providing, or arranging for the provision of, *inter alia*, nursing and related services and medically related social services that attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, and pharmaceutical services and dietary services that ensure that the meals meet the daily nutritional and special dietary needs of each resident.[4]

Moreover, the Social Security Act mandates that skilled nursing facilities that participate in the Medicare program and nursing facilities that participate in the medical assistance program, known as Medicaid, meet certain specific requirements in order to qualify for such participation. These requirements are set forth at 42 C.F.R. § 483.1 et seq. and "serve as the basis for survey Activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid."[5]

Federal regulations, when addressing quality-of-care concerns, mandate that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care."[6] The regulations specifically address the area of nutrition:

> (i) Nutrition. Based on a resident's comprehensive assessment, the facility must ensure that a resident—
>
> (1) maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and
>
> (2) Receives a therapeutic diet when there is a nutrition problem.[7]

Additionally, the federal regulations specifically address those individuals who are tube-fed:

> (g) naso-gastric tubes. Based on the comprehensive assessment of a resident, the facility must ensure that—
>
> (1) a resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and
>
> (2) A resident who is fed by naso-gastric or a gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers, and to restore, if possible, normal eating skills.[8]

Nursing homes are also subject to state regulations. By New York State regulation, facilities are required to meet the daily nutritional needs of patients.[9] Additional-

ly, each facility must employ a qualified dietitian.[10] The dietitian is responsible for the nutrition services in the nursing home.[11] The statute sets forth qualifications for a dietitian.[12] The statute also mandates satisfaction of patient nutritional needs.[13]

Under state regulations, rules are also set forth pertaining to the various professional personnel responsible for the provision of care to nursing home residents. Facilities are required to provide nursing services that meet the needs of residents.[14] it is incumbent upon the nursing home administrator to assure that preventive measures, treatments, medications, diet and other health services as prescribed in section 415 are properly carried out.[15]

Finally, a nursing home administrator is charged with ensuring the nursing home shall employ on a full-time, part-time, or consultant basis a sufficient number of professional staff members who are educated, oriented and qualified to carry out the provisions of this part and to assure the health, safety, proper care, and treatment of the residents.[16]

According to regulations promulgated by the nursing home administrators board, a nursing home administrator's responsibilities include the following areas: (a) evaluating the quality of resident care and efficiency of services; (b) maintaining compliance with government regulations, and (c) developing policies which govern the continuing care and related medical and other services provided by the facility.[17]

III. Quality of Care Areas that Dominate the Prosecutorial Focus

A. The Quality Indicator Summary Report

This report is taken from the MDS which is submitted by the nursing facility to CMS. The MDS assessment data is used to calculate the RUG III classification for payment. The MDS contains extensive information on the resident's nursing needs, activities of daily living (ADL), impairments, cognitive status, behavioral problems and medical diagnosis. The MDS is required to be done five days after admission and then again in 30, 60, 90 days if the patient is readmitted and/or if there is a significant change in the resident status.

B. Weight Loss

The unplanned weight loss of 5% or more of the resident's weight in 30 days or 10% or more in three months. Risk for malnutrition is defined as some residents who have low oral intake, a blood test for albumin with levels of 3.5 or less, and a chart diagnosis of malnutrition.

C. Pressure Sores

A critical inquiry relates to the genesis of the decubitus ulcer; i.e., was the wound facility acquired or community-acquired? A pressure sore is an injury caused by constant pressure to the skin and muscle which develops on the bony parts of the body, such as the tailbone, hip, buttocks, and ankle. All residents with limitations in their mobility should be receiving skin care to prevent pressure sores. Residents need to be turned and repositioned every 2-3 hours, eat adequate amounts of food, drink adequate amounts of fluids, and be kept clean and dry. Pressure sores may also be reduced through the use of pressure relieving devices such as gel flotation pads or special padding on beds and wheelchairs.

The nursing staff may need to be educated and trained on the importance of repositioning residents every 2-3 hours and using pressure reduction devices correctly. Having an adequate number of staff to reposition residents frequently is critical. It is critical to have a repositioning plan; it is more critical to implement the plan—actually turn the resident.

D. Quality Indicator Summary Report for Pain

Pain often results in depression, anxiety, decreased socialization, sleep disturbance, impairment in walking, and moving. Residents in pain can have weight loss issues, dehydration, incontinence and loss of physical and mental function. Pain treatment includes pharmacological and other techniques, i.e., relaxation, distraction, therapeutic touch, positioning, and hot or cold applications.

E. Quality Indicator Summary Report for Infection

Review the report for falls and urinary tract infections associated with behavior problems. The falls can result from the resident having the need to void frequently with no assistance available and, therefore, attempts to self-transfer resulting in a fall. The facility should have a call system. These call systems can be activated by the resident. These call systems also may be activated by loss of weight—the resident stands and the alarm is activated by the change in weight due to the attempt to ambulate. These systems ensure staff assistance is available to meet the ambulation needs of the patient. Change in the resident's behavior can also be the result of infection.

When the resident is discharged from the skilled nursing home to the hospital, monitor the hospital admitting diagnosis. Red flags include the diagnoses of fecal impaction or dehydration. This may mean the resident's bowel status is not being monitored closely or the resident is not being adequately hydrated. Most facilities monitor the frequency of the resident's bowel movements and should have a regimen in place that relates to fluid intake, fiber in the diet, use of laxatives/cathartics, and finally, enemas to ensure that their residents do not end up constipated.

F. Staffing

Nursing staffing (RNs, LPNs, and nursing assistants) on duty in sufficient numbers is frequently an issue.

Checking the vacancy rate of these positions may be revealing. Review total staffing complement for the facility, as well as the actual staffing for several days prior to the survey and include a weekend, and optimally, a holiday. Bottom line: Are there staffing spikes associated with a survey or a specific shift? The labor cost is the most significant fixed cost for a facility. The reduction of the staffing level is a direct and immediate method to reduce costs.

IV. Theory of Prosecution

The False Claims Act theory of prosecution is akin to any other health care fraud case. Focus on the content of the certification(s) coupled with an analysis of the *prima facie* statutory elements—a false claim submitted in reckless disregard or in deliberate ignorance of the truth.[18] The nursing home provider will have agreed to the following provisions pursuant to the annual cost report submitted to Medicare:

> Misrepresentations or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative Action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative Action, fines and/or imprisonment may result.
>
> Certification by officer or administrator of provider(s):
>
> I hereby certify that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the balance sheet and statement of revenue and expenses prepared by _____ (provider name(s) and number(s)) for the cost reporting period beginning _____ and ending _____ and that to the best of my knowledge and belief, it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. *I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.* (Emphasis added).[19]

The provider enrollment application for Medicare contains additional certifications. The relevant certifications follow:

> I agree to abide by the Medicare laws, regulations, and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.
>
> I have read the contents of this application. My signature legally and financially binds this provider to the laws, regulations, and program instructions of the Medicare program. By my signature, I certify that the information contained herein is true, correct, and complete, to the best of my knowledge, and I authorize the Medicare program contractor to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare program contractor of this fact immediately.

The relevant Medicaid certifications associated with the services provided to the nursing home resident also will impute knowledge of relevant authority and compliance with such authority in the submission of the claim.

These provisions make clear the submission of a claim to the government for payment certifies that the services billed were provided. The government interprets these requirements to include the provision of the services in a manner that comports with federal and state law and regulations. The government will argue the nursing home was responsible for ensuring that all state and federal laws, regulations, and requirements were complied with at all times.

The specific nature of the argument depends on the area of concern. For example, a nutritional deficiency associated with pressure sores would involve a theory that nutritional requirements for the victims were not met, yet claims for such care were submitted to and reimbursed by Medicare and Medicaid programs. The facility was responsible for the provision of nutrition, and employed nutritionists/dietitians to perform nutritional evaluations of residents of the nursing home. By state and federal regulations, the nutritionists also were responsible for ensuring that residents received adequate nutrition. The government would contend that this did not occur.

The government would complete the argument by alleging that false, fictitious, or fraudulent claims were submitted to the Medicaid and the Medicare programs for nutritional services that were not adequately rendered. These claims certified that the billing information contained on the invoices, diskettes, or tapes was accurate and complete with the understanding that payment and satisfaction of the claims were from federal and state funds and the prosecution for false claims, statements or documents, or concealment of material facts was a part of the certification.

Finally, the government would contend the facility failed to ascertain the truth or falsity of the claims for services, and acted in reckless disregard of the care and services ordered and provided in submitting claims to the Medicare and Medicaid programs. From the government's perspective, the continued submission of claims notwithstanding the actual physical condition of the patient(s) constitutes a potential violation of the False Claims Act.

V. Conclusion

The need to protect residents of nursing homes from abuse and neglect is patently obvious. The implications of the failure-of-care case are dramatic from a quality-of-care perspective in that the knowing provision of inadequate care may now translate into a false claim to the government for payment. The potential economic consequences to owners and/or managers of long-term care facilities that engage in inadequate care of the frail and most vulnerable members of our society are significant.

VI. Exhibits—Post Script Material

1. HUD insurance and violations of the HUD regulatory agreement may provide an additional area of litigation exposure for the nursing home.
2. Case identification
   - A. MDS.
   - B. Emergent transfers from nursing home to emergency department for presenting conditions or "sentinel events" set forth in section III.
   - C. Review civil court docket for tort cases that implicate the nursing home.
   - D. Coordinates with local ombudsmen and state enforcement component.
3. Obtain from the provider:
   - A. Wound care program.
   - B. Quality assurance program.
   - C. Compliance plan and audits.
   - D. 2801-d and 2803-d incidents (relate to abuse reporting).
   - E. FHA insured.
   - F. Bonuses for matters that negatively impact staffing? (Staffing is generally the largest fixed cost of a facility. The reduction of staff, therefore, is the most direct and immediate manner to reduce such cost.)
4. Additional area to review
   - A. Premature insertion of peg tube due to staffing shortages?
5. Focus on bad outcomes

Endnotes

1. 42 U.S.C. § 1396r(b).
2. 42 U.S.C. § 1396r(b)(1)(A).
3. 42 U.S.C. § 1396r(b)(2)(A).
4. 42 U.S.C. § 1396r(b)(4)(A)(i-iv).
5. 42 C.F.R. § 483.1.
6. 42 C.F.R. § 483.25.
7. 42 C.F.R. § 483.25(i).
8. 42 C.F.R. § 483.25(g).
9. 10 N.Y.C.R.R. § 415.12(a)(3) and (i).
10. 10 N.Y.C.R.R. § 415.14.
11. *Id.*
12. *Id.*
13. *Id.*
14. 10 N.Y.C.R.R. § 415.13.
15. 10 N.Y.C.R.R. § 415.26.
16. 10 N.Y.C.R.R. § 415.26.
17. *Id.*
18. 31 U.S.C. § 3729(a).
19. *See* form CMS 2552 (cost report).

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The opinions expressed herein do not represent the position of the United States Department of Justice and are solely those of the author. The opinions of the author include remarks from David Hoffman, Assistant United States Attorney, Eastern District of Pennsylvania.

Legal Implications of the Smallpox Vaccine Program

By Peter J. Millock

In December 2002, President George W. Bush initiated a program to vaccinate millions of Americans against smallpox. The program began with military personnel and health care workers. On January 24, 2003, Tommy G. Thompson, the Secretary of the Department of Health and Human Services, issued a declaration (the "Declaration") stating that "given the potential for a bioterrorist incident," certain countermeasures were appropriate, including smallpox vaccinations of response teams, health care workers and others.[1]

This article analyzes the legal implications of the vaccination program with particular attention to the legal protections offered public health care workers and agencies that, as vaccinators, are sued by vaccinees for damages associated with adverse outcomes from vaccination. This article focuses on the applicable law in New York, but also cites California, Florida, and Massachusetts laws for comparison.

Sources of Liability

Smallpox is a virulent, highly contagious disease. Mortality rates in smallpox epidemics have reached as high as 30%.[2] Although adverse reactions to smallpox vaccination pale in comparison to the dire effects of the disease itself, the smallpox vaccine is considered less safe than other vaccines in use today.[3] Among the most common complications from smallpox vaccination are progressive vaccinia, generalized vaccinia, postvaccinial encephalitis, eczema vaccinatum, inadvertent inoculation, and rashes. Although not as common a complication, death may result in one or two out of every million persons vaccinated.

A person harmed through a smallpox vaccination may seek compensation for injuries from any person or entity in any way connected with the vaccination program, including the vaccine manufacturer, the vaccine distributor, the government agency or voluntary hospital that managed the vaccination program, and the health care workers who administered the vaccine, took a medical history to identify contraindications, and educated the vaccinee about postvaccination precautions against spread of the vaccinia virus.

Injured vaccinees may identify one or more sources of the harm they have suffered, including the following:

- the vaccine manufacturer's production of a bad batch of vaccine
- the vaccine distributor's failure to store the vaccine properly
- the vaccinator's failure to take a complete medical history identifying contraindications to vaccination or to recognize contraindications that are elicited when the history was taken
- the vaccinator's failure to advise the vaccinee of the possible adverse outcomes of vaccination
- the vaccinator's improper inoculation of the vaccinee
- the vaccinator's inadequate and incomplete education of the vaccinee about post-vaccination precautionary measures
- the vaccinator's failure to have drugs available to treat complications from vaccination

A plaintiff bringing legal action today for adverse outcomes from a smallpox vaccination may allege either that the vaccine manufacturer, the vaccine distributor, or the vaccinator had been negligent or that the vaccinator had not secured the plaintiff's informed consent for the vaccination.

To establish negligence by the manufacturer, the distributor or the vaccinator under current law, the plaintiff will have to show that the defendant had a duty to the vaccinee to exercise reasonable care in accordance with an accepted standard of care, the defendant deviated from that standard and the deviation caused injury to the plaintiff. Some of these elements will be easier to prove than others.

Establishing that public health agencies, voluntary hospitals, clinics, and their employees and agents have a duty to provide adequate care to vaccinees should not be difficult. Public health agencies and the hospitals, clinics, and individuals they enlist to implement the vaccination program are doing so to prevent vaccinees from contracting smallpox. This will be clear from general agency mission descriptions in statute and organizational documents and in public statements and commitments specific to the smallpox vaccination program. It may be more difficult to show a duty to persons who are not vaccinated but who contract the vaccinia virus from persons who are.

Demonstrating the existence of a standard of care to which manufacturers, distributors, and vaccinators are expected to adhere should not be difficult for an injured vaccinee because the procedures for manufacturing, distributing, and administering the smallpox vaccine and interviewing and educating vaccinees have become

more explicit, particularly with the issuance of numerous guidelines and forms by the federal Centers for Disease Control and Prevention.[4]

Finally, the injury itself should not be hard to show. The more likely adverse outcomes from smallpox vaccination are well documented.

Proof of other elements of negligence will not be so straightforward. The vaccinee will have more difficulty proving that the vaccinator deviated from the applicable standard of care and that the deviation caused the injury to the vaccinee. Both showings are fact-intensive and case-specific. For example, a vaccinee may have to show that a public health worker used improper inoculation technique and that this failure was causally linked to an adverse outcome. In most cases vaccination complications will not be causally linked to improper activities and thus not actionable by the vaccinee.

A legal action grounded on lack of informed consent to vaccination will be even more difficult. Generally, a plaintiff alleging lack of informed consent must show that he or she was not informed of the risks of a particular medical procedure and consequently suffered harm. In more specific terms, the vaccinee must show that a public health worker failed to disclose the risks from smallpox vaccination that a reasonable person would want to know and a reasonable person with such information would have declined to be vaccinated and thus avoided the ensuing complications.

With information about the contraindications to and the complications from smallpox vaccination readily available to public health agencies and the public at large, a vaccinee will be hard pressed to show that he or she was unaware of the risks from smallpox vaccination. The vaccinee's best chance may be to prove that a vaccinator failed to take a proper history from the vaccinee and failed to advise the vaccinee of all of the serious complications from smallpox vaccination associated with those contraindications.

Defenses

If a vaccinee believes that he or she can overcome the obstacles outlined above and initiates litigation against a government agency, a hospital, a clinic, a health care worker or a vaccine manufacturer or distributor for harm resulting from a vaccination and/or for lack of informed consent, what defenses are available to the person or entity sued? The three key protections available to a defendant in this situation are Section 304 of the Homeland Security Act, state indemnification statutes, and state workers' compensation laws.

The effect of each protection is to shift liability to another party. Section 304, as described below, shifts liability to the federal government. State indemnification statutes shift liability from an individual state or local government health employee (and some others) to the state or local government. Workers' compensation laws shift liability from the employer to its workers' compensation insurance carrier.

Section 304 of the Homeland Security Act

The Homeland Security Act of 2002[5] covers a myriad of subjects from cybersecurity to explosive detention systems. Section 304 of the Homeland Security Act (Section 304) amended Section 224 of the Federal Public Health Service Act[6] to shield vaccine manufacturers, health care workers, and public health agencies, among others, from liabilities arising from federally sanctioned countermeasures against actual or potential acts of bioterrorism.

The shield offered by Section 304 covers all "countermeasures" specified in the Declaration issued by Secretary Thompson.[7] Under Section 304, if the United States Attorney General certifies that the defendant is a "covered person" and personal injury or death has arisen from smallpox vaccination, then only the federal government is liable for damages resulting from the vaccination.[8]

A covered person includes the following:

- a manufacturer or distributor of the countermeasure
- a health care entity under whose auspices the countermeasure was administered
- a "qualified person" who administered the countermeasure
- an official, agent or employee of a person or entity described above[9]

Qualified person is defined to mean a "licensed health professional or other individual who is authorized to administer such countermeasures under the law of the state in which the countermeasures is administered."[10]

The shield of Section 304 is not available to covered persons who fail to cooperate with the federal government in defense of the case.[11] The federal government is also given the right to recover the amount of payments made to claimants from covered persons whose grossly negligent, reckless, illegal, or willful misconduct caused the injury in question.[12] The line between simple negligence and gross negligence and the line between negligence and recklessness are not drawn in Section 304 and, in practice, are very case-specific and fact-dependent.

The Federal Torts Claims Act (FTCA)[13] is the legal mechanism through which injured persons may secure relief from the federal government under Section 304.

The standard for negligence is the standard set in the state where the act or omission complained of occurred, though the proceeding, including the trial, if any, is in federal court. Actions commenced in state court will be removed to a federal court. A judge, not a jury, is the finder of fact under the FTCA.

On its face, Section 304 will protect manufacturers, distributors, and vaccinators from liability for damages resulting from their negligent (but not grossly negligent, reckless, illegal, or willful) acts. Section 304, however, does raise some questions of coverage which public health agencies and others were quick to identify in the weeks between the adoption of the statute and the issuance of the Declaration. Many of these questions were answered in the expansive interpretation of the scope of Section 304 offered by Secretary Thompson in the Declaration. Here are three important questions Secretary Thompson addressed.

First, do specified countermeasures extend beyond vaccine manufacture, distribution, and administration to include taking medical histories, assessing contraindications, securing informed consent, and educating about postvaccination precautions? As noted above, deviations from standards for these activities could cause harm and trigger a lawsuit.

Comment: Section 304 defines "covered countermeasure" to include the "substance" specified by the HHS Secretary in his Declaration.[14] The Declaration states that countermeasures to be administered are vaccinia vaccines, Cidofivir, and vaccinia immune globulin.[15] The Declaration's definition of "administration of a covered countermeasure" is broad and includes "education and screening of covered countermeasure recipients; monitoring, management and care of the covered countermeasure site; [and] evaluation of covered countermeasure 'takes.'"[16]

Second, does the term qualified persons include all persons taking histories and providing guidance about postvaccination precautions?

Comment: Section 304 defines qualified person to mean "a licensed health professional or other individual who is authorized to administer" a covered countermeasure under the law of the state where the countermeasure is administered.[17] By expanding the definition of the phrase "administration of a counter-measure," as noted above, the Declaration expands the group of persons who are authorized to administer some or all of the included services and thus protected by Section 304.

Third, does a covered person include a state or local public health agency and independent contractor or volunteers engaged by a public health agency for the vaccination program?

Comment: As noted above, Section 304 defines covered person to include a health care entity under whose auspices the smallpox countermeasure is administered.[18] Section 304 does not define health care entity. The Declaration defines that term to include hospitals, clinics, local health departments and officials, agents, and employees of such entities[19] and defines "official, agent or employee" to include "health care workers who share any employment or other staffing relationship with the health care entity.[10]

The gloss placed on Section 304 by the Declaration may or may not please an injured vaccinee depending on whether or not the vaccinee wants to pursue an action against the federal government under the FTCA. If a plaintiff takes issue with Secretary Thompson's effort in the Declaration to strengthen the Section 304 shield, the plaintiff may allege that the Secretary in interpreting Section 304 through his Declaration exceeded the authority granted him by Section 304 and went beyond the language of the statute and the intent of Congress when it enacted the statute.

The courts have generally recognized that an agency's interpretation of an ambiguous provision in a statute that the agency administers is entitled to deference.[21] One indication that such deference should be accorded the Declaration is the express statutory authorization for the Declaration itself.

Congress sought to allay any doubts about and forestall any challenge to the validity of the Declaration when it amended Section 304 in the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA).[22] This new law was adopted after the Declaration was issued, but it was made effective November 25, 2002, the effective date of the Homeland Security Act.

Although noted for its creation of a fund for coverage of injured health care workers as discussed as follows, the new law clarified each of the three questions posed above. The law:

- Amended the definition of "Arising Out of Administration of a Covered Countermeasure" to include liability arising from "(i) determining whether and under what conditions, an individual should receive a covered countermeasure; (ii) obtaining informed consent of an individual to the administration of a covered countermeasure; [or] (iii) monitoring, management, or care of an immediate site of administration on the body of a covered countermeasure, or evaluation of whether the administration of the countermeasure has been effective."[23]
- Amended the definition of "qualified person" to include anyone who "is otherwise authorized by the Secretary to administer such countermeasures."[24]

- Amended the definition of "covered person" to include "a State, a political subdivision of a State, or an agency or official of a State or of such a political subdivision, if such State, subdivision, agency or official has . . . supervised or administered a program with respect to administration of such countermeasures."[25]

State Indemnification Laws

Some government health care workers may also be shielded from liability by state laws covering the actions of government agencies and their employees. In New York, for example, Public Officers Law §§ 17 and 18 provide for the defense and indemnification of state and local government employees by the government entities that employ them.[26] Section 18 defines "public entity" to include counties, which in New York are responsible for most hands-on public health programs like smallpox vaccination.[27] Section 18 defines "employee" to include any commissioner or employee of a public entity and a volunteer in a "publicly sponsored volunteer program," but does not include an "independent contractor."[28]

Sections 17 and 18 provide that the public entity shall defend and indemnify any employee in any civil action arising from any act or omission that occurred when the employee was acting within the scope of his or her employment. A county health department employee performing tasks under a smallpox vaccination program will likely be acting within the scope of his or her employment and should be protected from liability for his or her acts or omissions in New York State.

However, the protection under the New York Public Officers Law is not complete. It does not cover independent contractors engaged by a local health department. It does not cover volunteers unless, as **may** become the case with the smallpox vaccination program, they are working under a publicly sponsored volunteer program. And the law does not cover punitive or exemplary damages or damages resulting from an employee's intentional wrongdoing or recklessness.

If the state indemnification law made the state or local government liable for the acts of its employees, Section 304 would allow the state or local government, in turn, to shift liability to the federal government. If a government employee is not indemnified under state law, he or she may shift liability directly to the federal government through Section 304. However, as can be seen above, Section 304 does not apply in some situations (e.g., employee recklessness) which are also not covered by the New York Public Officers Law and, in those situations, neither the federal nor the state statute will shield the government workers from personal liability.

Other states offer public employees protections similar to the protections offered by New York law.

In Florida, a state agency or county is authorized to pay judgments resulting from acts or omissions of any officer, employee or agent (but not an independent contractor) unless the employee or agent acted outside the scope of his employment, in bad faith, with malicious purpose, or in a manner showing wanton and willful disregard of human rights, safety or property.[29] Volunteers for state agencies are also shielded from personal liability.[30]

In Massachusetts, "public employers" are liable for injuries caused by the negligent or wrongful act of a public employee acting within the scope of employment provided that the public employee cooperates with the public employer.[31]

In California, a state and local government employee (but not an independent contractor) may request his or her employer to defend the employee and the employer will pay any judgment or settlement arising from activities within the employee's scope of employment.[32]

State Workers' Compensation Laws

What if the plaintiff is the health care worker himself or herself who, in the course of the worker's employment, as a vaccinator or vaccinee, has been harmed? The most likely harm to a vaccinator would come from contracting vaccinia and suffering other complications of vaccination through contact with the vaccine or with vaccinees. Possible injuries to vaccinees are described above.

Subject to the limitations outlined above, a vaccinator's action against a vaccine manufacturer, vaccine distributor, or public health care agency may be brought under Section 304 of the Homeland Security Act against the federal government. Section 304 states that a person to whom vaccinia vaccine is not administered but who contracts the vaccinia virus anyway is rebuttably presumed to be a person to whom a covered countermeasure was administered with the right to sue through Section 304.[33] However, Section 304 has been interpreted to bar actions against the federal government if a state's workers' compensation law provides an exclusive remedy for injured workers.[34]

New York's Workers' Compensation Law is the exclusive remedy for the workers it covers[35] and injured employees in New York must bring an action for an injury suffered in the smallpox vaccination program as

a workers' compensation claim. New York's law covers county employees but explicitly does not cover any independent contractors.[36] Whether a worker is an employee or independent contractor depends on the facts and circumstances of the worker's engagement and not on the label applied to the worker by his or her employer or by any contract of engagement for his or her services.

The New York State Workers' Compensation Board interprets the law to cover state volunteers.[37] Volunteers in local government programs, however, may not be covered.

Workers' compensation is also the exclusive remedy for injured workers in Florida.[38] In Massachusetts, an injured worker has a right to bring a private action but may waive that right and be restricted to a workers' compensation claim.[39] In California, if the worker is not covered by the state's workers' compensation law, he or she may bring an independent action against his or her employer. Otherwise, workers' compensation is the exclusive remedy.[40]

Smallpox Emergency Personnel Protection Act of 2003

Because of the anxieties among health care workers about possible adverse reactions to smallpox vaccination, the much lower than expected vaccination rates among health care workers, and, as outlined above, the difficulties an injured health care worker would face making a case in negligence, it is not surprising that proposals to afford compensation for vaccination injuries without a showing of fault emerged soon after Secretary Thompson issued the Declaration.

On February 13, 2003, California Congressman Henry A. Waxman introduced the "Smallpox Vaccine Compensation and Safety Act of 2003,"[41] which, among other things, would have established a no-fault compensation program for persons injured by the smallpox vaccine. Congressman Waxman's bill was modeled on the National Vaccine Injury Compensation Program[42] adopted in 1986. The National Vaccine Injury Compensation Program provides compensation without a showing of fault to persons injured by one of several listed vaccines administered to children. The smallpox vaccine was not listed, presumably because it was no longer being administered when the program was adopted.

On March 5, 2003, Secretary Thompson proposed a compensation fund for health care workers injured by the smallpox vaccine similar to benefits available to police and firefighters.[43] The four elements of the plan were permanent and total disability benefits, death benefits, temporary and partial disability benefits (two-thirds of lost wages after the fifth day of work), and health care benefits (covering reasonable out-of-pocket medical costs).

Only weeks later, on April 30, 2003, President Bush signed SEPPA into law. SEPPA gives health care workers and others implementing a smallpox emergency response plan who suffer a covered injury the right to recover amounts set forth in an injury table.[44]

Under the SEPPA, the Secretary of the Department of Health and Human Services is charged with determining whether an eligible individual has suffered a covered injury and the amount of medical benefits and compensation to which the individual is entitled.[45] These determinations are made on a "preponderance of the evidence standard"[46] and are not subject to judicial review.[47]

Benefits and compensation received under SEPPA are secondary to other coverage received by the injured individual (e.g., through state workers' compensation laws),[48] but, with limited exceptions, nothing in SEPPA prevents an individual from seeking benefits and compensation from other sources, and in fact, SEPPA amends Section 304 to provide that no claim may be made under Section 304 until the individual has exhausted his remedies for relief from the SEPPA injury table.[49]

Conclusion

In the absence of a no-fault compensation statute that extends beyond health care workers, most persons injured through the smallpox vaccination program will be required to file claims against the federal government alleging negligence. State indemnification statutes may protect government health care workers from personal liability and, in some situations when Section 304 does not apply, may be the only protection available for them. Workers' compensation, in those states where it is the exclusive remedy for injured employees, will be the only source of relief for plaintiffs injured at work, and, therefore, a defense for employers sued directly. Injured health care workers may secure scheduled compensation without having to prove anyone's negligence.

Public health agencies can protect themselves against liability in the first instance by assuring that only trained and appropriately credentialed and licensed health care workers serve as vaccinators and that these health care workers follow recommended procedures for interviewing, inoculating, and educating vaccinees. This will help eliminate the source of liability claims.

Public health agencies should also maximize the protection offered by Section 304 by assuring that the requirements for Section 304 coverage set forth in the

statute itself and in the Declaration are satisfied. For example, only persons who are covered persons under Section 304 should be vaccinators and any health care worker who is not a government employee should be individually designated as an agent of the government health agency for the smallpox vaccination program.

Public health agencies in all states must examine their particular state indemnification laws and workers' compensation laws to determine how these laws affect liability claims.

Endnotes

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Incapacity and the Privacy Rule: With a Nip and a Tuck They Might Fit

By Rose Mary Bailly and Barbara S. Hancock

Introduction

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)[1] was enacted to make the health care system of the United States more effective and efficient, including national standards for electronic health care transactions.[2] After concerns were raised during the legislative process that the privacy of a patient's health care information could be jeopardized through the use of electronic transmissions, privacy protection provisions were added to the statute.[3] At the behest of Congress, the Department of Health and Human Services promulgated a regulation addressing the subject.[4] That regulation, "Standards for Privacy of Individually Identifiable Health Information," known as the "Privacy Rule," was issued in December 2000 and subsequently amended four times.[5] Pursuant to HIPAA, the regulation establishes national standards for an individual's rights regarding his or her health information.[6] However, the regulation is not intended to preempt any federal, state, or other law that establishes requirements, standards, or implementation specifications that are more stringent than the regulation.[7]

In the aftermath of the promulgation of the Privacy Rule, confusion about its applicability has reigned as health care providers, patients, and third parties work to understand the scope and breadth of the Privacy Rule.[8] This is complicated by the fact that interpretations of the Privacy Rule continue to evolve. The concern generated by the Privacy Rule has been altogether understandable in light of the stiff monetary penalties for violating its provisions.[9] This article presents our understanding of the impact of the Privacy Rule on the disclosure of medical information for a person who is incapacitated to holders of powers of attorney and health care proxies and in guardianship proceedings.

The Privacy Rule and Incapacity

Under the Privacy Rule, an individual has certain rights regarding the use and disclosure of "individually identifiable health information."[10] Individually identifiable health information is "health information created or received by a covered entity" and "relates to the past, present, or future physical or mental health condition of an individual; the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual."[11] When the individually identifiable health information is transmitted or maintained in electronic or other form, it is protected from unauthorized use or disclosure.[12] The covered entity may disclose the protected health information to the individual[13] and is required to do so when the individual requests it.[14] Covered entities include health plans, health care clearinghouses[15] and health care providers "who transmit[ ] any health information in electronic form with respect to a transaction covered by [the Privacy Rule]."[16] In certain circumstances, the covered entity may disclose protected information to third parties. Subpart E of Part 164, "Security and Privacy," sets forth the rules and guidelines for use and disclosure to third parties, including uses and disclosure when the individual agrees or has an opportunity to object, and uses and disclosure where the individual's agreement or opportunity to object is not required.[17]

If the individual is incapacitated and unable to request the information from the covered entity, the question then arises as to who may make a request and under what circumstances the information can be disclosed. The Privacy Rule addresses this situation in a variety of ways.

Under Subpart E's general rules, the covered entity must recognize the authority of the "personal representative" of the individual to request and receive such information.[18] A personal representative is the person who has authority under applicable law "to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care."[19] The law of New York will thus determine whether a particular individual is a "personal representative." The personal representative's access to the protected health information is limited to information that is relevant to the personal representation.[20]

The Privacy Rule permits someone who is not a personal representative to have limited access to an individual's protected health information.[21] The person may be a family member, other relative or close personal friend, or any other person identified by the individual.[22] These disclosures are limited to health information "directly related to the person's involvement with the individual's health care" or to notification of the individual's location, general condition, or death.[23] The covered entity may make such disclosures with the individual's express or implied consent.[24] If the individual is not present or if the individual is incapacitated, the decision to disclose is within the professional judgment of the covered entity that disclosure is in the best

interest of the individual.[25] This section does not envision that the disclosure would involve past medical history with no bearing on the individual's current condition.[26] One comment by the drafters explains that the intent behind this section was to allow continuation of

> most covered entities' current practices with respect to informing family members and others with whom a patient has a closed personal relationship about a patient's specific health condition when a patient is incapacitated due to a medical emergency and the family member or close personal friend comes to the covered entity to ask about the patient's condition.[27]

Another comment suggests a broader interpretation, referring to "the need that covered health care providers may have, in some cases, to have routine, informal conversations with an individual's family and friends regarding the individual's treatment."[28] Taken together, the comments indicate that the drafters of this section were trying to strike a balance, upon learning during the public comment period of the diversity of practices. It is arguable that under some circumstances, as explained below, the language of this section may provide access to information when needed for the benefit of an incapacitated person.

Under its rules regarding disclosures where authorization or an opportunity to object are not required, the Privacy Rule provides that the covered entity may also be required to disclose information in certain situations including where there is an investigation of a complaint of abuse or neglect,[29] in response to a discovery device during the course of a judicial or administrative proceeding under certain circumstances,[30] or in response to an order of a court or administrative tribunal where the disclosure is required for a judicial or administrative proceeding.[31]

These various rules must be considered when attempting to obtain access to protected health information regarding an incapacitated individual; however, it is not always readily apparent whether their application will result in access to the information sought.

Planning for Incapacity

New York law allows an individual to appoint agents to make decisions and act on his or her behalf if he or she should ever become incapacitated. With a durable power of attorney, the individual, known as the principal, can appoint an agent, known as the "attorney-in-fact," to manage the principal's financial matters. With a health care proxy, the individual appoints an agent for health care decisions. Access to the individual's protected health information by these agents for bill-paying and health care decision-making is governed primarily by a determination of whether they are regarded as personal representatives under the Privacy Rule.

Powers of Attorney

Decision-Making for Health Care Billing and Payment Matters

Under New York's General Obligations Law, the principal may grant authority to the attorney-in-fact to handle a broad variety of financial matters on the principal's behalf, including real estate transactions, banking transactions, business operating transactions, insurance transactions, estate transactions, claims and litigation, retirement benefit transactions, gifting, and tax matters. Corresponding to each of the sixteen powers listed on the statutory form is a construction section detailing what is included in that power.[32] The principal may include additional powers, supplement or limit the attorney-in-fact's authority with respect to a particular power, or eliminate a particular power.[33]

Under a standard power of attorney, the attorney-in-fact has the authority to access the principal's funds, records, and billing statements for the purpose of paying the principal's bills. The broadly written construction section that lays out the specifics of this power dates from 1963, long before HIPAA and the Privacy Rule, and makes no specific reference to medical bills and records. Even before the Privacy Rule, attorneys-in-fact have reportedly run into trouble when seeking records related to health care billing because of New York's law governing access to patient records. Under this law, the attorney-in-fact would have access to bills, but not to the substantiating examination, assessment, or treatment records,[34] which are available only to "qualified persons."[35] The attorney-in-fact, who is not listed as a "qualified person," is at a loss to check the accuracy of a billing statement. However, if the principal expressly grants authority for such access in the power of attorney, under the public health law the document may now qualify as a permissible written authorization for release of records to a third party.[36]

The problem of access is exacerbated by the Privacy Rule's definition of personal representative as a person with authority to make decisions related to health care. Characterizing an attorney-in-fact as the principal's personal representative according to this definition is difficult because New York's General Obligations Law limits the authority of the attorney-in-fact to financial matters, and expressly prohibits the attorney-in-fact from making health care decisions for the principal.[37] In New York, applicable law makes a health care agent appointed pursuant to a health care proxy (or a guardian appointed pursuant to court order) the principal's personal representative.[38] Since only the principal

and the health care agent (or a court-appointed guardian for the principal) have broad access to the principal's health care records under the Privacy Rule, an incapacitated principal's attorney-in-fact seeking information from these records to clarify or contest a medical bill would have to gain access through the health care agent. In this way, the Privacy Rule's restriction of access to records does not take into account a statutory structure such as New York's, which divides responsibilities for health care decisions and bill-paying between two representatives, the health care agent and the attorney-in-fact.

Many people do, in fact, designate the same person to serve as both health care agent and attorney-in-fact under a health care proxy and power of attorney, respectively. In those cases, the person acting in a dual capacity should have no problem gaining access to medical information and records necessary to make health care and payment decisions.[39] However, in creating two separate consumer documents for people to use in planning for health care and financial matters, the New York Legislature clearly intended that New Yorkers have the option to name different individuals to serve as decision-makers in these different capacities. At issue is how to ensure that a person acting only in the role of attorney-in-fact can have access to underlying health care information if the attorney-in-fact finds reason to question the accuracy of a bill.

Despite the difficulties associated with the definition of "personal representative" under the Privacy Rule, the attorney-in-fact could argue that the covered entity can make some disclosures of protected health information to the attorney-in-fact under the Privacy Rule's standard for permitted "uses and disclosures for involvement in the individual's care and notification purposes."[40] Under this standard, the covered entity may disclose to "[a] person identified by the individual the protected health information directly relevant to such person's involvement with . . . payment related to the individual's health care."[41] If the individual is incapacitated, the provider may determine whether the disclosure is in the individual's best interest.[42] Since the attorney-in-fact has been identified by the principal as the person involved with bill payment, this standard should apply. However, since the standard grants only as much access as the provider decides to allow,[43] it is not ideal from the point of view of the principal, who would want to assure that the attorney-in-fact has the authority to access all needed records if there were a question about a bill.

To clarify concerns about the authority of an attorney-in-fact under the Privacy Rule, the New York State Law Revision Commission's recently completed proposal to amend the General Obligations Law as it relates to powers of attorney[44] includes a provision addressing access to health care billing and payment records, to make the power of attorney law consistent with the health care proxy law and the Privacy Rule. Under the Commission's proposal, the attorney-in-fact's authority with respect to "records, reports and statements" on the statutory short form has been revised to include "health care billing and payment matters." The corresponding new paragraph (1) added to construction section 5-1502K clarifies that the authorization to act with respect to records, reports and statements includes the authorization to access records relating to the provision of health care and to make decisions relating to payment for health care services to which the principal or the principal's health care agent has consented. This clarification removes any ambiguity about whether an attorney-in-fact acting under an existing or future power of attorney can access health care records in connection with the payment of health care bills. The amendment does not change current law limiting the authority of a third party to make health care decisions to a health care agent acting under a health care proxy or a guardian appointed by the court. Under the Commission's proposal, the health care agent or guardian remains the person's personal representative with respect to health care decisions as defined in the public health law.

The Commission's proposed amendment to section 5-1502K of the General Obligations Law would redefine the authority of the attorney-in-fact so that the attorney-in-fact becomes the individual's personal representative for purposes of accessing medical records in connection with paying medical bills.[45] This provision of the amended law will apply to all validly executed New York powers of attorney, including those already in effect at the time of the bill's passage. It should not be necessary to execute a new power of attorney under the amended law solely for the purpose of ensuring access to medical records.

Authorization for the Release of Protected Health Information Related to Capacity

The Privacy Rule has another completely separate impact on certain powers of attorney, namely, whether protected health information related to a determination of an individual's incapacity can be released to a third party. This information is necessary in certain circumstances in order to determine whether the power of attorney is legally in effect. New York authorizes three types of powers of attorney, nondurable, durable and springing. A nondurable power of attorney, effective as soon as it is signed, ceases to be effective when the principal becomes incapacitated.[46] A durable power of attorney, effective as soon as it is signed, continues in effect after the principal becomes incapacitated.[47] A springing power of attorney, formally a "power of attorney effective at a future time," takes effect upon the occurrence

of an event specified by the principal.[48] In many cases, the specified event is the principal's incapacity, as certified by a physician or physicians identified in the document.[49] A determination of incapacity thus plays a key role in the effectiveness of two of the three types of powers of attorney, nondurable and springing.

The Privacy Rule's protection against the unauthorized disclosure of protected health information extends to information about the individual's incapacity.[50] Unlike the situation regarding billing and payment information where the attorney-in-fact, identified as the person involved with bill payment, may be permitted access to protected health information, in this situation, such an argument simply does not apply, because access to protected information about incapacity is needed for a purpose unrelated to health care billing and payment. The information sought determines whether the power of attorney is in effect.[51] Furthermore, the person seeking the information may not come within the parameters of the standard for uses and disclosure when the individual is incapacitated, because that information-seeker may be a financial institution or other third party not included in the standard. However, the problem of access may be resolved under the Privacy Rule by allowing disclosure pursuant to, and in compliance with, a HIPAA authorization.[52] With a HIPAA-compliant authorization, a doctor's written certification that an individual is incapacitated, potentially needed for terminating a nondurable power of attorney or triggering a springing power of attorney, can be disclosed to the attorney-in-fact, financial institutions, or other third parties, thus ensuring the principal's intention that his or her capacity properly controls the effectiveness of the power of attorney.[53]

The Commission's proposal to amend the General Obligations Law as it pertains to powers of attorney includes two new, separate forms to accompany a nondurable general power of attorney or a durable general power of attorney effective at a future time if the triggering event is the principal's incapacity. These forms are needed in order to obtain from a medical provider a written statement of the principal's incapacity.

These forms were designed to meet the requirements for a valid authorization listed in the Privacy Rule, namely: a description of the information to be disclosed, the person or class of persons authorized to request disclosure, a description of the purpose for the disclosure (e.g., "at that person's request"), an expiration date, the signature of the principal or, alternatively, his or her "personal representative," the date of signature, and several required statements.[54]

If the principal is unable to execute this form due to incapacity, the principal's health care agent appointed under the principal's health care proxy could do so in his or her role as personal representative, since the health care agent's authority begins when the principal becomes incapacitated.[55] Unless the attorney-in-fact is also the principal's health care agent, the attorney-in-fact cannot execute this document. Where the principal has no health care agent and wishes to use a nondurable or springing power of attorney, the principal should be aware that the effectiveness of his or her power of attorney may depend upon the principal's execution of this authorization form at the same time as the power of attorney.

Health Care Proxies

A principal's incapacity is also at issue in determining when a health care proxy takes effect. New York's health care proxy law allows the principal to appoint a person as agent with the authority to make any and all health care decisions on his or her behalf, subject to any limitations specified by the principal in the proxy form.[56]

New York's health care proxy is essentially a springing instrument: the agent's authority begins when the attending physician determines that the principal lacks capacity to make health care decisions.[57] This determination of lack of capacity is solely for the purpose of empowering the health care agent.[58] The physician makes the determination in writing in the patient's medical record, specifying her opinion regarding the cause and nature of the principal's incapacity, and its extent and probable duration.[59] The determination may be requested by the agent.[60] When the attending physician has made this determination, the health care agent has full authority to make health care decisions on the principal's behalf, subject to any limitations that the principal may insert in the instrument.[61] The agent also has the right to receive health care information and records necessary to make informed decisions concerning the principal's health care.[62]

The determination of incapacity for purposes of triggering a health care proxy may appear analogous to the determination for purposes of triggering or terminating a power of attorney, but it is not. The determination for the power of attorney is for a purpose unrelated to health care decision-making. Accordingly, for a power of attorney, the principal should affirmatively grant access to this information through a HIPAA-compliant authorization, as explained above. The determination for triggering the health care proxy, on the other hand, is for the purpose of empowering someone to make treatment decisions. The Privacy Rule specifically allows disclosures without authorization when needed for treatment purposes.[63] Disclosure to the designated health care agent would qualify under the standard "uses and disclosures for involvement in the individual's care and notification purposes."[64] This standard permits disclosure to "any . . . person identified by the

individual, the protected health information directly relevant to such person's involvement with the individual's care."[65] The person identified by the individual is the designated health care agent, and the protected health information pertaining to incapacity is directly relevant to the agent's involvement in the principal's care. Thus, the Privacy Rule does not appear to prevent the health care agent from knowing that the principal is incapacitated and, therefore, that the health care proxy is in effect; in other words, the Privacy Rule should not indirectly cause denial of care to an incapacitated individual. We are aware that some attorneys are preparing separate authorizations solely for the purpose of obtaining the determination of incapacity that triggers the health care agent's authority, but we are of the opinion that these separate authorizations are unnecessary.

Under the Privacy Rule, the health care agent qualifies as the individual's personal representative[66] who must be treated as the individual for purposes of disclosure of protected health information.[67] The Rule provides the individual or the individual's personal representative with an affirmative right of access to protected health information.[68] With such broad rights of access already assured to the health care agent under the Privacy Rule, it should not be necessary to modify New York's statutory health care proxy to spell out the access that is already guaranteed.[69]

Guardianship

Incapacity is the central determination required for the appointment of a guardian for a person unable to make decisions for himself or herself. New York has three guardianship statutes allowing the appointment of a guardian for an incapacitated adult: article 81 of the Mental Hygiene Law (guardian of an incapacitated person);[70] article 79 of the Mental Hygiene Law (guardian for veterans and infant wards of the United States Veterans Administration);[71] and article 17-A of the Surrogate's Court Procedure Act (guardian of a person with mental retardation or developmental disabilities).[72] Once a guardian with authority with respect to the person's health care decisions is appointed, the guardian can be treated as the individual's personal representative for purposes of the Privacy Rule.[73] However, the Privacy Rule may play out differently in each statute during the process by which the need for a guardian is determined.

Article 81 of the Mental Hygiene Law

Under article 81 of the Mental Hygiene Law, a guardian can be appointed for an individual who consents to the appointment or whom the court finds by clear and convincing evidence to be incapacitated.[74] In order to understand the interrelationship between the Privacy Rule and the need for health information under this guardianship statute in cases where the individual is alleged to be incapacitated, it may be helpful first to consider what incapacity means under the statute.

The determination of incapacity turns on three key elements: 1) whether the person is able to provide for his or her personal needs and financial management, 2) whether the person is at risk of harm because of his or her limitations, and 3) whether the person adequately understands and appreciates the nature and consequences of his or her inabilities. [75] The main focus of this standard is on the person's functional limitations with respect to activities of daily life (ADLs) and instrumental activities of daily living (IADLs). ADLs include "activities related to personal care and include bathing or showering, dressing, getting in or out of bed or a chair, using the toilet, and eating."[76] IADLs are "activities related to independent living and include preparing meals, managing money, shopping for groceries or personal items, performing light or heavy housework, and using a telephone."[77] The statute bases the determination of capacity on the individual's functional ability because information regarding a person's functional abilities is critical to a decision as to whether a surrogate decision maker should be appointed with power over those areas of the person's life.[78]

The statute's emphasis on the individual's functional limitations arose out of concern that the standards under prior laws "encouraged the use of diagnostic labels and conclusory statements that a person could not care for himself or herself to satisfy the legal criteria of incompetency and or impairment and discouraged the specific effects, if any, of those diagnoses on the actual ability of the person to function in everyday life."[79] As a practical matter, this reliance on medical information arose out of the practice under repealed articles 77 and 78 (conservator and committee statutes, respectively), by which courts required a physician's affidavit as to the individual's mental and/or physical condition as part of the petition.

Under article 81, the court must give "primary consideration" to the individual's functional abilities and limitations.[80] This emphasis on the individual's behavior is not intended, however, to diminish the influence of medical information in reaching a decision about capacity. Where appropriate, the court's determination should include an assessment of any physical or mental illness or disability and its prognosis, and any medications that the person is taking.[81] The prognosis may be key to determining whether the individual's condition is reversible. Likewise, the medications involved may induce conditions mimicking dementia which can be corrected if the medication usage is changed.

The effect of the Privacy Rule on the availability of the health information for the guardianship proceeding essentially involves the phase of the proceeding at

which the request is made for information and the authority of the person seeking it. For purposes of this discussion, the guardianship proceeding can be divided into three phases: commencement, hearing,[82] and post appointment.

Commencement

In order to initiate a proceeding, the petitioner must submit an order to show cause and petition to the court for the judge's signature. The petition must contain a "description of the alleged incapacitated person's functional level including that person's ability to manage the activities of daily living, behavior, and understanding and appreciation of the nature and consequences of any inability to manage the activities of daily living."[83] If the petitioner is seeking the appointment of a guardian with the authority to make decisions regarding the allegedly incapacitated person's health care and other matters relating to the individual's person,[84] the petition must also contain "specific actual allegations as to the personal actions or other actual occurrences involving the person alleged to be incapacitated which are claimed to demonstrate that the person is likely to suffer harm because he or she cannot adequately understand and appreciate the nature and consequences of his or her inability to provide for personal needs."[85]

Given the statute's focus on behavior, the first issue is whether medical information must accompany the petition. The answer is no. Nothing in the statute requires that a diagnosis and related medical information be included with the petition.[86] Although there has been some debate about such a requirement in cases involving the appointment of a surrogate decision maker,[87] recent case law makes it clear that medical affidavits are not necessary and, in fact, improper under article 81. These courts have held that if a petition contains medical information or is accompanied by an affidavit containing medical information that was obtained in violation of the patient physician privilege, it will be dismissed as improper.[88] In *England*, for example, the court held that "absent consent, inclusion of medical affidavits with the petition seeking the appointment of a Guardian is a violation of patient-physician privilege. . . ."[89] Hence, there should be no need to seek health information from a covered entity to initiate the proceeding.[90]

Although the views expressed in these recent decisions are very clear, some areas of controversy remain. Some courts may still require medical affidavits as part of the petition and practitioners are struggling with how to treat the patient-physician privilege, and now the Privacy Rule, in those situations.[91] In cases where the petitioner is a covered entity or the department of social services, additional issues may arise about disclosure of protected information.

Particular Courts' Requirement for Medical Affidavit

The Privacy Rule makes complying with a particular court's requirement for a medical affidavit at the time of commencement very difficult in most circumstances. If the person can consent to the guardianship, in all likelihood, the person can also authorize the release of the medical records to the attorney who is preparing the petition and to the court evaluator at the hearing phase.

If the individual is alleged to be incapacitated, his or her ability to authorize the release of the health information is most likely compromised. If he or she has designated a health care agent, the health care agent can request the release as the personal representative.[92] In the absence of a designated personal representative under the Privacy Rule, resort must be had to other provisions of the Privacy Rule. As discussed earlier, the Privacy Rule permits a covered entity, if consistent with professional judgment, to disclose information about an incapacitated patient's condition to a family member.[93] However, the disclosure is permissive and limited in scope to the person's involvement with the individual's current medical condition. If interpreted narrowly,[94] this provision may not be available as an avenue for the type of disclosure needed to satisfy the court. Moreover, it would seem that New York's case law regarding the use of medical affidavits during the initiation phase provides more protection to an alleged incapacitated person than this provision of the Privacy Rule, and hence, this provision would not preempt state law. However, if a relevant disclosure is made, in all likelihood the petitioner's attorney can use it in an affidavit prepared for the petitioner as a way to satisfy the court.

Petitioner Health Care Facility

A health care facility may petition for guardianship when its patient appears to be incapacitated and no one else can or is willing to consent to the discharge plan. If the petitioner is a health care facility, different considerations may be involved. As noted earlier, medical information is not required to commence the proceeding. However, the covered entity may take the position that the only information available for its use in the petition is the protected health information. As a covered entity, the health care facility is unable to use the individual's protected health information without the consent of the patient or the health care agent. However, there may be provisions of the Privacy Rule that arguably can be used to justify the disclosure. One such provision permits disclosure to a limited degree if the covered entity "in good faith, believes the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person . . ."[95] While the safety of an alleged incapacitated person residing in a facility should not be in doubt, most covered entities seeking

a guardian for a patient are doing so because they believe that the patient will be at risk if he or she is discharged into the community.[96] How broad an interpretation this section can be given is unclear. The commentary to the Privacy Rule suggests that the circumstances contemplated by this provision are more akin to situations where the threat is posed by a third party and the "rule's approach is consistent with the 'duty to warn' third persons at risk which has been established by case law."[97]

Another approach would be for the covered entity's attorney to prepare two petitions: one containing the protected health information and one without it.[98] When the petitioner's attorney presents the order to show cause for the judge's signature, [99] the attorney can request that the court review the materials *in camera* and then sign an order authorizing the covered entity to release the information. This type of procedure was described in *In re John Doe (St. Luke's Hospital),*[100] a case predating the Privacy Rule that dealt with an analogous situation, the privacy and confidentiality of information about AIDS and HIV provided by article 27-f of the Public Health Law.[101]

In *John Doe,* the hospital sought the appointment of a guardian for an individual suffering from an AIDS-related dementia. The issue before the court was how the petitioner could comply with the stringent provisions of the Public Health Law, which penalizes those who acquire information about AIDS during the course of providing health care or social services, and thereafter disclose it, and initiate a guardianship proceeding.[102] The court held that the need for the information for the guardianship proceeding satisfied the showing of compelling need for adjudication of a civil proceeding under section 2785(2) of the Public Health Law because the information was relevant as to the individual's capacity, but even more importantly, to the nature of the powers the guardian needed.[103] The court devised a procedure to address the timing problem of commencing the article 81 proceeding while also needing a court order to compel the disclosure. It suggested that "[p]etitioner should supply the redacted information accompanying the OSC [order to show cause] in an affidavit, placed in a sealed envelope accompanying it. If necessary, petitioner should simultaneously serve a second OSC seeking an order to compel disclosure."[104]

Department of Social Services Petitioner

The department of social services, through its office of Adult Protective Services (APS), may petition for the appointment of a guardian for a person in the community who is eligible for adult protective services because the individual is unable to care for himself or herself due to a physical or mental impairment and has no one willing or able to assist him or her.[105] As noted earlier, article 81 does not require medical information to be included in the petition, so APS can proceed without it. Information from the caseworker can support the petition. The Privacy Rule's exception for disclosures to APS involving an individual as the subject of abuse or neglect does not appear to be relevant. If the person is incapacitated, disclosure to APS can only take place if it is expressly authorized by law. In New York the only mandatory reporters of abuse and neglect are APS[106] and a list of persons if the abuse occurs to a resident of a facility.[107] Even if the exception were applicable, the standard would appear to prevent APS from using the information in a guardianship petition because APS must affirmatively represent to the covered entity that the information will not be used "against the individual."[108]

Hearing

Once the guardianship proceeding is commenced, any further need for protected health information can be addressed by seeking an order of the court.[109] Article 81 contemplates that the court evaluator who seeks medical information can do so only with the consent of the alleged incapacitated person or by an order of the court.[110] As noted earlier, if the individual can consent to disclosure, the requirements of both the Privacy Rule and article 81 are satisfied. If the individual cannot consent, the court evaluator must obtain an order of the court. The alleged incapacitated individual has notice in the order to show cause that he or she has the right to object to the disclosure of medical records. This process would satisfy both the statute and the Privacy Rule. The statutory showing required from the court evaluator for a court order is minimal: "that the records are likely to contain information which will assist the court evaluator in completing his or her report to the court notwithstanding the physician-patient privilege in CPLR 4504."[111]

In certain circumstances, the showing required may be more stringent. If the court evaluator seeks medical records from alcohol and substance abuse facilities, federal law and regulations govern.[112] Records of "identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment rehabilitation or research . . ." shall be authorized "by an appropriate order of a court of competent jurisdiction granted after application good cause therefor. . . ."[113]

Records sought from state mental hygiene facilities are governed by section 33.13 of the Mental Hygiene Law. These records are available to the Mental Hygiene Legal Service or with the consent of the patient or client, but otherwise they are subject to disclosure only in limited circumstances. The relevant provision for dis-

closure in a guardianship proceeding requires a court order based upon a finding that "the interests of justice significantly outweigh the need for confidentiality. . . ."[114] The order authorizing the disclosure should provide for the sealing of the records, because any information disclosed pursuant to section 33.13 must be kept confidential.[115]

As noted earlier, records containing HIV-related information are governed by section 2785 of the Public Health Law, which authorizes disclosure of confidential HIV-related information in a civil proceeding such as a guardianship matter upon a showing of "a compelling need" for such information.[116] A determination that disclosure is appropriate will result in an order sealing all the papers that are part of the application.[117]

If the court orders the records disclosed to the court evaluator, the court may also direct disclosure to counsel for the alleged incapacitated person and to the petitioner. To the extent that the protected health information is not required to be sealed by another statute, article 81 provides that the court can seal the records.[118]

Post Appointment

As noted earlier, once the guardian with authority for personal affairs has been appointed, he or she would be treated as the personal representative for purposes of the Privacy Rule. This result is consistent with New York's rule regarding the article 81 guardian's access to the incapacitated person's health care records.[119]

Article 79 of the Mental Hygiene Law—Guardian for Veterans and Infant Wards of the United States Veterans Administration

Capacity is the basic element of a proceeding under article 79 of the Mental Hygiene Law. This article provides for the appointment of a guardian for a beneficiary of the United States Veterans' Administration (VA) when the VA requires the appointment of a guardian before paying benefits.[120] This statute does not define incapacity or incompetence. It relies instead on the VA's determination that the person is incompetent. The VA's examination must be in accordance with the administration's rules and regulations.[121] That showing is deemed *prima facie* evidence of incapacity for purposes of the statute.[122]

Commencement

Under article 79, a petition must show, among other things,[123] that the individual "has been rated incompetent on examination by the administration in accordance with the laws and regulations governing the administration."[124] This requirement would appear to implicate the Privacy Rule. While certain provisions of the Privacy Rule govern veterans specifically, the permissible disclosures involve intra-agency disclosures for purposes of determining eligibility for benefits.[125] They do not address the use of VA determinations of incompetency in court proceedings. Additionally, the VA has its own privacy rules which have been recently amended to provide that uses and disclosures of individually identifiable health information "must be either required by law or permitted by the Privacy Rule before the VHA may disclose the covered information."[126] Thus it would appear that the petitioner is constrained by the Privacy Rule in obtaining information about an incapacitated veteran. If the veteran has a health care agent, he or she can obtain the information as the personal representative.[127] The petitioner can seek the information prior to initiating the proceeding by requesting it from the covered entity as a person interested in the care of the veteran or commence the proceeding and seek a court order for disclosure, in the same way as one might proceed under article 81.

Hearing

Article 79 does not require the appointment of a court evaluator; however, if the court consolidates an article 79 proceeding with an article 81 proceeding,[128] it must appoint a court evaluator; the court evaluator's role would involve obtaining access to medical records in the same way as under article 81.

Post Appointment

Since the purpose of an article 79 proceeding is to obtain benefits for the veteran, an appointment under article 79 does not authorize the article 79 guardian to have access to the veteran's medical records thereafter.[129]

Article 17-A of the Surrogate's Court Procedure Act—Guardian of a Person with Mental Retardation or Developmental Disabilities

The standard for determining the need for a guardianship under article 17-A of the Surrogate's Court Procedure Act is whether the person is mentally retarded or has a developmental disability. Under the statute, a mentally retarded person is a "person certified by one licensed physician and one licensed psychologist, or by two licensed physicians . . . as being incapable to manage him or herself and/or his or her affairs by reason of mental retardation and that such condition is permanent in nature or likely to continue indefinitely."[130]

The statute defines a developmentally disabled person as "a person who has been certified by one licensed physician and one licensed psychologist, or by two

licensed physicians . . . as having an impaired ability to understand and appreciate the nature and consequences of decisions which result in such person being incapable of managing himself or herself and/or his or her affairs by reason of developmental disability and that such condition is permanent in nature or likely to continue indefinitely."[131] The statute further provides that the developmental disability must be caused by "cerebral palsy, epilepsy, neurological impairment, autism or traumatic head injury," or "any other condition of a person found to be closely related to mental retardation because such condition results in similar impairment of general intellectual functioning or adaptive behavior to that of mentally retarded persons" or "dyslexia resulting from a disability . . . or from mental retardation." To qualify as a developmental disability under the statute, the condition must originate before the person's 22nd birthday."[132] There is no such age restriction for a person with a traumatic head injury.[133]

Commencement

The statute requires that the petition for the appointment of an article 17-A guardian be accompanied by the certificate of the underlying diagnosis of mental retardation or developmental disability.[134] In the case of a person with mental retardation, the certificate must also state whether the individual has the capacity to make medical decisions.[135] The certificate must be prepared by two physicians or a physician and a psychologist who is an expert in the subject of the diagnosis.[136]

While past practices and to some extent current practices have made obtaining these records relatively easy, such readily available documentation would seem to contradict New York law and certainly the requirements of the Privacy Rule.[137] Under section 18 of the Public Health Law, access to health information is limited to the patient, an article 81 guardian, and the guardian of an infant.[138] If the person is receiving services from the Office of Mental Retardation and Development Disabilities (OMRDD), access to patient information may be available to the petitioner, depending on the petitioner's status. Access to confidential records of a person receiving services from OMRDD are governed by article 33 of the Mental Hygiene Law.[139] Under article 33, that information may be disclosed pursuant to court order "upon a finding that the interests of justice significantly outweigh the need for confidentiality . . . "[140] or with the consent of the client or his or her authorized representative "to persons and entities who have a demonstrable need for such information. . . ."[141] Article 33 also permits access to the OMRDD clinical records to the parent, spouse, or adult child who is authorized by law, rule or regulation to provide consent for care and treatment.[142] OMRDD regulation 633.11 allows an actively involved parent, adult spouse or adult child to give informed consent when the individual residing in an OMRDD operated or certified facility is unable to do so.[143]

The fact that article 33 grants certain limited access to an actively involved parent, spouse or adult child would appear to give such a person status as the individual's personal representative.[144] Under the Privacy Rule, the status of personal representative is determined by state law, which is, in turn, defined to include regulations and rules.[145] Thus the combined effect of article 33 and OMRDD regulation 633.11 gives the actively involved parent, spouse or adult child the authority as personal representative to obtain protected health information from OMRDD facilities. As to protected health information maintained by other covered entities, the petitioner would have to assert the right to obtain such information as a family member, relative or close personal friend under the rule which permits someone who is not a personal representative limited access to an individual's protected health information "directly related to the person's involvement with the individual's health care."[146] If the covered entity declines to disclose the information pursuant to that provision, the petitioner may have to file the guardianship application and seek a court order to compel disclosure.[147]

Hearing

Under article 17-A, the court may appoint an attorney as *guardian ad litem* or Mental Hygiene Legal Service as *guardian ad litem*.[148] As in an article 81 proceeding, a guardian ad litem or Mental Hygiene Legal Service could obtain a court order to compel disclosure of protected health information from a covered entity. Under New York law, Mental Hygiene Legal Service has access to OMRDD records without the patient's consent.[149] This access generally would appear to continue under the Privacy Rule.[150] As for other records, MHLS would appear to need a court order.

Post Appointment

Under the Privacy Rule, an article 17-A guardian would be regarded as a personal representative for purposes of access to records,[151] a result consistent with New York law.[152]

Conclusion

Incapacity under the Privacy Rule affects powers of attorney, health care proxies and guardianship proceedings in a variety of ways. For powers of attorney, the question is whether the Privacy Rule limits the attorney-in-fact's access to protected information for bill paying, and for determining whether the person is inca-

pacitated for purposes of terminating a nondurable power of attorney or activating a springing durable power of attorney. For health care proxies, the question is whether the agent can find out about the principal's capacity in order to activate the agent's authority. For guardianship, the most important question is how to obtain medical information to support a petition when the information is required by the guardianship statute or by the court.

The Privacy Rule does not provide ready answers to these questions. Various sections, however, may provide clues for a successful resolution of them.

Endnotes

1. Public Law 104-191.
2. General Overview of Standards for Privacy of Individually Identifiable Health Information, *available at* www.hhs.gov/ocr/hipaa/guidelines/overview.
3. *Id.*
4. Public Law 104-191 § 264.
5. *See* Standards for Privacy of Individually Identifiable Health Information, Regulation Text December 28, 2000 as amended: May 31, 2002, August 14, 2002, February 20, 2003, and April 17, 2003—Unofficial Version, *available at* http://www.hhs.gov/ocr/combinedregtext.pdf. The official Version is available in the Code of Federal Regulations. *See* 45 C.F.R. Parts 160 and 164.
6. Public Law 104-191 § 264(b).
7. Public Law 104-191 § 264(b); 45 C.F.R. § 160.203(b).
8. The authors expressly disavow any expertise on the subject of the Privacy Rule and ardently hope that they do not add to the confusion.
9. 42 U.S.C. § 1302d-5.
10. 45 C.F.R. 164, Subpart E.
11. 45 C.F.R. § 160.103.
12. 45 C.F.R. § 160.103; 45 C.F.R. § 164.502(a).
13. 45 C.F.R. §§ 164.502(a)(1), (a)(2)(1).
14. 45 C.F.R. § 164.524(a).
15. A health care clearinghouse is an organization that "processes or facilitates the processing of health information." 45 C.F.R. § 160.103. It can include "a billing service, repricing company, community health management information system or community health information system, and value-added networks and switches. . . . " *Id.*
16. 45 C.F.R. § 160.102(a); 45 C.F.R. § 160.103(3).
17. 45 C.F.R. §§ 160.500–160.534.
18. 45 C.F.R. § 160.502(g)(1).
19. 45 C.F.R. § 164.502(g)(2).
20. 45 C.F.R. § 164.502(g)(2).
21. 45 C.F.R. § 164.510(b).
22. 45 C.F.R. § 164.510(b)(1).
23. *Id.*
24. 45 C.F.R. § 164.510(b)(2).
25. 45 C.F.R. § 164.510(b)(3)
26. 65 Fed. Reg. 82,665.
27. 65 Fed. Reg. 82,664.
28. 65 Fed. Reg. 82,663.
29. 45 C.F.R. § 164.512(c).
30. 45 C.F.R. § 164.512(e)(1)(ii)
31. 45 C.F.R. § 164.512(e)(1)(i).
32. *See* N.Y. General Obligations Law §§ 5-1502A through 5-1502O (GOL).
33. *See* GOL § 5-1503.
34. N.Y. Public Health Law § 18(1)(e) (PHL).
35. *See* PHL § 18(1)(g).
36. PHL § 18(6).
37. GOL §§ 5-1501, 5-1501(a), 5-1506, and 5-1502O.
38. PHL §§ 2980 *et seq.*
39. *See* PHL § 2982(3).
40. 45 C.F.R. § 164.510(b).
41. *Id.*
42. 45 C.F.R. § 164.510(b)(3).
43. *Id.*
44. Submitted to the Judiciary Committees of the Senate and Assembly in February 2004. The proposal is available online at the Commission's website, www.lawrevision.state.ny.us, under "Recent Commission Reports," "Powers of Attorney."
45. If under applicable law a person has authority to act on behalf of an individual who is an adult or emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative . . . with respect to protected health information relevant to such personal representation. 45 C.F.R. § 164.502 (g)(2).
46. *See* GOL § 5-1501(1)(a).
47. *See* GOL § 5-1501(1).
48. *See* GOL § 5-1506.
49. The principal is not restricted to choosing incapacity as the triggering event, and may specify another event, and another person to certify that it has taken place.
50. New York law would have the same effect. *See* PHL § 18(1)(e) (defining patient information as "any information concerning or relating to the examination, health assessment . . . or treatment."). Persons defined under this section as qualified to have access to a patient's health care information do not include attorneys-in-fact. PHL § 18(1)(g).
51. A similar issue arises in many revocable living trusts, where the person who creates the trust (the grantor or settlor) also serves as trustee. The trust document, in naming a successor trustee to take over if the grantor/trustee becomes incapacitated, often calls for physicians' certification of incapacity.
52. 45 C.F.R. §§ 162.502(a)(1)(iv) and 164.508(a)(1).
53. The same problem can arise even with durable powers of attorney, which survive the principal's incapacity. Some clients ask their attorneys to hold their powers of attorney until needed. In this situation, prudence suggests that the attorney obtain independent confirmation of the client's incapacity before turning the instrument over to the attorney-in-fact.
54. 45 C.F.R. § 164.508(c).
55. *See* 45 C.F.R. § 164.502(g) and PHL § 2981(4).
56. PHL § 2982(1).
57. PHL § 2981(4). This definition by law of the triggering event distinguishes the health care proxy from a springing power of attorney, where it is the principal who determines the triggering event. *See* GOL § 5-1506.

58. PHL § 2983(4).

59. PHL § 2983(1)(a).

60. PHL § 2983(2). The health care agent's authority to receive this information is not reflected in the Public Health Law section generally governing access to patient health information. *See* PHL § 18(1)(e) (defining patient information as "any information concerning or relating to the examination, health assessment . . . or treatment."). Persons defined under this section as qualified to have access to a patient's health care information do not include health care agents. *See* PHL § 18(1)(g).

61. PHL § 2982(1).

62. PHL § 2982(3).

63. 45 C.F.R. § 164.502(a)(1)(ii).

64. 45 C.F.R. § 164.510(b).

65. 45 C.F.R. § 164.510(b)(1)(i).

66. If under applicable law a person has authority to act on behalf of an individual who is an adult or emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative . . . with respect to protected health information relevant to such personal representation. 45 C.F.R. § 164.502 (g)(2).

67. 45 C.F.R. § 164.502(g)(1).

68. 45 C.F.R. § 164.524(a)(1).

69. We are aware that to ensure compliance, some attorneys recommend modifying the form to authorize disclosure of protected health information to the health care agent. We do not believe such modification is necessary.

70. Article 81 can also be used for an infant. *See, e.g, In re Maryanne Cruz* (Sup. Ct., N.Y. Co.), N.Y.L.J., July 30, 2001; *In Re Addo* (Sup. Ct., Bronx Co.), N.Y.L.J., September 30, 1997, p. 25; *In re Marmol (Pineda)*, 168 Misc. 2d 845, 640 N.Y.S.2d 969 (Sup. Ct., N.Y. Co. 1996). However, some courts do not agree. *See, e.g, In re Forcella*, 726 N.Y.S.2d 243 (Sup. Ct., Suffolk Co. 2001); *In re Lavecchia,* 170 Misc. 2d 211, 650 N.Y.S.2d 955 (Sup. Ct., Rockland Co. 1996). *See also In re Elizabeth Grace Rooney*, Index No. 003373/2001, slip. op. (Sup. Ct., Suffolk Co. March 19, 2001).

71. N.Y. Mental Hygiene Law §§ 79.00 *et seq.* (MHL).

72. N.Y. Surrogate's Court Procedure Act 1750 *et seq.* (SCPA). Article 17-A can also be used for an infant. *Id.*

73. 45 C.F.R. § 160.503(g)(1). For New York State's treatment of guardians' access to health records, see PHL § 18 (1)(g).

74. MHL § 81.02.

75. MHL § 81.02(b)(1)&(2).

76. NCHS Definitions, National Center of Health Statistics, *available at* http://www.cdc.gov/nchs/datawh/nchsdefs/iadl.htm.

77. *Id.*

78. Law Revision Commission Comments to Section 81.02, 34A McKinney's Consolidated Laws 258, citing *In re Grinker (Rose)*, 77 N.Y.2d 703, 570 N.Y.S.2d 448, 573 N.E.2d 536 (1991).

79. Law Revision Commission Comments to Section 81.02, 34A McKinney's Consolidated Laws 258, citing T. Grisso., Evaluating Competencies—Forensic Assessments and Instruments 273 (1986).

80. MHL § 81.02(c).

81. MHL § 81.02(c)(4)(i)–(iv).

82. Much happens between the initiation of the proceeding and the actual hearing, but this phase is described as the hearing for simplicity's sake.

83. MHL § 81.08(3).

84. A guardian with such authority is known as the "guardian of the person."

85. MHL § 81.08(4). If the petitioner is seeking the appointment of a guardian with the authority to make decisions regarding the allegedly incapacitated person's financial affairs, the petition must also contain "specific actual allegations as to the personal actions or other actual occurrences involving the person alleged to be incapacitated which are claimed to demonstrate that the person is likely to suffer harm because he or she cannot adequately understand and appreciate the nature and consequences of his or her inability to provide for property management." MHL § 81.08(5)

86. *See In re Kustka*, 622 N.Y.S.2d 208 (Sup Ct., Queens Co. 1994) (noting that "[t]here is nothing in Article 81 that mandates medical testimony in a guardianship proceeding.").

87. *See In re Tara X.* (Sup. Ct., Suffolk Co.), N.Y.L.J., Sept. 18, 1996, p. 27 ("Since neither the CPLR nor Article 81 provide particulars for the existence, waiver or judicial extinguishment of the physician/patient privilege, the legal discourse regarding its application to Article 81 proceedings continues.") The debate over the role of the patient-physician privilege in guardianship proceedings is not unique to article 81. *Compare In re Allen (Mauceli),* 24 Misc. 2d 763, 204 N.Y.S.2d 876 (Sup. Ct., N.Y. Co. 1960) ("use of competent and expert medical testimony [in a commission to determine competency] is not only proper but highly desirable, if not essential, as an aid to the court.") and *In re Benson*, 16 N.Y.S. 111 (Co. Ct., Monroe Co. 1891) ("No physician can be better qualified to testify to the sanity or insanity of a person than he who has for some time attended such person in a professional capacity. Indeed, the cases are not rare where none but an attending physician could intelligently testify to a person's mental condition.") *with In re Gates*, 170 App. Div. 921, 154 N.Y.S.2d 782 (3d Dep't 1915) ("It was error to permit the defendant's personal physician to testify as to the competency of his patient. Clearly it was indelicate for a physician in attendance upon a patient to permit himself to be heard by another and go and make an examination of the patient for the purpose of testifying against him. In our judgment it was not only indelicate, but in violation of the privilege given to the patient. . . .") and *In re J. D.*, 107 Misc. 2d 288, 289, 433 N.Y.S.2d 717 (Sup. Ct., N.Y. Co. 1980) ("If the law were to be that there was no privilege in this type of case, a chill would be cast over all medical treatment of persons who might consider themselves as potential subjects of an attempt by relatives or by others, to take control of their property. Public policy is clearly in favor of complete freedom of medical treatment and openness in communications between patient and doctor.").

88. *See, e.g., In re England* (Sup. Ct., N.Y. Co.), N.Y.L.J., Oct. 6, 1995, p. 27; *In re Goldfarb*, 160 Misc. 2d 1036 (Sup. Ct., Suffolk Co. 1994).

89. N.Y.L.J., Oct. 6, 1995, p. 27.

90. The Law Revision Commission has recommended an amendment to article 81 to provide that the court cannot require medical affidavits to accompany the petition. The Commission's proposal is *available online* at the Commission's website, www.lawrevision.state.ny.us, under "Recent Commission Reports," "Revisions to Article 81 of the Mental Hygiene Law."

91. *See* Transcript, New York State Bar Association, The Dilemma of Patient Privilege in Guardianship Proceedings, January 29, 1998; Michael Miller, *Guardianship Proceeding and the Patient-Physician Privilege*, Guardianship Practice in New York (Robert Abrams, Esq., editor-in-chief, New York State Bar Association 1997). The transcript is on file at the office of the Executive Director of the New York State Law Revision Commission, Albany Law School, Albany, N.Y.

92. To the extent the individual has a health care proxy, a guardian with authority for personal matters may be found unnecessary by the court.

93. 45 C.F.R. § 164.510(b).

94. An illustration of how this section might be narrowly interpreted can be found at 65 Fed. Reg. no. 250, p. 82,523.

95. 45 C.F.R. § 164.512(j).

96. *See, e.g., In re Louis Koch* (Sup. Ct., Queens Co.), N.Y.L.J., November 29, 1999; *In re Columbia Presbyterian Hospital (Early)* (Sup. Ct., N.Y. Co.), N.Y.L.J., July 2, 1993, at 23.

97. 65 Fed. Reg. 82,538 (December 28, 2000), citing *Tarasoff v. Regents of the University of California,* 17 Cal. 3rd 425 (1976).

98. While this is part of initiating the proceeding, it is comparable to the section of the Privacy Rule which permits the covered entity to respond to a discovery request and seek a protective order for the disclosed material. *See* 45 C.F.R. § 164.512(e)(vi).

99. MHL § 81.07.

100. Sup. Ct., N.Y. Co., N.Y. L.J., June 1, 1995, p. 27, col. 4.

101. PHL §§ 2780 *et seq.*

102. PHL § 2782.

103. Sup. Ct., N.Y. Co., N.Y. L.J., June 1, 1995, p. 27, col. 4.

104. *Id.*

105. N.Y. Soc. Serv. L. § 473-d(2).

106. N.Y. Soc. Serv. L. § 473(5).

107. PHL § 2803-d (listing "any operator or employee of such facility, any person who, or employee of any corporation, partnership, organization or other entity which, is under contract to provide patient care services in such facility, and any nursing home administrator, physician, medical examiner, coroner, physician's associate, specialist's assistant, osteopath, chiropractor, physical therapist, occupational therapist, registered professional nurse, licensed practical nurse, dentist, podiatrist, optometrist, pharmacist, psychologist, certified social worker, speech pathologist and audiologist.").

108. 45 C.F.R. § 164.512(c)(1)(iii)(B).

109. 45 C.F.R. § 164.512(e)(1)(ii).

110. *See* MHL § 81.09(e).

111. *Id.*

112. 42 U.S.C.A. § 290dd-3(b)(2); 42 C.F.R. § 2.64.

113. 42 U.S.C.A. § 290dd-3(b)(2).

114. MHL § 33.13(c)(1).

115. *See* MHL § 81.14(b).

116. PHL § 2785(2).

117. PHL § 2785(3). *See* MHL § 81.14(b).

118. MHL § 81.14(b).

119. PHL § 18(1)(g) (qualified persons who have access to a patient's information includes an article 81 guardian.) Interestingly, this section of the Public Health Law does not restrict access to the guardian of the person, which suggests that the guardian of the property, unlike an attorney-in-fact, also has access to this information.

120. MHL § 79.03.

121. MHL § 79.07.

122. MHL § 79.11.

123. MHL § 79.07 ("The petition for appointment of a guardian, whether the ward be a mental incompetent or an infant, shall set forth the name, age, place of residence of the ward, the names and places of residence of the nearest relative, if known, and the fact that such ward is entitled to receive moneys payable by or through the administration and shall set forth the amount of moneys then due and the amount of probable future payments. The petition shall also set forth the name and address of the person or institution, if any, having actual custody of the ward.").

124. MHL § 79.07.

125. 45 C.F.R. § 164.512(k)(iii).

126. Fed. Reg. Doc. 04-2405, p. 5668, *available at* http://edocket.access.gpo.gov/2004/04-1762.htm.

127. 45 C.F.R. § 160.503(g)(1).

128. *See* MHL § 79.09 (permitting a consolidated procedure for the sake of judicial economy if there are assets other than the veteran's benefits).

129. *See* MHL § 79.03. *See also* PHL § 18(1)(g) (qualified persons with permitted access to a patient's information does not include an article 79 guardian).

130. SCPA 1750.

131. SCPA 1750-a.

132. SCPA 1750-a(1)-(3).

133. SCPA 1750-a (4).

134. SCPA 1750.

135. SCPA 1750B.

136. SCPA 1750-a (4).

137. Indeed, the commentary to the Privacy Rule's section 164.510(b) ("uses and disclosures for involvement in the individual's care and notification purposes") says there should be no special treatment of people with mental retardation. 65 Fed. Reg. 82,665–6.

138. PHL § 18(1)(g).

139. 14 N.Y.C.R.R. Part 633, 633.4(vii).

140. MHL § 33.13(c)(1).

141. MHL § 33.13(c)(7) ("provided that such disclosure will not reasonably be expected to be detrimental to the patient . . .").

142. MHL § 33.16(b)(4). MHL § 33.16(a)(6) (defining a qualified person who can have access to the records to include article 17A guardians and "a parent, spouse or adult child of an adult patient or client who may be entitled to request access to a clinical record pursuant to paragraph four of subdivision (b) of this section.").

143. *See* 14 N.Y.C.R.R. Part 633.11.

144. 45 C.F.R. § 164.502(g)(2).

145. 45 C.F.R. § 160.202 ("*State law* means a constitution, statue, regulation, rule, common law, or other State action having the force and effect of law.").

146. 45 C.F.R. § 164.502(g)(2).

147. 45 C.F.R. § 164.512(e)(1)(ii).

148. SCPA 1754(1) & (4).

149. MHL § 33.13(c).

150. *See* HIPAA Privacy Rule, New York State Office of Mental Health Preemption Analysis, *available at* http://www.omh.state.ny.us/omhweb/hipaa/preemption%5Fhtml/preemption%5Fupdate.htm.

151. 45 C.F.R. § 164.502(g)(2).

152. *See* MHL 33.16(a)(6). *But see* PHL § 18(1)(g) (an article 17-A guardian is not listed as a qualified person for access to patient health information.).

An Ounce of Prevention: Enhancing the Confidentiality of IPA Quality Improvement Records

By Kathleen Duffett, R.N., J.D.

The confidentiality of the minutes of hospital quality improvement committees pursuant to New York Education Law Section 6527(3)(e) and New York Public Health Law (PHL) Section 2805-m is an issue that has been raised before the courts many times.[1] As a general rule, the courts have consistently held that hospital quality improvement committee minutes or other hospital quality improvement records are considered confidential under these statutes and, as such, are protected from disclosure in subsequent civil litigation.

But hospitals are not the only health care entities conducting quality improvement activities. Health maintenance organizations (HMOs) and independent practice associations (IPAs) also evaluate quality of care issues. A question yet unanswered by the courts is whether the minutes of an IPA quality improvement committee are protected from disclosure in civil litigation under New York law. This article discusses the current state law and regulations that address IPA quality improvement committee activities and provides recommendations for how to strengthen an argument that the minutes or other records of such committees should be afforded protection from disclosure in civil litigation.

"A question yet unanswered by the courts is whether the minutes of an IPA quality improvement committee are protected from disclosure in civil litigation under New York law."

The Relationship Between IPAs and HMOs

Very briefly, in New York State, an IPA is an organization that has a contract with one or more HMOs to deliver services to some or all of the HMO's members.[2] The IPA itself is typically paid on a capitation basis. The IPA then contracts with individual providers to provide the necessary services. How the IPA providers are paid is determined by the IPA itself and can take different forms (for example, capitation for primary care providers (PCPs) and discounted fee for service for specialists). Since the IPA must abide by all laws and regulations governing HMOs,[3] for all practical purposes, the IPA becomes the HMO. Consequently, the growing trend to name HMOs as defendants in malpractice actions has implications for any entity that provides or arranges for medical services to HMO members, such as an IPA. This is especially so when the IPA conducts its own quality improvement review of services rendered to the members of the HMOs with which the IPA is contracted.

New York Statutes and Regulations Addressing IPA QI Confidentiality

PHL Article 44 and Part 98.1 of the New York Compilation of Codes, Rules and Regulations are the statute and regulations, respectively, that govern HMOs. Neither Article 44 nor Part 98.1 expressly address the issue of the confidentiality of the minutes of IPA quality improvement committees, although 10 N.Y.C.R.R. 98.18 appears to contemplate that IPAs that contract with HMOs will conduct quality improvement activities on behalf of the IPA.[4] The New York State Department of Health (DOH) confirms this in Section E(I)(15) of its HMO & IPA Provider Contract Guidelines, which states, "[a]n IPA may perform QA activities on behalf of its contracted providers but not on behalf of an HMO. An IPA may share the results of its QA activities with an HMO."[5]

Application of New York Statutes and Regulations to IPA QI Records

PHL Section 2805-m, which is a frequently cited legend on the quality improvement committee minutes of many health care entities, applies exclusively to hospital committees and thus would not be applicable to the minutes of an IPA quality improvement committee.[6] However, New York Education Law Section 6527(3)(f) states in relevant part:

> No individual who serves as a member of . . . a committee established to administer a utilization review plan, **or** a committee having the responsibility of evaluation and improvement of the quality of care rendered, in a health maintenance organization organized under article forty-four of the public health law or article forty three of the insurance law, **including a committee of an individual practice association or medical group acting pursuant to a contract with such a health maintenance organization,** shall be liable in

damages to any person for any action taken or recommendations made, by him *[sic]* within the scope of his *[sic]* function in such capacity provided that (a) such individual has taken action or made recommendations within the scope of his function and without malice, and (b) in the reasonable belief after reasonable investigation that the act or recommendation was warranted, based upon the facts disclosed.

Neither the proceedings nor the records relating to performance of a medical or a quality assurance review function . . . shall be subject to disclosure under article thirty-one of the civil practice law and rules except as hereinafter provided or as provided by any other provision of law. No person in attendance at a meeting when a medical or a quality assurance review . . . was performed . . . shall be required to testify as to what transpired thereat. The prohibition relating to discovery of testimony shall not apply to the statements made by any person in attendance at such a meeting who is a party to an action or proceeding the subject matter of which was reviewed at such meeting.[7]

At present, there is no case law on the protections afforded to IPA quality improvement committee minutes under Section 6527(3)(f). However, the language of that section is substantially the same as that of PHL § 2805-m(2), which provides protection to the quality improvement minutes of hospital quality improvement committees. The case law construing the latter statute has consistently held that records relating to a "quality review function," such as quality improvement committee minutes, are confidential and therefore are protected from disclosure in any subsequent civil litigation.[8]

When Is a "Quality Review Function" Really a Quality Review Function?

As a practical matter, the case law governing PHL § 2805-m would very much inform the courts' construction of Education Law Section 6527(3)(f) based on the substantially similar goal and wording of the two statutes. As such, the issue becomes how to demonstrate that the IPA is in fact performing a quality review function such that the documentation relating to such function should be treated as privileged. Based on a review of the case law involving the confidentiality of hospital quality improvement records, it appears that the more formalized the quality improvement process and lines of reporting, the more likely it is that the courts will treat the resulting minutes or other records as confidential. It is the author's belief that the guidelines provided below would provide counsel with the ability (i.e., evidence) to support an assertion that an IPA's quality improvement committee minutes or other quality improvement records should be treated as privileged under Education Law Section 6527(3)(f).

Risk Management Guidelines for Enhancing Confidentiality of IPA Quality Improvement Committee Minutes and Other Records

1. The IPA's quality improvement committee should be a formal committee of the IPA's board of directors. Ideally, a written document, such as a program description, should be created to explain the committee's relationship to the IPA board. The program description should also state the membership of the committee (typically by titles), purposes of the committee, meeting schedule, quorum requirements, reporting structure and frequency, etc. Although IPA board minutes should be used to reflect the committee's creation by the board, a program description would likely provide more useful evidence to support an assertion of the confidentiality of any IPA quality improvement committee minutes or other records in the event such a challenge was made.

   For any IPA that utilizes a management services organization (MSO) for its day-to-day administration, the program description or other document should specifically reference the titles of any MSO staff that act as staff to the committee. Such staff may include the MSO medical director and/or the director of utilization review. This is recommended because in the event the MSO staff are called upon to investigate a quality-of-care concern involving an HMO member treated by the IPA, there will be no question that such staff are acting on behalf of the IPA quality improvement committee.

2. The IPA quality improvement committee should have a defined purpose (for example, to review quality-of-care issues involving patients of the HMOs with which the IPA is contracted).

3. The IPA quality improvement committee should have regularly scheduled meetings.

4. Written quality improvement committee minutes should consistently contain the legend, "The IPA Board considers this document privileged under Section 6527 of the New York State Education Law and any other applicable law."

5. Quality improvement committee minutes should routinely reflect that the IPA quality improvement committee reviewed and approved the minutes of any prior quality improvement meetings.

6. Dissemination of the minutes should be limited to the IPA quality improvement committee members and its staff, and, if indicated, the IPA board.

7. An official copy of the minutes should be maintained by a designated individual of the committee (e.g., the committee secretary). Ideally, all other copies, such as those handed out for review at any given meeting, should be collected and destroyed. If legal advice is necessary, the minutes should be shared with counsel under attorney-client privilege. If an HMO requests the minutes as part of an audit, it would be preferable to have the auditor review the originals under supervision rather than to provide the HMO with copies.

8. Last but not least, minutes should be written in an objective and fair manner, keeping in mind that a court may order their disclosure in a subsequent civil action.

Conclusion

The confidentiality (or lack thereof) of quality improvement committee minutes is a common issue raised by plaintiffs' attorneys in medical malpractice actions against hospitals. There is a growing trend to name HMOs as defendants in malpractice actions. HMOs often have contracts with IPAs, which themselves may conduct quality improvement activities related to the care provided to HMO members. In the event an HMO member who was treated by an IPA provider was injured due to alleged malpractice, the plaintiff's attorney would likely attempt to access any and all of the quality improvement records relating to that member, including any IPA quality improvement records. This situation, combined with the weakening of the ERISA preemption defense (which historically has provided protection for HMOs when a malpractice cause of action has been asserted), make it essential for IPAs to take an "ounce of prevention" approach. Structuring an IPA quality improvement program based on the above guidelines would provide counsel with a persuasive argument that the documentation of the IPA's quality improvement activities is entitled to protection under Education Law Section 6527(3)(f).

Endnotes

1. *See, e.g.*, Notes of Decisions following N.Y. Education Law § 6527 (McKinney's 2001) (Supp. 2004) and N.Y. Public Health Law § 2805-m (McKinney's 2001) (Supp. 2003).
2. N.Y. Comp. Codes R. & Regs. tit. 10, § 98.18 (hereinafter "N.Y.C.R.R.")
3. 10 N.Y.C.R.R § 98.18(b).
4. *See* 10 N.Y.C.R.R. § 98.18(c).
5. N.Y.S. Department of Health HMO and IPA Provider Contract Guidelines (Oct. 1, 2002), *available at* http://www.health.state.ny.us/nysdoh/mancare/hmoipa/guidelines.htm.
6. *See* PHL § 2805-m (1) and (2).
7. N.Y. Education Law § 6527(3)(f).
8. *See, e.g.*, *Megrelishvili v. Our Lady of Mercy Medical Center,* 291 A.D.2d 18, 739 N.Y.S.2d 2, (1st Dep't 2002), *leave to appeal dismissed by* 99 N.Y.2d 532, 752 N.Y.S.2d 591 (2002); *Zion v. New York Hospital,* 183 A.D.2d 386, 590 N.Y.S.2d 188 (1st Dep't 1992).

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Social Security Numbers as Identifiers

By Jill Trachtenberg

Over the past few years, we as a society have been inundated by privacy concerns. We turn on the television and see commercials about credit card fraud and identity theft. It's no surprise that in the wake of all of this, privacy laws are being enacted at a rapid rate. In particular, over the past few years, the insurance industry has been targeted. New laws have been passed in a number of states which prevent insurers from using social security numbers on identification cards. California was among the first states to enact this type of legislation in 2001.[1] California Code 1798.85, effective in 2002, required entities to provide covered individuals with an annual disclosure notice notifying them that they could elect to have the entity stop using their social security number on public documents.[2] Beginning in 2003 (with varying effective dates for individuals and groups), the statute prohibited a person or entity, including a state or local agency, from:

(1) publicly posting or publicly displaying in any manner an individual's social security number. "Publicly post" or "publicly display" means to intentionally communicate or otherwise make available to the general public;

(2) printing an individual's social security number on any card required for the individual to access products or services provided by the person or entity;

(3) requiring an individual to transmit his or her social security number over the Internet unless the connection is secure or the social security number is encrypted;

(4) requiring an individual to use his or her social security number to access an Internet Web site, unless a password or unique personal identification number or other authentification device is also required to access the Web site; or

(5) printing an individual's social security number on any materials that are mailed to the individual, unless state or federal law requires the social security number to be in the document mailed. Notwithstanding this provision, applications and forms sent by mail may include social security numbers.[3]

Although California's law appears to be among the most stringent, numerous states, including Arizona, Utah, Connecticut and Texas, among others, have followed suit.[4] Some states have limited the requirements to insurers licensed within their specific state; however, others have had a broader-reaching effect and extended the requirements to insurers providing coverage to residents within that state regardless of where the insurer itself was licensed. Laws of this nature have had the insurance industry scrambling to achieve compliance on a timely basis. Until now, most insurers used an individual's social security as their policy number. However, insurers now have to devise new ways to identify policyholders, which is a difficult and expensive proposition. Not only do insurers have to reissue new identification cards to their entire membership (which could be millions of people) but they also have to have the technology to identify one individual using numerous numbers. The insurerwill also have to ensure that a claim that was submitted with the individual's new and anonymous identification number will be linked to the appropriate individual (who was previously known only by their social security number) and be paid.

While this presented a challenge to many, at least New York insurers believed that they were not yet on the hot seat and had a bit of time to comply. However, that may all be changing in the very near future. In January of this year, the New York State Assembly introduced "An Act to amend the insurance law and the public health law, in relation to the use of a person's social security number during the course of business."[5] The proposed legislation states the following:

> No person, firm, corporation, or other entity that issues insurance policies under this chapter shall cause an insured's social security number to be printed on any document, unless otherwise mandated by state or federal law. The prohibition shall include, but not be limited to, insurance identification cards, billing statement, notices, intake forms, and any other document printed in the normal course of business.[6]

The bill contains an effective date of one hundred eighty (180) days after it becomes law.[7]

In February of this year, the New York State Senate proposed its own version.[8] The state Senate's version mirrored California's statute with two exceptions. First, California's exception which permits "applications and forms sent by mail to include social security numbers" was slightly expanded. The New York Senate version

states that "social security numbers may be included in applications and forms sent by mail, including documents sent as part of an application or enrollment process, or to establish, amend or terminate an account, contract or policy, or to confirm the accuracy of the social security number."[9] Second, the bill contains language which states that if a national unique patient identifier program goes into effect, compliance with this law shall be deemed to be compliance with the federal law.[10] If this version were to be passed (or the enacted version contains this last statement), it might give New York insurers some confidence that whatever process they devised would not potentially have to be re-evaluated and revised resulting in greater expenditures and greater confusion. However, it would still remain to be seen how such language would be enforced given that when federal and state governments legislate in the same areas, the federal laws set forth the minimum levels for compliance and leave states free to set forth more stringent requirements. Since the unique patient identifier program has not yet been defined, we are unable to determine if the standards set forth by New York law would meet or exceed these requirements. Finally, the state Senate version states it will be effective two (2) years after it becomes law, giving insurers time to comply.[11]

It is anyone's guess what the New York State law will eventually look like. However, it seems probable that it will happen. Given that so many states have already enacted legislation, most insurers have likely been looking at this issue for some time. Unfortunately, it appears that the resolution may need to come sooner than expected.

Endnotes

1. Cal. Civ. Code § 1798.85 (West 2001 & Supp. 2003).
2. Cal. Civ. Code § 1798.85(c) (West 2001 & Supp. 2003).
3. Cal. Civ. Code § 1798.85(a) (West 2001 & Supp. 2003).
4. *See* Ariz. Rev. Stat. Ann. § 44-1373 (2003); Utah Code Ann. § 31A-22-634 (2003); 2003 Conn. Pub. Acts 03-156 (Reg Sess.); Tex. Bus. & Com. Code Ann. § 35.58 (2003).
5. A.9541, 227th N.Y. Leg. Sess.
6. *Id.*
7. *Id.*
8. S.6142, 227th N.Y. Leg. Sess.
9. *Id.*
10. *Id.*
11. *Id.*

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The Executive Summary from the HANYS/HTNYS Guidebook on Non-Profit Corporate Accountability

Healthcare Association of New York State / Healthcare Trustees of New York State[1]

Guidebook Overview

Non-profit Corporate Accountability—A Guidebook was developed as a joint effort of the Healthcare Association of New York State (HANYS) and Healthcare Trustees of New York State (HTNYS) to assist non-profit corporate board members and officers in carrying out their responsibilities to each other and the communities they serve. It draws on many sources, including government, private agencies, and our members themselves, to describe current accountability expectations and provide recommendations on how entities may address them.

Many features of the new accountability expectations draw on existing programs and systems. In this regard, applying many of the recommendations should involve enhancing existing programs: "Reinventing the wheel" is not required or expected. Several excellent resources are available, many on the Internet, and are referenced in the bibliography.

An underlying premise of the document is that board member education is imperative to promote good decision-making and to encourage good governance. In addition, transparency of appropriate information between the board and management is essential to ensure that the board and the management team are working collaboratively to enhance organizational integrity.

The *Guidebook* addresses those issues and activities that today may be viewed as appropriate accountability practices. The sections move from widely encompassing issues to more specific and technically complex matters. Each section concludes with suggested "best practice" recommendations to help meet the elevated accountability expectations currently facing non-profit organizations.

The *Guidebook* covers a wide spectrum of accountability topics that all flow from a common source: the fiduciary responsibilities of corporate board members and officers. Therefore, the *Guidebook* begins with a discussion of the three recognized duties—the duty of care, the duty of loyalty, and the duty of obedience or mission to the corporation—to place the following sections in a broader context. The three duties—prudent decision-making, elevating the corporation's interests above personal gain, and promoting the organization's mission—are the legal foundation for implementing accountability initiatives.

Section-by-Section Synopsis

The sections following the first on governance principles cover the following topics and their respective recommendations:

Section 2—Relationship Between Corporate Compliance Programs and Recent Accountability Recommendations

Corporate compliance programs provide an administrative structure within which many accountability activities can be carried out. The "seven elements" of compliance share many characteristics with techniques for promoting corporate-wide accountability:

- written standards of conduct;
- establishment of an organizational system, including direct reporting to the chief executive officer (CEO) and board, to operate the compliance program;
- regular training for all staff;
- maintenance of a system for anonymous reporting, with firm non-retaliation policies;
- a system to respond to questions or concerns;
- the use of audits and other techniques to monitor and evaluate compliance; and
- the review and remediation of identified problems.

Because health care providers are familiar with compliance programs and since the purpose and implementation of accountability initiatives parallel compliance activities, HANYS and HTNYS recommend the use of the existing compliance program structure rather than the creation of a new structure.

Section 3—Code of Ethics

The corporate code of ethics, or code of conduct, is one of the principal documents that defines and promotes a culture of integrity, openness, and responsible behavior, from the board to all employees. Codes of ethics vary widely in size and style, but no matter how lengthy, general, or specific, a code should contain the following elements:

- an ethical mission statement;
- an affirmation that honest conduct is the norm;

- a clear emphasis on personal responsibility and accountability;
- an affirmation that corporate integrity is applicable to all employees and board members;
- references to the corporate compliance and other similar policy documents such as the conflict of interest policy;
- unambiguous commitment to enforcement of the code; and
- reassurance that the option of anonymous reporting is available and that such good faith reporting is not subject to retaliation.

Section 4—Conflict of Interest Policy

Conflict of interest policies tend to be more uniform than ethics codes. The Internal Revenue Service (IRS) has issued an often-cited model that addresses board member and officer conflicts and how to deal with them. Many policies adopted recently by members extend further than the IRS's model and, therefore, the recommendations in this section exceed the IRS standards to include:

- adoption of the policy by the full board;
- application of the policy to boards, officers, and key managers and their family members;
- a clear definition of what "interests" are covered;
- a process for determining if a conflict exists;
- identification of individuals to consult in the event of a question;
- a clear description of the process to be used when a conflict exists;
- affirmation that violations are subject to discipline; and
- an annual disclosure statement to be completed by all board members, officers, and key employees.

Section 5—Audit Committee

The role and responsibilities of the audit committee and the expectation that committee members are independent, well informed, and active, have never been greater. As overseer of the corporation's finances and, frequently, the board-level overseer of the compliance program, the significance of the audit committee cannot be overstated. Audit committees are now operating under their own board-adopted "charters" and should have the following attributes:

- A clearly delineated board level committee, however named, should expressly take on audit committee functions.
- The purpose, membership, and function of the committee should be spelled out in a charter or other similar document.
- Committee members should meet strict independence standards.
- Committee members should possess a minimum level of financial expertise.
- Duties and responsibilities of the committee should extend to relationships with the external auditors, the internal control program, corporate conflicts of interest policy, and the corporate compliance program.
- The committee must be provided with adequate resources to carry out its duties.
- The committee may appropriately rely on information and advice from management and external advisors.

Section 6—Internal Control

In general, an internal control program is a mechanism to help ensure that institutional mission and objectives are being furthered, financial reporting is transparent, and the entity is legally compliant. While the internal control program purpose focuses more on financial compliance, features of the program are similar to those of compliance programs in general. Recognized authorities including the Committee of Sponsoring Organizations of the Treadway Commission (COSO) Report of the American Institute of Certified Public Accountants and others recommend that an internal control program should:

- be grounded in an ethical organizational environment;
- identify areas of greater compliance risk;
- establish a process to apply preventive strategies to high-risk areas;
- maintain an effective communication system that keeps senior management and the board well informed; and
- maintain a system for monitoring and remedying identified problems.

Section 7—Reporting Financial and Other Information

Adequate accountability cannot be achieved without a robust communication system. Nowhere in the corporate structure is this more crucial than in the relationship between executive officers and the board of directors. Because "accountability" to a great extent means financial accountability, it is important that the board remain confident that financial transparency is not compromised. As the final oversight level in a corporation, the board should be aware of financial and related documents and exercise its responsibilities diligently and prudently by examining those documents necessary for it to fulfill its duty of care. Accordingly, this *Guidebook* recommends that:

- the CEO and chief financial officer periodically provide the board with a listing of financial and related documents they have certified, or in some fashion verified, such as the Medicare cost report, the Internal Revenue Service Form 990, and the management representation letter provided to external auditors;
- upon the board's examination of the list, it may determine which of the documents it, or a committee such as the audit committee, may appropriately review in more detail; and
- such requested documents should be provided by executives, along with other information and observations, as appropriate.

Section 8—Compensation and Interested Party Transactions

IRS rules regarding business transactions and compensation arrangements with "interested" board members, officers, and influential employees are closely linked to several of the topics addressed in the *Guidebook.* The IRS's so-called "Intermediate Sanctions" rules, finalized in January 2002, spell out what constitutes an "interest" covered by the rules, the process a board should follow to properly reach an "untainted" decision, and the objective information that should be gathered and analyzed for the transaction or compensation to be considered "fair and reasonable." Failure to follow the rules may result in the imposition of fines, penalties, and the forfeiture of funds received by persons involved in making the decision or participating in the transaction. The IRS criteria that qualify a transaction or arrangement as fair and reasonable are:

- Board policies should define what "interests" are subject to the criteria.
- Decisions should be made without the vote of the "interested" person.
- The transaction or compensation arrangement should be approved in advance, not ratified after consummation.
- Comparability data relevant to the specifics of the transaction should be gathered and reviewed by the decision makers.
- Contemporaneous documentation should record the action taken, the participants, the basis for the decision, and the identification of the "interested" person.

Common Threads

The introductory section of the *Guidebook* includes a discussion of common themes that recur throughout the document. A few general observations bear mention here. First, with nearly every topic, there is no "one size fits all" model that dictates how an entity should structure its accountability strategy. Government agencies and private commentators acknowledge that accountability mechanisms must be scaled to the size, resources, cost versus benefit, and cultural factors of each facility. "Scalability," rather than rigid formulas or models, should guide corporate decision makers.

Second, current accountability initiatives are not solely attributable to the enactment of the federal Sarbanes-Oxley Act, or in New York, a legislative proposal by the Attorney General. These are pieces of a much larger picture. Government agencies have approached corporate ethics and disclosure in a variety of ways. The IRS, for example, is exploring whether extensive new disclosures should be made by non-profit organizations in the course of filing Form 990. In April 2003, the Health and Human Services' Office of Inspector General (OIG), in collaboration with the American Health Lawyers Association, issued an instructive resource guide on compliance for health provider boards of directors. An advisory committee to the United States Sentencing Commission in October 2003 released a sweeping report calling for extensive new accountability and governance standards to be built into the Commission's corporate sentencing guidelines. This is significant because the sentencing guidelines are the foundation for compliance program elements. The federal General Accounting Office issued new standards in October 2002 imposing specific accountant independence requirements. Private organizations, such as the Health Care Compliance Association, are producing a steady stream of informative materials on responsive governance activities.

Third, it is striking that several common characteristics recur from one topic to another, regardless of whether the issue is familiar or relatively new and evolving. While not perfect "fits," seven characteristics extensively overlap across the areas of general accountability principles, compliance program elements, audit committee functions, and the basic components of an appropriate internal control program. This commonality across discrete topics underscores that these are not "stand-alone" issues; their interrelationship becomes more evident the deeper they are reviewed.

The *Guidebook* is intended to be a tool for non-profit directors, officers, and others with an interest in accountability. Rigid formulas or specific directions for the "right way" to do things are avoided to the extent possible so that the recommendations are applicable to, and adaptable by, non-profit organizations of all sizes and complexity.

Endnote

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   This Executive Summary does not in any way constitute the provision of professional advice or services and should not be relied upon as such. This document is a guide to assist not-for-profit directors and officers in developing their own individual internal standards and policies that are appropriate for their own institutions. It is not an endorsement of any specific legislative or policy proposal, nor is it intended to suggest that any existing or proposed legislation or regulation that does not apply to the not-for-profit sector should apply by implication to this sector. Similarly, while there are many specific tools and recommendations provided in the Executive Summary that may be implemented in whole or in part, they are not intended to constitute minimum requirements or standards below which there is failure or non-compliance. It is recognized that institutions may adapt, adjust or disregard any of the recommendations as they deem appropriate to meet the needs of their own institutional environment.

Copies of the 142-page *Guidebook on Non-Profit Corporate Accountability* can be ordered from Heathcare Trustees at 1-800-360-7211.

Charles G. Smith, Appellant, v. Augustin J. Delago et al., Respondents

App. Div. Third Dept. December 31, 2003.

Appeal from an order of the Supreme Court (Malone Jr., J.), entered June 5, 2003 in Albany County, which, *inter alia*, granted defendants' motions for a protective order.

Capasso & Massaroni L.L.P., Schenectady (Virginia A. Gettmann of counsel), for appellant.

Carter, Conboy, Case, Blackmore & Laird P.C., Albany (William D. Yoquinto of counsel), for Augustin J. Delago, respondent. Maynard, O'Connor, Smith & Catalinotto L.L.P., Albany (Laura A. Sprague of counsel), for Albany Medical Center Hospital and others, respondents.

Before: Cardona, P.J., Mercure, Peters and Spain, JJ.

MEMORANDUM AND ORDER

Peters, J.

A complaint was made to the Department of Health (hereinafter DOH) as a result of care that plaintiff received from defendants Albany Medical College, Albany Medical Center Hospital and Albany Medical Center (hereinafter collectively referred to as Albany Med) and defendant Augustin J. Delago, his treating physician. Thereafter, in response to a Freedom of Information Law (see Public Officers Law art 6) (hereinafter FOIL) request, plaintiff acquired documents generated as a result of DOH's investigation, which included redacted interviews with Albany Med staff and DOH's independent review of the medical care provided.

After plaintiff commenced a medical malpractice action against Albany Med and Delago, they made separate motions to prohibit plaintiff's use of the FOIL documents, contending that they were confidential under Education Law § 6527 Educ. (3) and Public Health Law article 28. Plaintiff cross-moved for the production of further information to make such documents more useable. Although Supreme Court agreed that plaintiff was entitled to disclosure of the names and addresses of Albany Med employees who rendered treatment or care to him, it found the documents generated by DOH to be privileged under both Education Law § 6527 Educ. (3) and Public Health Law § 2805-m Pub. Health. Plaintiff appeals.

Public Health Law article 28 authorizes the Commissioner of Health "to inquire into the operation of hospitals" (Public Health Law § 2803 Pub. Health [1] [a]) to determine their compliance with statutes and regulations governing the quality and adequacy of patient care (see Public Health Law § 2803 Pub. Health [1] [b]). Hospitals have a quality assurance committee which also processes grievances (Public Health Law § 2805-j Pub. Health [1] [d], [e]) and reports incidents of potential malpractice (see Public Health Law § 2805-l Pub. Health [2] [a]); a hospital is required to cooperate with all DOH investigations or inquiries (see Public Health Law § 2803 Pub. Health [1] [d] [i]; [4]) and the law is clear that certain records, documentation or committee actions required to be collected and maintained will remain confidential (see Public Health Law § 2805-m Pub. Health [2]).

Working within these parameters, we find that petitioner is entitled to the production of DOH's Statement of Deficiencies (see Public Health Law § 10 Pub. Health [2]), redacted to remove conclusions of law and the opinions of DOH (see Cramer v. Benedictine Hosp., 301 A.D.2d 294, 927 [2003]; Maldonado v. Cotter, 256 A.D.2d 1073, 1074-1075 [1998]). As to the remaining documents found to be privileged under Public Health Law § 2805-m Pub. Health, we find no abuse of discretion (see Matter of Andrews v. Trustco Bank, Natl. Assn., 289 A.D.2d 910, 913 [2001]). The purpose of this statutory protection is "to promote the quality of health care through self-review without fear of legal repercussions by assuring confidentiality to those performing the review" (Brazinski v. New York Chiropractic Coll, 648 [2001]; see Logue v. Velez, 92 N.Y.2d 13, 17-18 [1998]). In seeking such protection, Vickey Masta, Vice President of Risk Management of Albany Med, averred that after the complaint was lodged, Albany Med was required to and did promptly report to DOH the circumstances pertaining to plaintiff's care (see Public Health Law § 2805-l Pub. Health). Masta stated that all interviews and documents made available to DOH were in furtherance of its internal quality assurance review obligations under Public Health Law article 28. We agree with Supreme Court's determination that defendants met their burden of establishing that these documents were entitled to statutory confidentiality and affirm the order issued with the limitations noted.[1] We have reviewed and rejected all remaining contentions.

Cardona, P.J., Mercure and Spain, JJ., concur.

ORDERED that the order is modified, on the law, without costs, by reversing so much thereof as granted defendants' motions prohibiting the use of the redacted Statement of Deficiencies; motions denied to that extent and plaintiff is allowed to use said document; and, as so modified, affirmed.

1. As the records were not obtained pursuant to CPLR article 31, there remains no need for an analysis under Education Law § 6527 Educ. (3).

Annual Meeting Focused on Quality of Health Care

NEWS flash
What's Happening in the Section

The program at the Health Law Section's 2004 Annual Meeting examined legal, policy and ethical issues relating to quality of care in health care. Entitled "First Do No Harm: Does the Health Care Legal Environment Improve or Diminish the Quality of Health Care?", the program described and discussed the merits of various policy approaches to promoting quality, including the use of civil and criminal enforcement laws, mandatory error reporting, medical malpractice actions and professional misconduct prosecutions, and protecting the confidentiality of peer review activities.

From left, Arthur Levin, Jim Lytle, Robert Trusiak.

The Annual Meeting was held on January 28, in the middle of a blizzard, at the Marriott Marquis in Times Square in New York City.

First Barry Gold Award for Health Law Writing Presented

Brett Farrow, a student at Albany Law School, was the winner of the first Barry Gold Memorial Health Law Writing Competition. Mr. Farrow received the award for his article, *The Goal of a Medicare Pharmaceutical Drug Benefit: Balancing Low Costs With Continued Research and Development.* An award and a $1,000 prize were presented to Mr. Farrow at the Section's Annual Meeting by Section Chair Jim Lytle.

The award is named after the Section's founder and first Chair, Barry Gold, a health lawyer from the Capital District. Barry Gold's wife, Sherry, was the Section's guest at the meeting and the award presentation.

In-house Counsel Committee Calls for Model Contracts and Policies

The In-house Counsel Committee is now collecting model health care facility contracts and policies for use by Section members as templates. As Karen Gallinari, Chair of the Committee explains, "This started as just a Committee project. In-house counsels are too busy to spend a lot of time drafting contracts and policies from scratch. We each were willing to share some of the model contracts and policies that we created, if we could see and adapt the documents our colleagues created. Then we decided we should make this contract/policy bank available to all Section members."

Accordingly, Section members are urged to submit those model contracts or policies that they believe are carefully drafted, legally sound, and of general utility for health care facilities. Those submitting documents created by others, such as law firms, will be expected to first secure permission from the author, and the document should indicate that authorship.

Documents can be submitted by e-mailing them to NYSBA staff member Kathy Plog at kplog@nysba.org. Submitted documents will be posted on the Section's Web site for use by Section members. The site will also provide a way for Section members to comment on submitted documents.

Karen asks users to respect the concept of sharing that is at the heart of the project: "If you're using the documents from the site, you should be contributing documents to the site."

New Section Officers Elected

The following officers were elected at the 2004 Annual Meeting, for one-year terms beginning June 1:

Chair:	Philip Rosenberg
Chair-Elect:	Lynn Stansel
Vice-Chair:	Mark Barnes
Secretary:	Peter J. Millock
Treasurer:	Ross P. Lanzafame

Philip Rosenberg

The incoming Chair, Philip Rosenberg, is a partner in the law firm Wilson, Elser, Moscowitz, Edelman & Dicker, and is based in the firm's Albany office. His practice concentrates in the areas of health care and employment law. Mr. Rosenberg has extensive experience in representing health care providers in a wide range of transactional, regulatory and litigation matters, with particular emphasis in reimbursement, fraud and abuse, licensure, tax-exemption and ERISA.

Mr. Rosenberg has authored numerous published articles discussing reimbursement, licensure, fraud and abuse, managed care, employment and ERISA topics, and he is a frequent lecturer on health law topics. He is a graduate of Cornell University School of Industrial and Labor Relations (B.S. 1982) and the Benjamin N. Cardozo School of Law (J.D. magna cum laude, 1986).

Section Committees and Chairs

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

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The Health Law Section is pleased to announce the creation of two new Committees. The Special Committee on Long-Term Care and the Public Health Committee are looking for new members.

Health Law Section

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