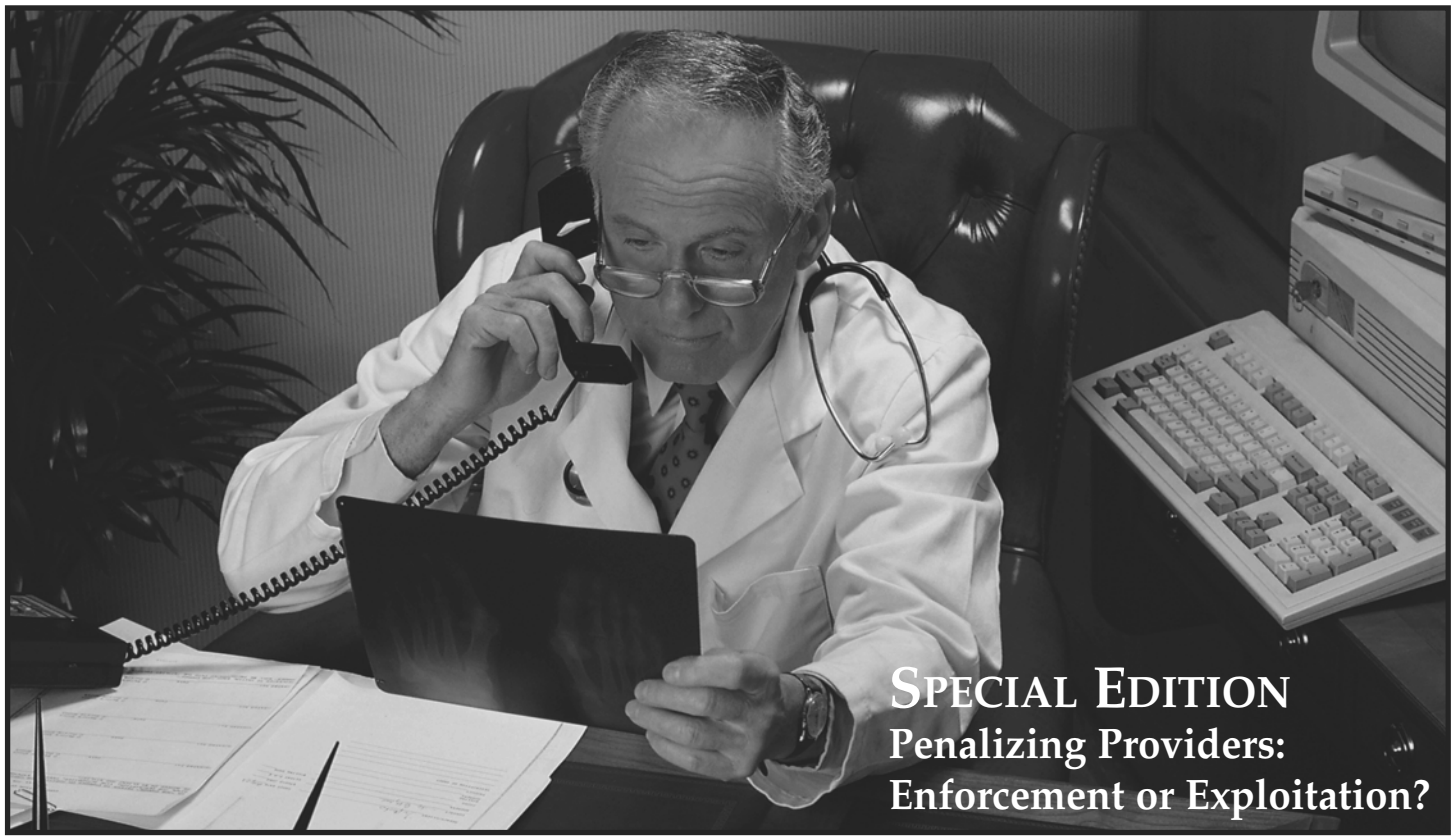
NYSBA WINTER 2002 | VOL. 7 | NO. 1

Health Law Journal

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



Inside

HEALTH LAW JOURNAL

WINTER 2002

Vol. 7, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

Introduction
Penalizing Health Care Providers: Enforcement or Exploitation?

Robert Abrams, Chair, NYSBA Health Law Section
Philip Rosenberg, Program Chair
Robert N. Swidler, Acting Editor, NYSBA *Health Law Journal*

Robert Abrams

Philip Rosenberg

Robert Swidler

This special edition of the NYSBA *Health Law Journal* is designed to complement the featured conference at the Health Law Section's Annual Meeting in January 2002, entitled "Penalizing Health Care Providers: Enforcement or Exploitation?" The edition and the conference raise a sensitive but pressing question: Has government become unduly harsh and unfair, even exploitative, in its enforcement efforts aimed at health care professionals and institutions?

"Health care is not organized crime. The doctors, nurses and other health care workers who care for the sick and disabled, and the administrators and staff who support them, are overwhelmingly honest and capable people."

Government plays an essential role in the oversight of health care. It sets quality standards and strives to see that they are followed. It establishes reimbursement rules, and tries to ensure that its funds are used appropriately. It also advances critically important health policy initiatives, such as protecting the confidentiality of health information, ensuring emergency medical treatment, and promoting the safety and autonomy of research subjects.

In order to achieve its aims, government must regulate conduct and police health care providers to ensure compliance with its regulations.

Health lawyers firmly support the government's objectives, and the need for diligent regulatory enforcement of the health care industry. Indeed, the NYSBA Health Law Section has called for an extension of the government's role in various health care areas. On a personal level, as patients and family members of patients, we absolutely rely on government to do these things.

However, over the past few years, those of us who represent health care providers have noted a palpable and ominous shift in climate. We have seen a dramatic expansion in the amount and complexity of regulatory requirements imposed on providers, and in the breadth of prohibitions. We have seen a trend toward more draconian penalties for violations of those requirements. We have observed an exponential increase of governmental resources devoted to investigating and prosecuting alleged violations of its rules. We have seen far greater powers and discretion conferred on enforcement agencies—and questionable uses of that discretion. Perhaps of greatest concern, we sense a change in the way government perceives providers—from colleagues, with a common interest in promoting public health, to suspects.

Health care is not organized crime. The doctors, nurses and other health care workers who care for the sick and disabled, and the administrators and staff who

support them, are overwhelmingly honest and capable people. Indeed, for most of them, health care is not so much a business as a calling: they are in this field to do good. And they *are* doing good, each day, despite worker shortages, inadequate reimbursement, escalating costs, competitive pressures and many other obstacles and pressures.

In this environment, government needs to be more supportive and less punitive in its oversight of the public health system. It needs to recognize that there are limits to the tactics and weapons it can deploy—even in its legitimate fight against fraud, abuse, misconduct and poor care—before it harms the health care system it seeks to purify. When government agencies impose rules that are ever changing, counterintuitive, and mind-numbingly complex, when they compel providers to divert more and more resources from the provision of care to compliance activities, when they threaten severe penalties for inadvertent and minor infractions, when they issue one-sided press releases that harm reputable providers—the agencies exact a toll that is predictable and regrettable: Many dedicated professionals leave health care; others who remain are demoralized and distracted.

Can government achieve its laudable aims without exacting such a heavy a toll? In defense of its efforts, government agencies portray fraud and abuse as rampant. An oft-cited study suggests that 10 percent of all expenditures in the health care industry are attributable to fighting fraud. The regulators contend that their aggressive enforcement tactics serve as a necessary deterrent of fraudulent activities, and are effective in curbing a range of excesses that would otherwise jeopardize patients and tax the health care system. We also know that, in light of the economics of health care, where the provider not only controls the supply of, but also strongly influences the demand for, health care, many inside and outside government believe that health care providers must be policed with heightened scrutiny.

To be sure, there are merits to the positions of both the providers and the enforcers. In fact, the current enforcement environment has both positive and negative impacts on health care. The challenge is to reduce the negative impacts of aggressive enforcement without sacrificing effective oversight of health care.

We seek to initiate a dialogue between providers and government on improving the oversight of health care. That dialogue should focus on certain basic principles rooted in fairness and respect, including the following:

Clarity. Rules of enforcement must be clear and easy to comprehend (and to locate). When government auditors find widespread noncompliance with a rule, the rule is, in all likelihood, unintelligible, impractical or obscure.

Specificity. Prohibitions, particularly criminal prohibitions, must be specific. Sweeping, general prohibitions like the anti-kickback law move us from a system of law to a system of prosecutorial discretion.

Substantive fairness. Rules must be substantively fair, and less skewed toward expanding government's parochial interest as a payor. Government must reduce its reliance on technical grounds as a way to avoid paying for medically necessary care.

Procedural fairness. Government should re-examine the procedural rules that govern health care enforcement activities, including audits and administrative actions, to restore greater fairness.

Proportionality. Enforcement agencies need to re-calibrate their sense of proportionality. They have been too anxious to impose and collect fines, revoke licenses, secure criminal convictions and seek harsh sentences—in instances that should have been resolved with lesser sanctions—or no sanction.

"The challenge is to reduce the negative impacts of aggressive enforcement without sacrificing effective oversight of health care."

Publicity. Health care professionals and facilities value their reputations. Government needs to be more circumspect about issuing press releases that can harm a provider far more than the statutory penalty provided by law. Equally important, government must not unnecessarily alarm the public with misleading and/or useless information.

Compliance support. Government should reallocate a portion of its resources from investigations and prosecutions to supporting compliance. It could, for example, produce and distribute compliance training materials. It could subsidize the hiring of compliance officers and internal auditors or provide the services of confidential compliance reviewers.

Respect. Above all, government needs to improve its attitude toward providers. Just as the government urges providers to instill a culture of compliance in the workplace, government agencies need to do more internally to adopt a culture of respect—for nursing home nurses, lab technicians, group practice administrators, pharmacists, community hospitals and home health agencies. The work these health care professionals and facilities

do each day is invaluable and difficult. They deserve respect. All the other needed reforms will flow from this.

At the same time, health care professionals and institutions share a responsibility to examine their own behavior. Government regulators and other public employees also deserve to be treated with respect. Moreover, those providers who intentionally defraud the government, or provide truly deficient care, deserve to be penalized, and have only themselves to blame—not government regulations or regulators—for the consequences of their behavior.

Despite the different venues from which government and providers derive their perspective, both groups would agree that the ultimate goal of the health care delivery system is the provision of quality care in the most effective and efficient manner. The current climate, rife with over-regulation, zero tolerance and mutual distrust does not serve that objective. Indeed, a large percentage of provider resources is squandered on serving compliance, not patients, and meeting the letter, not the spirit of regulation. The government has an enormous opportunity to partner with providers by codifying the costs associated with unproductive use of staff dedicated to myriad and duplicative documentation, and to bring to the table, in a consultative, non-punitive manner, standards that reflect the best practices the health care industry has to offer. Working together, government and providers can stem the flight of professionals from health care, contain escalating costs, and provide patients with the quintessential model of a health care delivery system that meets, and even exceeds, their mutual objectives.

This Special Edition, and the corresponding conference, will elaborate on the preceding ideas and raise others. Moreover, both the edition and conference will offer practical information and advice to health lawyers who must advise and defend clients in this anxious environment.

It is our hope that the ideas and information presented here will offer a basis to evaluate and improve the current environment. We also hope that the enforcement agencies will accept, indeed embrace, them. We welcome the suggestions of the government agencies, and look forward to discussing this topic at the Annual Meeting.

We would like to acknowledge and thank the health lawyers and others who contributed articles to this Special Edition—Robert Belfort, Joseph Curran, Tom D'Antonio, Patrick Formato, Hermes Fernandez, Stuart Klein, Ross Lanzafame, Lourdes Martinez, Nora Colangelo, Gregg Naclerio, Douglas Sansted, David Steckler, Melissa Zambri and the New York Association of Homes & Services for the Aging—as well as those who will participate in the conference. And, of course, we again thank our steadfast regular columnists, Jim Lytle, Leonard Rosenberg, Frank Serbaroli and Claudia Torrey. These participants not only advance, but exemplify the mission of the Section: to provide professional education, exchange information and perspectives, address issues relating to health law, and serve the public.

Request for Articles

If you have written an article and would like to have it published in the *Health Law Journal* please submit to:

Dean Dale L. Moore
Albany Law School
80 New Scotland Avenue
Albany, NY 12208

or

Robert N. Swidler, Esq.
Northeast Health
2212 Burdett Avenue
Troy, NY 12180

Articles should be submitted on a 3 1/2" floppy disk, preferably in WordPerfect or Microsoft Word, along with a printed original and biographical information, and should be spell checked and grammar checked.

In the New York State Courts

Court Awards Attorneys' Fees Under Health Care Quality Improvement Act to Prevailing Hospital and Physician Defendants in Peer Review Lawsuit

Sithian v. Staten Island University Hospital, (Sup. Ct., Richmond Co. Sept. 2001). The lawsuits at issue were brought by a physician whose clinical privileges to perform certain surgical procedures at a hospital were suspended. The physician filed lawsuits against the hospital, hospital administrators, members of the medical staff and members of the hospital's Board of Trustees, as well as the outside expert retained to review the physician's medical charts. The physician alleged among other things that statements made in the medical peer review proceedings were defamatory. The suits sought over $30 million in damages against the hospital and the individual defendants. One of the suits was commenced while the suspension was under review by the hospital's Board of Trustees.

After the New York Public Health Council ruled that the hospital's actions complied with Public Health Law § 2801-b (which requires that hospital credentialing determinations be related to patient care, competency, or institutional objectives), and that the physician had been provided with due process, the defendants moved for summary judgment dismissal of all claims. The motion asserted immunity from liability under the federal Health Care Quality Improvement Act of 1986 (HCQIA) (42 U.S.C. § 11112). The HCQIA provides participants in the medical peer review process with immunity from liability if certain due process and other criteria are met. Congress enacted the HCQIA to discourage retaliatory litigation and encourage meaningful medical peer review. Defendant's motion was granted and the dismissal was affirmed on appeal by the Appellate Division for the Second Department (724 N.Y.S.2d 906 (2d Dep't, 2001)). Thereafter, the defendants moved for an award of costs and attorneys' fees.

In a decision issued by Justice Joseph J. Maltese, the court awarded over $235,000 to the defendants in costs and attorneys' fees. The award is based on a HCQIA provision which states that an award of fees and costs shall be made to prevailing defendants if the court finds that the suit was brought for frivolous reasons, without foundation, or in bad faith (42 U.S.C. § 11113).

Noting the congressional finding underlying the HCQIA that the threat of financial liability unreasonably discourages physicians from participating in effective peer review, the court ruled that the suits in this case were retaliatory, frivolous, and in bad faith. The court relied in part on a prior finding in the underlying order granting summary judgment, that "retaliatory lawsuits of this nature are precisely what the HCQIA and the state immunity statutes were intended to discourage in order to encourage frank, open, and meaningful medical peer review." The court also found that it was bad faith for plaintiff to commence suit while the matter was still under consideration by the Board of Trustees, as such an action would have a chilling effect on the process.

This case appears to be the first instance in which a New York State court has awarded attorneys' fees under the HCQIA. [Garfunkel, Wild & Travis, P.C., represented all defendants in this case except the outside physician reviewer].

Lack of Informed Consent Does Not Convert a Battery Into an Action for Negligence

Messina v. Matarasso, 729 N.Y.S.2d 4 (1st Dep't 2001). Plaintiff alleged that during cosmetic surgery on her face, her physician negligently performed a surgical procedure on her breasts to alleviate hardness caused by silicone implants. As a result of the procedure, plaintiff claimed that her implants ruptured, causing serious injury. The motion court dismissed the action as untimely, concluding that the one-year statute of limitations for battery applied, not the two-and-a-half-year statute of limitations applicable to medical malpractice actions.

The court noted that when informed consent is lacking, there are generally two different factual scenarios—one for a battery and one for negligence. An action is based in negligence when the doctor obtains consent from a patient to perform a certain procedure, and due to complications about which the patient was not informed, the physician deviates from the consent. In such a circumstance, the courts have found that this is not an intentional deviation but rather "a deviation from the duty to disclose the information that a competent physician would have provided." On the other hand, under traditional tort law, an action is based in battery when a patient agrees to a certain procedure and is subjected to a completely different or unrelated procedure. In this case, the Appellate Division reaffirmed the legal distinction between cases of wholly unauthorized treatment, and cases of consent to treatment without full disclosure of the risks.

Because plaintiff claimed that she gave no consent at all to the alleged procedure on her breasts, her claim sounded in battery, which bore a lower standard and proof. However, the claim was barred by the one-year statute of limitations. The Appellate Division further held that once a battery has been established, the physician may not be held liable for negligence, regardless of whether there was a lack of care causing physical injuries.

Appellate Division Annuls Physician Disciplinary Determination Because Hearing Panel Did Not Include a Lay Person

Orens v. Novello, 284 A.D.2d 26, 726 N.Y.S.2d 499 (3d Dep't 2001). Section 230(6) of the New York Public Health Law requires that a state Board for Professional Medical Conduct hearing committee in a physician disciplinary proceeding "consist of two physicians and one lay member."

In a recently decided Third Department case, a physician's license had been revoked by the unanimous vote of a hearing committee comprised of two physicians and one physician's assistant. During the course of the hearing, the physician being disciplined objected to the composition of the committee, contending that, under the Public Health Law, a physician's assistant did not meet the definition of a "lay member" because a physician's assistant is a licensed professional subject to discipline by the state Board for Professional Medical Conduct. The committee rejected this challenge, finding that the Public Health Law only required that one of the committee members be a non-physician. The Administrative Review Board for Professional Medical Conduct upheld the committee's determination.

The disciplined physician then brought a CPLR Article 78 proceeding in the Third Department to challenge his license revocation, and raised the issue of the committee's composition. The Third Department, reviewing the legislative history of section 230 of the Public Health Law, annulled the disciplinary determination. The court ruled that the Legislature, when enacting section 230(6), clearly intended that a hearing committee include one member who is independent of the profession being regulated. Since a physician's assistant is a licensed professional medical practitioner whose profession is also subject to the disciplinary process set forth in section 230 of the Public Health Law, the Third Department concluded that a physician's assistant could not, under section 230(6), be the lay member of a committee.

Tracing the history of the current physician disciplinary process, the court noted that the current version of section 230 was enacted in 1975 as part of medical-malpractice reform legislation. The Legislature at that time believed that strengthening the disciplinary procedures applicable to physicians might lead to a reduction in the incidents of medical malpractice.

When debating changes to section 230, the Legislature received reports recommending that the hearing committees include lay persons so that the committees could take into account and judge the effects of a physician's professional performance upon lay persons. These reports, plus calls for an overall strengthening of the power of the hearing committees, led to proposals that the entire responsibility for physician disciplinary proceedings be transferred from the state Board of Regents to the state Health Department.

The court noted that the proposed transfer of physician disciplinary proceedings to the Department of Health drew significant opposition from the state Board for Medicine as well as the Commissioner of Education. The Commissioner of Education asserted that transfer of physician disciplinary proceedings from the Board of Regents to the state Health Department would be "contrary to the long-standing policy of the state of New York that licensed professions be subject to disciplinary action by a lay board rather than through a system managed exclusively by members of the profession." Likewise, the state Board for Medicine expressed concern that decisions in medical professional discipline should be vested "in the hands of a lay board of consumer representatives" so as to avoid "potential criticism of professional self-protection."

These two conflicting views resulted in a 1975 Legislative compromise: the creation of the current state Board for Professional Medical Conduct that consists of both physicians and lay members. It is from this Board that the hearing committees are chosen. Initially, section 230 of the Public Health Law required that the committees be composed of five members, four of whom were physicians, and one of whom was a layperson. In 1984, section 230 was amended to create the current three-member committees.

Because the hearing committees were the product of this legislative compromise, the Third Department concluded that the Legislature's intent was that the non-physician on a committee had to be a true "layperson," i.e., someone who is not a licensed professional whose conduct is regulated under section 230. Accordingly, the Third Department found that hearing committees consisting of two physicians and one physician's assistant "are not properly constituted."

The Third Department therefore annulled the hearing committee's determination, and remitted the matter for a new hearing before a properly constituted hearing committee.

Commissioner of Health Has Authority to Suspend Processing of Nursing Home Construction Application

Jay Alexander Manor, Inc. v. Novello, 727 N.Y.S.2d 560 (3d Dep't 2001). Petitioner commenced an Article 78 proceeding to challenge the Commissioner of Health's (the "Commissioner") temporary moratorium on processing its application to construct a 240-bed nursing home in Kings County. The court noted that the development and construction of a nursing facility is governed by the Public Health Law (PHL), which requires a showing of need for the

establishment of a nursing facility in a particular location. Pursuant to PHL § 2801-a, the Public Health Council (PHC), consisting of a 15-member group appointed by the Governor, must approve the "establishment" of the nursing home facility. The PHC may not act on an application until the local agencies having geographical jurisdiction of the area where the facility is proposed have had an opportunity to review the application and submit their recommendations.

Assuming the applicant obtains a "Certificate of Need" for the establishment of the facility, construction of the facility requires approval of the Commissioner.

After four years in the process, petitioner obtained the approval of the PHC to establish and construct the facility, subject to various contingencies. In August 2000, however, the Department of Health issued a temporary moratorium on the processing of "nursing home pipeline applications." In other words, those projects that had been approved, but had yet to receive permission to commence construction, were stayed.

Petitioner commenced an Article 78 proceeding challenging the Commissioner's authority to issue the moratorium, and seeking to compel the Commissioner to continue processing its application. To the extent that petitioner challenged the Commissioner's authority to issue the moratorium, the relief sought was in the nature of a prohibition. The court noted that an Article 78 proceeding seeking the remedy of prohibition "is only available to prevent a judicial or quasi-judicial body or officer from proceeding . . . without or in excess of its jurisdiction, and then only if a clear legal right to that relief has been established."

PHL § 2802(2) states that an application for construction of a nursing home requires that the Commissioner "[be] satisfied as to the public need for the construction, at the time and place and under the circumstances proposed." The Appellate Division ruled that given the statute's language, the petitioner could not establish that the Commissioner acted beyond the scope of her authority; thus, petitioner had no clear legal right to the relief sought.

Petitioner also sought to compel the Commissioner to process its application. Noting that a *mandamus* to compel lies only when the right to relief is clear and the performance of an act is commanded by law or involves no exercise of discretion, the court held that the petitioner could not establish a clear right to the relief sought because PHL does not require the Commissioner to process or approve an application within a specific time period.

Court May Not Order Patient's Continued Involuntary Retention on Hospital's Kendra's Law Petition

In re Manhattan Psychiatric Center, 728 N.Y.S.2d 37 (1st Dep't 2001). In this notable decision construing Kendra's Law (Mental Hygiene Law § 9.60), the Appellate Division clarifies that a court has no discretion under that statute to determine if a patient should be released; it may only determine whether, upon release, assisted outpatient treatment may be imposed.

Manhattan Psychiatric Center petitioned the court pursuant to Kendra's Law for an assisted outpatient treatment (AOT) order, with the patient's consent. As part of the required elements of proof, the hospital established that if the patient was released without an AOT order, the patient would become noncompliant with treatment and a danger to himself or others. Troubled by this evidence, the lower court appointed an independent psychiatrist to evaluate the patient's readiness for discharge from the hospital. Following the evaluation and testimony of the independent psychiatrist, the lower court denied the AOT petition.

Several months later, the hospital made a second AOT application, which was subsequently granted. The patient was then discharged under the terms of the AOT order. The appellate court found that while the subsequent order mooted the appeal from the prior order, "the case falls within the exception to the mootness doctrine, because it is likely to be repeated, it involves a phenomenon that typically evades review, and it implicates substantial and novel issues."

After a full discussion of the statutory framework of Kendra's Law, the appellate court held that the lower court had no discretion to bar the release of the patient, but only discretion to determine whether the patient should be released with or without an AOT order. "When a hospital seeks an AOT order for one of its patients, it has already made the decision to release the patient, and that decision is not at issue in the AOT proceeding." The issue is limited to whether the hospital has proven, by clear and convincing evidence, that the patient meets the statutory criteria for AOT and whether the treatment plan is the least restrictive alternative.

The court held that review of evidence demonstrating that the patient is likely to become a danger to himself or others without compulsory outpatient treatment "is not an invitation to the court to consider the issue of dangerousness in respect of a decision to release the patient." Instead, Kendra's Law was intended to "insure that the patient residing in the community receives the treatment that will, inter alia, prevent him from becoming a danger to himself or others."

The court stated:

> The court's role in an AOT proceeding is limited to deter-

> mining whether or not the petitioner has proved that it is justified in seeking to restrict the patient's liberty to the extent of ordering him to obtain outpatient treatment. If the hospital has not so proved, then the court may not restrict the patient's liberty even to that extent, and must dismiss the petition. The result is that the subject is released from the hospital (or remains in the community) without conditions.

The court found this approach consistent with the legislative intent of placing as few restrictions as possible on the liberty interests of persons who suffer from mental illness.

The court also considered the trial court's appointment of an independent psychiatrist to evaluate the patient's impending release from the hospital and whether the patient would be dangerous if released. Because the Appellate Division found that the issue of whether or not the patient should be released from the hospital was not properly before the trial court, the appointment of an independent psychiatrist was improper.

Appellate Division Orders Continued Involuntary Hospitalization of Psychiatric Patient with History of Noncompliance with Treatment

Anonymous v. Carmichael, 727 N.Y.S.2d (1st Dep't 2001). Petitioner sought a review and rehearing of an order authorizing his continued involuntary care and treatment at a state mental hospital, pursuant to Mental Hygiene Law § 9.35. After a trial, the lower court directed that petitioner be released. On appeal, the order was reversed and appellant's motion for a judgment notwithstanding the verdict ordering petitioner's retention was granted.

The court held:

> [I]n order for a hospital to retain a patient for involuntary psychiatric care under New York law, the hospital must establish, by clear and convincing evidence, that the patient is mentally ill and in need of continued, supervised care and treatment, and that the patient poses a substantial threat of physical harm to himself and/or others.

The evidence convincingly established that petitioner was mentally ill and that he had a history of noncompliance with prescribed treatment that repeatedly led to psychotic decompensations, marked by personal neglect, and dangerous and aggressive behavior, including attacks on hospital staff and threatening family members with a weapon. These decompensations occurred both within and outside the hospital. The court held "there is no rational interpretation of the evidence presented which would support the finding that the petitioner is not in need of involuntary hospitalization."

Court Upholds Revocation of Physician's License Based on Consensual Sexual Relations with Patients

St. Lucia v. Novello, 726 N.Y.S.2d 488 (3d Dep't 2001). This proceeding was brought to challenge a license revocation decision by a hearing committee of the state Board for Professional Medical Conduct.

OPMC issued 11 charges against the physician, a general surgeon, stemming from his care of five patients. As to three patients, OPMC charged the physician with moral unfitness to practice medicine based upon his consensual sexual relationships with the patients. With regard to two other patients, the physician was charged with two specifications each of gross negligence, gross incompetence and failure to maintain accurate patient records, and one specification each of negligence on more than one occasion and incompetence on more than one occasion. Following a lengthy hearing, the hearing committee sustained eight of the eleven specifications, and voted to revoke his license to practice.

The court rejected the physician's contention that the statutory language which defines "professional misconduct" (Education Law § 6530(20)) was unconstitutionally vague. Relying on prior case law, the court held that the statutory provision in question provided sufficient warning concerning the manner in which the profession must be practiced. The court further stated that the term "moral unfitness" encompassed misconduct of a sexual nature, and that the statutory language gave fair notice to a person of ordinary intellect of the nature of impermissible conduct.

The physician also argued that he had been denied due process due to the admission of hearsay testimony during his hearing before the committee. The court was not persuaded by this argument, stating that the committee was not bound by the strict rules of evidence. The court cited prior case law which held that "it is axiomatic that hearsay is admissible in administrative hearings and may be used to support a finding of substantial evidence."

Finally, the court affirmed that the committee's holding was supported by substantial evidence. The court noted that conflicting evidence and issues of credibility were within the exclusive province of the com-

mittee and that the record as a whole did not support any basis upon which to disturb the committee's resolution of the issues.

Minutes of Nursing Home Quality Assurance Committee Dealing with Construction and Maintenance Activities Not Privileged Under Federal or State Law

Hale v. Odd Fellow & Rebekah Health Care Facility, 728 N.Y.S.2d 649 (Sup. Ct., Niagara Co. 2001). Edward Hale, a resident of the defendant nursing home facility (the "facility"), died after he fell through a hole in the first floor of the facility, which was created in the course of ongoing construction. Shortly after Hale's estate filed suit against the facility for the accident, a dispute arose concerning the plaintiff's right to obtain minutes of the facility's quality assurance committee concerning inspection and maintenance of the premises, and a plan of correction prepared by the facility's consultant. The facility asserted that such information was privileged under 42 U.S.C. § 1395i-3 and Education Law § 6527(3), as relating to its quality assurance functions.

Upon review of the scope of the protections offer by 42 U.S.C. § 1395i-3 and Education Law § 6527(3), the court determined that much of the information contained in the meeting minutes of the facility's quality assurance committee was privileged. The court found, however, that the specific information sought by plaintiff relating to maintenance and inspection of the premises was not protected in these circumstances, because it was more akin to records of security measures rather than patient care quality assurance. Thus, the court ordered disclosure of the portions of the committee meeting minutes relating to maintenance of the premises.

The court also ordered disclosure of the minutes of the quality assurance committee meeting, which involved several representatives of the construction contractor. In so holding, the court found that having such representatives present at the meeting effectively waived the facility's right to claim privilege of the minutes under the statutes. The court also ruled that any incident reports created in connection with the matter would not be protected by Public Health Law § 2805, which the court found applies to hospitals but not nursing facilities.

Confidentiality Protections of Education Law § 6527(3) Apply to Chiropractors

Brazinski v. New York Chiropractic College, 725 N.Y.S.2d 457 (3d Dep't 2001). Plaintiff filed a malpractice action against defendant New York Chiropractic College (the "College") and individuals associated with the College for injuries allegedly sustained as a result of chiropractic treatment he received by the defendants. Thereafter, plaintiff served a discovery request seeking all documents relating to an investigation performed by the College concerning plaintiff's treatment, and all statements made by the individual defendants in connection with proceedings held by the College's review committee, quality committee or peer review committee. Defendants declined to produce the requested information, asserting that it was protected quality assurance information, and moved for a protective order pursuant to Education Law § 6527(3). The court granted defendants' motion as to the College's quality assurance review proceedings, but not as to the statements made by the individual defendants. Plaintiff appealed the lower court's decision.

Plaintiff asserted that a 1977 Amendment to Education Law § 6527 that deleted "chiropractors" from the statute demonstrated an intent to remove chiropractors from its protections. The Appellate Division found that the purpose and legislative history of the statute clearly showed that chiropractors were intended to be included. Education Law § 6527 was enacted in 1971 to provide immunity to physicians serving as members of a review committee, and to exempt from disclosure under CPLR Article 31 any information related to the proceedings of that review committee. The court noted that the purpose of the statute, as well as Public Health Law § 2805-m, was "to promote the quality of health care through self-review without reprisal, by assuring confidentiality to those performing the review." Although subsequent amendments added other health care providers, including chiropractors, to the list of those entitled to the statute's protections, a 1976 amendment replaced the list of protected health care providers with a more general reference to "individuals," and a 1977 amendment then eliminated all references to "chiropractor."

The Appellate Division held that the 1977 amendment to Education Law § 6527 was a technical revision intended to make the term "individual" "all inclusive of the . . . professions" previously listed. Accordingly, the court held that the statute applies to chiropractors involved in quality assurance activities to the same extent it applies to physicians.

Compiled by Leonard Rosenberg. Mr. Rosenberg is a partner at Garfunkel, Wild & Travis, P.C., a full-service health care firm representing hospitals, health care systems, physician group practices, individual practitioners, nursing homes and other health-related businesses and organizations. Mr. Rosenberg's practice is devoted primarily to litigation, including medical staff and peer review issues, employment law, disability discrimination, defamation and directors' and officers' liability claims.

In the New York State Legislature

A Preview of the 2002 Health Care Legislative Session

At press time, it is more than usually daunting to predict which health legislative issues are likely to dominate the 2002 legislative session—particularly when the 2001 legislative session appears likely to extend itself into November and December, making it one of the most extended legislative sessions in at least the last quarter-century.

As noted in this space in the last issue, despite the length of the 2001 legislative session, relatively few health-related bills, other than extenders of otherwise expiring laws, reached the Governor's desk during 2001. As a result, many of the more controversial and complex health bills are still before the Legislature and could be considered during this second year of the two-year legislative cycle. The September 11 terrorists' attack and subsequent acts of bio-terrorism could, together with the impact of a faltering economy and diminished state resources, inspire a host of new health-related issues to emerge. Between the unfinished business of this past year and new demands for legislative action arising from more recent events, 2002 could prove to be a crowded health care legislative agenda.

Add to this mix the fact that every member of the Legislature will be running for election in newly redrawn legislative districts and that 2002 is also a gubernatorial election year. Any assessment of what will actually occur in this context has about as much predictive value as a pre-season football forecast. Nevertheless, throwing caution to the wind, here are some pre-season legislative musings as they relate to the provision and regulation of health care.

Financial and Budget Issues

The drastic revenue reductions for New York State caused by the terrorists' assault on such a critical part of the New York City economy, compounded by a broader economic downturn, promise to result in calls for health care spending reductions—just when New York State health care facilities appear to be in already severe financial distress. During the six weeks following the terrorist attack, New York City hospitals lost more than $360 million from emergency expenditures, deferred elective surgery and other unanticipated expenditures—losses that compounded already thin financial margins caused by Medicare payment reductions and managed care.

Under these circumstances, much of the legislative debate in Albany will almost certainly focus on Medicaid cost containment proposals that may be expected to be unveiled to restore balance to the state's budget and their inevitable collision with proposals from the advocates for health care providers for restoration of financial support. Health care providers of all descriptions have already identified new significant financial needs—relating to information technology requirements, new quality initiatives, and the health care personnel shortage, among other things—and may require even more help to meet the new clinical, reporting and surveillance challenges stemming from the bio-terrorism threat.

Bio-terrorism and Public Health

In that regard, proposals were already under legislative consideration during the closing weeks of the 2001 session that would impose new criminal penalties on bio-terrorism. New administrative initiatives by the Department of Health were unveiled in mid-October to address the diagnosis and treatment of individuals suspected of being exposed to biological and chemical agents. Legislation might be anticipated that would impose new reporting obligations on health care providers, mandate additional continuing bio-terrorism education that would address diagnosis and treatment issues, or initiate new public health measures to protect the safety of drinking water, food and the environment.

Biomedical Research

During the 2001 legislative session, a number of proposals were advanced by the Governor and both legislative leaders to maintain New York State's competitive position in biomedical and biotechnological research. Because New York State's dominance in biomedical research has been eclipsed by several other states and is threatened by many more, renewed efforts have been undertaken in recent years to expand the role played by the state in supporting research activities through the establishment of a new state agency, the Office of Science, Technology and Academic Research (or NYSTAR), and through the appropriation of grant funds to spur research.

Last year, a Senate proposal to substantially increase state support for biomedical research, dubbed Gen*NY*Sis by its sponsors, would have devoted several hundred million dollars to spur research efforts throughout New York State. The worsening state economy, the prolonged budget battle and the terrorist attack combined to shrink this effort: in the so-called "supplemental budget," a total of only $10 million was earmarked for this effort. The strong support for the initiative and the necessity for jump-starting the state's economy are likely to result in reconsideration of the proposal during 2002.

Meanwhile, the New York State Task Force on Life and the Law last

year issued an extensive report on genetic medicine, entitled *Genetic Testing and Screening in the Age of Genomic Medicine*, that contains dozens of legislative and regulatory recommendations that might be considered by the Legislature in 2002. Among other things, the report recommended tightened informed consent and confidentiality requirements, the licensure or certification of genetic counselors and a moratorium on the use of genetic testing for life, disability and long-term care insurance purposes.

Health Insurance and Managed Care

Just as the managed care debate appears stalled in Washington, the New York State Legislature acted on very few bills that relate to the regulation and cost of health insurance in New York. As a result, a slew of insurance mandates (such as a package of women's health coverage requirements that include coverage for contraception), a bill that was intended to provide affordable coverage for sole proprietors and a "parity" proposal that would preclude the imposition of disparate limitations or requirements on mental health insurance coverage might be considered during 2002, together with a controversial proposal that would impose liability on managed care organizations for coverage determinations. Recent increases in the cost of insurance coverage for small and large businesses in New York could make these issues even more difficult for the Legislature to address and other proposals, aimed at containing health care costs, might be considered.

At the same time, the Legislature may tackle proposals that are intended to streamline and simplify enrollment and eligibility for the state's array of coverage initiatives, such as Child Health Plus and Family Health Plus, and that would permit working New Yorkers with disabilities to purchase comprehensive Medicaid coverage. Any further expansion of New York's programs to extend coverage to the uninsured may, however, face tougher scrutiny as a result of the state's worsening fiscal condition.

* * *

While predicting the course of a legislative session may be precarious, one thing is virtually certain: health care will, because of its importance and its cost, remain an important part of the legislative landscape in New York during 2002. And it is also safe to conclude that new issues, unforeseen and unforeseeable at this time, will emerge in the Legislature during the coming legislative session that may affect health care law and regulation for years to come.

Compiled by James W. Lytle, resident partner from the Albany offices of Kalkines Arky Zall and Bernstein, LLP. The firm devotes a substantial part of its practice to health care and government relations.

A Change in the Editors of the *Journal*

Professor Audrey Rogers and Professor Barbara L. Atwell of Pace Law School have retired from their roles as co-editors of the *Health Law Journal*, in order to pursue other academic responsibilities. The NYSBA Executive Committee would like to express its deep appreciation to Professors Rogers and Atwell for their years of volunteer service. We also congratulate them on significantly improving the quality of the *Journal*, and its value to the members, during their tenure.

This Special Issue has been edited by Robert N. Swidler, Esq., who is General Counsel to Northeast Health in Troy, NY, and who was Chair of the Section in 1999-2000.

We are pleased to announce that, beginning with the Spring 2002 issue, the *Journal* will be co-edited by Dale L. Moore, Associate Dean for Academic Affairs and Professor of Law at Albany Law School, and Robert N. Swidler. We welcome Dean Moore, and thank her and Robert Swidler for their willingness to assume this task.

In the New York State Agencies

Department of Health Regulations

External Appeals Program

Notice of adoption. The Department of Health added a new subpart 98-2 to 10 N.Y.C.R.R. for the purpose of implementing an external appeals program. The rules provide guidance to health care plans, enrollees of health care plans and external appeal agents in implementing requirements of Chapter 586 of the Laws of 1998. The rules include definitions, a standard description of the external appeal process, and the certification process of external appeals agents. Filing date: January 17, 2001. Effective date: January 31, 2001. *See* N.Y. Register, January 31, 2001.

Partial Filling of Prescriptions, Electronic Transmission of Prescription Data and Official Prescription Form

Notice of adoption. The Department of Health amended 10 N.Y.C.R.R. §§ 80.46, 80.67, 80.68 and 80.71-80.75. The purpose of these amendments is to provide for the electronic transmission of prescription data by pharmacies, allow controlled substances to be prescribed on an official, single part, departmental form, and permit partial filling of some prescriptions. Filing date: March 26, 2001. Effective date: May 1, 2001. *See* N.Y. Register, April 11, 2001.

Civil Penalties Against Noncompliant Adult Care Facilities

Emergency rule-making. The Department of Health amended 18 N.Y.C.R.R. §§ 486.5 and 486.7 in order to ensure that residents of adult homes, residences for adults, and enriched housing are not subjected to dangerous or unhealthy conditions. The proposed regulations expand the authority of the Department of Health to impose civil penalties against facilities that endanger or cause harm to adult care facility residents. Filing date**:** June 5, 2001. Effective date: June 5, 2001. *See* N.Y. Register, June 20, 2001.

Monetary Penalties and Tax Intercepts to Deter Medicaid Fraud

Notice of proposed rule-making. The Department of Health gave notice of its intent to amend 18 N.Y.C.R.R. § 515.9 and add part 520 in order to give the department an additional method for recovering Medicaid overpayments. The proposed regulations provide for an interception of a Medicaid provider's state tax refund to repay identified Medicaid overpayments and establish procedures by which providers may contest a certification by the department of such Medicaid overpayments. *See* N.Y. Register, August 15, 2001.

Part-time Clinics

Emergency repealing of 10 N.Y.C.R.R. § 703.6 and the addition of a new section 703.6 in order to update standards under which part-time clinics are permitted to operate and establish new procedures for the process by which such clinics are approved to provide services. The proposed rule would help ensure the provision of quality health care through needed preventive health screening programs and other public health initiatives to underserved populations and others in safe environments that protect both the patient and the general public. Filing date: August 10, 2001. Effective date: August 10, 2001. *See* N.Y. Register, August 29, 2001.

Personal Care Services

Proposed amendment of 18 N.Y.C.R.R. § 505.14(b). The purpose of the proposed regulations is to establish general parameters for the administration, provision and reimbursement of Medicaid reimbursable personal care services. Personal care services must be denied or discontinued when such services are no longer medically necessary or when such services cannot maintain a patient's health and safety in his home. *See* N.Y. Register, August 29, 2001.

Adult Day Health Care Regulations

Emergency rule-making. The proposed regulations repeal 10 N.Y.C.R.R. parts 425, 426 and 427 and add a new part 425 to 10 N.Y.C.R.R. in order to ensure that individuals receive adult day health care when appropriate and that providers are accountable for providing necessary and appropriate care. The proposed regulations provide for general requirements for the operation of an adult day health care, as well as specified minimum program and service components that must be available. Filing date**:** October 5, 2001. Effective date**:** October 5, 2001. *See* N.Y. Register, October 24, 2001.

State Insurance Department Regulations

Financial Risk Transfer Agreements Between Insurers and Health Care Providers

Amended notice of adoption. This action amends the rule that was filed with the Secretary of State on August 1, 2001. The regulation adds a new part 101 to 11 N.Y.C.R.R., regulation 164, to implement standards

for financial risk transfer between insurers and health care providers.

The purpose of the regulation is to address the insurer's obligation to assess the financial responsibility and capability of health care providers to perform their obligations under certain financial risk-sharing agreements, and set forth standards pursuant to which providers may adequately demonstrate such responsibility and capability to insurers. Filing date: August 9, 2001. Effective date: August 22, 2001. *See* N.Y. Register, August 29, 2001.

Complied by Francis J. Serbaroli. Mr. Serbaroli is a partner in Cadwalader, Wickersham & Taft's 20-attorney Health Law Department. He is Vice-Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and has served on the Executive Committee of the New York State Bar Association's Health Law Section. He is the author of *The Corporate Practice of Medicine Prohibition in the Modern Era of Health Care* published by BNA as part of its Business and Health Portfolio Series.

The assistance of Ms. Vimala Varghese, an associate at Cadwaladder, Wickersham & Taft, in compiling this summary is gratefully acknowledged.

For Your Information

By Claudia O. Torrey

Our Annual Meeting theme revolves around the growing concern of "increased crime" within the health care industry. This is not to say that the health care industry has an inordinate amount of criminal activity; however, one must recognize and acknowledge the increased enforcement activity that has occurred within the health care industry since the passage of the 1989 Omnibus Budget Reconciliation Act.[1] Both federal and state agencies have focused increased enforcement efforts on such entities as nursing homes, home health companies, hospitals and clinical laboratories. While this increased focus primarily targets the delivery end (providers) of health care, one cannot overlook the fact that decisions made by such entities as insurance and pharmaceutical companies have often put providers in untenable positions. From Main Street to Wall Street, *proactive* compliance and enforcement efforts by providers are usually viewed as the foundation for trust-building. Quoting Dr. Uwe Reinhardt, a health care economist at Princeton University, who was describing the enforcement activities of the federal government regarding fraud, "For every one place they hit, ten other places are trembling in their boots and cleaning up their act. . . . It's like cops on a highway. They can't go after every speeder, but knowing that the one they go after could be you keeps people more honest."[2]

To understand where we are, a cursory overview or time line of where we have been will be given. One of the oldest legal tools for combating health care fraud is the civil False Claims Act of 1863 (FCA).[3] Signed into law by President Abraham Lincoln, the FCA was created to prevent fraud and price gouging in war procurement contracts. Often called the Lincoln Law, history suggests that such criminal activity was usually committed by those who sought to cheat the Union Army on sales of horses and supplies.[4] Thus, the FCA permits the federal government to sue for and to recover from any person funds that are knowingly put forward in a false or fraudulent claim for payment.[5]

"Both federal and state agencies have focused increased enforcement efforts on such entities as nursing homes, home health companies, hospitals and clinical laboratories."

Within the FCA is the "*qui tam*" provision.[6] *Qui tam* is an abbreviation of the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which means "who brings action for the king as well as himself."[7] *Qui tam* actions date back to English common law and were created in order to expose fraud against the Crown, and to allow the informant(s) to collect a portion of the recovered proceeds. The FCA *qui tam* provision allows the plaintiff, known as the relator or whistleblower, to act as a temporary attorney general in order to litigate an alleged false claim for the federal government, should the government choose not to do so. If the federal government does litigate the alleged claim, then the relator is entitled to share in any award[8] of the recovered funds.

Perhaps the next most significant piece of federal legislation regarding health care was the 1965 enactment of the Medicare and Medicaid programs, amendments to the Social Security Act.[9] This landmark legislation includes a prohibition against the making of false statements for the purpose of obtaining benefits. In 1972, the federal "anti-kickback" provision was created.[10] It prohibited the solicitation or payment of bribes, rebates, or kickbacks for the referral of Medicare or Medicaid patients. Violations constituted a misdemeanor. In 1977, violations of the anti-kickback law were bumped up to a felony,[11] and the Inspector General Act was established in 1978.[12] An OIG was created within each Cabinet department, and within several federal agencies including the DHHS. The charge of the OIG is to be the auditor and "watchdog" against fraud, waste, and abuse. The Omnibus Budget Reconciliation Act of 1980[13] graced the Amendment of 1977 with a high intent standard of proof for prosecutors. The onus on the prosecution is to prove a defendant acted *knowingly and willfully.*

Approximately 123 years after the enactment of the FCA, the FCA Amendments of 1986 made clear that the FCA applies to false claims submitted to the Medicare and Medicaid program. Also, while not making proof of intent to defraud a requirement, the federal government or the relator would now be required to prove that a person possessed actual knowledge of the information, or such person acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information.[14]

A pivotal point occurred in 1989 when the Ethics in Patient Referrals Act was created.[15] Stark I regulates self-referrals, in that it restricts a physician from referring a patient to a clinical laboratory for services, in which Medicare might pay, if the referring physician or the immediate family member of the referring physician has a financial interest in the entity. Stark II amends Stark I by expanding the self-referral prohibi-

tion to ten designated health services and aspects of the Medicaid program.[16] Exceptions to both Stark I and Stark II can apply.

Annual audits of governmental health programs, initiated by the OIG of the DHHS, provided the lightening rod for a demonstration project under the Clinton Administration known as Operation Restore Trust.[17] The purpose of this project was to target fraud, waste and abuse within four Medicare/Medicaid areas: durable medical equipment, home health, hospice/palliative care and nursing homes.

By the time the Health Insurance Portability and Accountability Act passed in 1996 (HIPAA), federal enforcement agencies had acquired the respect, research and precedent to command from Congress new funding and enforcement tools with which to fight health care fraud, abuse and waste. Among other things, HIPAA created a Medicare Integrity Program, a Health Integrity and Protection Data Bank within the Health Resources and Services Administration, a dedicated fund for fraud and abuse activities, and home health entities are required to post surety bonds of at least $50,000.

Three months ago, Inspector General Janet Rehnquist of the DHHS/OIG, stated that providers will be seeing modifications to corporate integrity agreements (CIAs).[18] Rehnquist emphasized that she prefers a holistic approach to systemic issues that tend to create fraud and abuse, rather than "cherry picking" problems. During 2002, Rehnquist plans, among other things, to issue compliance guidelines for ambulance companies, mental health providers and pharmaceutical companies.[19]

Many states have their own statutes regarding self-referrals, kickbacks, and other health care laws. It is left to the reader to decide whether the current enforcement trends reflect a balance between the honest mistake and the unscrupulous scheme. Clearly, yesterday's "error" could be today's "fraudulent act." Exploitation, in this author's opinion, is yet to be determined.

"By the time the Health Insurance Portability and Accountability Act passed in 1996, federal enforcement agencies had acquired the respect, research and precedent to command from Congress new funding and enforcement tools with which to fight health care fraud, abuse and waste."

Endnotes

1. Pub. L. 101-239 (1989). This law is commonly referred to as "Stark I," named after its principal sponsor Rep. Fortney H. Stark of California.
2. Esther B. Fein, *U.S. Auditing Five Hospitals in New York: Part of National Effort to Stop Medicare Fraud*, N.Y. Times, Apr. 5, 1998, at A31.
3. FCA; 31 U.S.C. §§ 3729-3733 (1994). *See also* 18 U.S.C. §§ 286, 287, 1001 (1994).
4. *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F. 3d 645, 649 (D.C. Cir. 1994); Neil Getnick & Lesley Skillen, *The Civil False Claims Act: Enlisting Citizens in Fighting Fraud Against the Government*, Report of the Civil Prosecution Committee of the New York State Bar Association Commercial and Federal Litigation Section (May 1996), *at* http://www.nysba.org.
5. 31 U.S.C. § 3729(a)(1)-(7).
6. 31 U.S.C. § 3730.
7. Carolyn J. Paschke, *Note, The Qui Tam Provision of the Federal False Claims Act: The Statute In Current Form, Its History and Its Unique Position To Influence The Healthcare Industry*, 9 J. L. & Health 163, 165 (1994) (quoting W. Blackstone, Commentaries on the Law of England 160 (1768)).
8. David J. Ryan, *The False Claims Act: An Old Weapon with New Firepower Is Aimed at Health Care Fraud*, 4 Annals Health L. 127, 128 (1995).
9. These programs are governed by the centers for Medicare and Medicaid (CMS; formerly known as the Heath Care Financing Agency), which is within the federal Department of Health and Human Services (DHHS; formerly the Department of Health, Education and Welfare). Needless to say, states adjusted their laws.
10. This statute is often referred to as section 1128B of the Social Security Act.
11. The Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. 95-142, § 4b ("Amendments of 1977").
12. Office of the Inspector General (OIG).
13. 42 U.S.C. § 1320a-7b (1994).
14. According to Jack A. Meyer, president of New Directions for Policy, a not-for-profit research organization, between 1986 and June 2001, the federal government recovered $8.66 billion from providers via the FCA. Meyer stated that "in the 15 years since Congress reinforced the anti-fraud provisions of the FCA the law has changed the way the health care industry does business with the government. . . . The evidence clearly shows that management is paying more attention to reforming questionable billing practices and avoiding other violations of the law. . . . Providers now take compliance seriously because it's the right thing to do." *See* BNA's Health Care Fraud Report, *$8.7 Billion Recovered Since 1986 Under False Claims Act, Study Says* (Oct. 2001), *at* http://pubs.bna.com.
15. 42 U.S.C. § 1395nn (1994); *supra* n.1.
16. Omnibus Budget Reconciliation Act of 1993, Pub. L. 103-66. *See also* 42 U.S.C.A. § 1395nn (h)(6) (Supplementary Pamphlet, 2001). CMS issued phase I of its final rule on Stark II last year, Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001)(to be codified at C.F.R. pts. 411 and 424). Phase II of the rulemaking is to cover certain exceptions, reporting requirements, sanctions and the Medicaid program.
17. This project was created in 1995 with its primary focus on the five states with the greatest numbers of beneficiaries (New York, California, Florida, Illinois and Texas). The project had much success and expanded to more states.
18. BNA's Health Care Fraud Report, Corporate Integrity Agreements Could Look Different in Future, Rehnquist Plans Show (Oct. 3, 2001), *at* http://pubs.bna.com.
19. *See* http://www.hhs.gov/oig/wrkpln/2002/workplan.2002.htm.

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

The Criminalization of Health Care

By Thomas S. D'Antonio and Joseph G. Curran

Let's face it—we live in a world dominated by acronyms. They are omnipresent, and seem to find annoyingly increasing usage in our daily jargon. Perhaps no segment of our society is as encumbered by acronyms as the health care industry, where for the past generation New York's health care professionals have needed to know the difference between a PPO and an HMO, between a PPS and a POS and a PHSP, or HCFA and BPACR, or NYPHRM and the SSA. Recently, however, the acronyms most frequently confronting health care providers have taken on a new, and decidedly more ominous, overtone. The peaceful tranquillity of the practice of medicine and the delivery of quality care to patients is shattered by the mere mention of the terms OIG, FBI, DOJ and FCA, to name just a few. While dealings with these bodies are always very serious business, in the worst cases the providers, and others, stare down the barrel of lengthy jail terms and the potential permanent loss of their livelihoods, not merely ruinous financial liability. As Dorothy remarked to Toto, "We're not in Kansas anymore."

In this article, we will survey the numerous criminal and quasi-criminal provisions that face our health care institutions and their staffs, as well as the various third parties that serve those providers. We also will discuss the developments, at least from our point of view, which primarily have fueled the increasing "criminalization" of health care in our society, and finally we will close with some commentary on the benefits, as well as the drawbacks, of this fundamental shift in policy and focus in the health care arena.

The Arsenal of Federal and State Criminal Enforcement Provisions

The most visible, and the most highly publicized, expansion in criminal enforcement options with regard to health care providers has come from Congress. As part of the Health Insurance Portability and Accountability Act (HIPAA) that was passed in the summer of 1996, the Crimes and Criminal Procedure title of the United States Code was amended to add a series of defined Federal Health Care Offenses.[1] Among the new Federal Health Care Offenses created by HIPAA were theft or embezzlement from a "health care benefit program,"[2] a term which is expansively defined in the statute to mean "any public *or private* plan or contract, affecting commerce, under which any medical benefit, item or service is provided to any individual."[3] Additional Federal Health Care Offenses are the making of materially false or fraudulent statements in connection with the delivery of or payment for health care benefits or services;[4] the knowing execution of a scheme to defraud or to obtain money or property from a health care benefit program in connection with the delivery of or payment for health care benefits;[5] and the obstruction of a criminal investigation into an alleged violation of a Federal Health Care Offense.[6]

Each of these new provisions was accompanied by a healthy sentencing stick, authorizing substantial fines and prison terms of between five and ten years for each offense. Indeed, in the case of health care fraud prosecutions authorized under section 1347 (the "scheme to defraud or obtain money from a benefit program" provision) if the alleged violation results in serious injury to a person, the term of imprisonment can be up to 20 years and if a death occurs, a sentence of life in prison is available to the sentencing court.[7] While there has been no reported case addressing the circumstances under which a life term would be warranted in connection with a section 1347 offense, as drafted the statute authorizes such punishment if the prosecution can demonstrate some nexus between the fraudulent act directed at the health care benefit program and the death of one of its beneficiaries.

If the foregoing seems like "déjà vu all over again," to coin a favorite Berra-ism, that's because it largely is. Well prior to the advent of HIPAA, health care providers and others could, and did, face serious criminal liability under federal law for the filing of false claims, for embezzlement from employee benefit plans, for the making of false or fraudulent representations with the intent of securing a benefit, for mail or wire fraud, or for an attempt to purchase influence in the operation of a benefit plan, at least where federal monies or programs were impacted.[8] What HIPAA did was to make clear, with respect to direct violations of these provisions or with respect to conspiracies to violate these provisions, that criminal prosecutions expressly were authorized when the act or conspiracy related to any health care benefit program,[9] including programs involving private entities and beneficiaries of those third-party payors.

With regard to the federal criminal landscape, certain provisions of the Medicare Act itself also merit serious attention. Section 1320a-7b of the Act provides an independent basis for the imposition of criminal liability upon those individuals or entities that engage in a variety of different fraudulent or dishonest acts or omissions with regard to a federal health care program such as Medicare and Medicaid;[10] who solicit or receive an illegal remuneration under such program as that term is defined by statute;[11] who falsely represent the qualification of a facility to participate in the program[12] or who charge fees or solicit monies in excess of allowable Medicaid rates or as a condition for the provision of care to Medicaid beneficiaries.[13]

Since much, if not most, of the institutional and individual provider exposure in this area flows from the allegedly illegal or improper billing for services provided

to Medicare or Medicaid beneficiaries, of particular note here is the following provision of section 1320a-7b(a):

> Whoever –
>
> * * *
>
> (3) having knowledge of the occurrence of any event affecting (A) [the provider's] initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf [the provider] has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized,
>
> * * *
>
> shall [be guilty of a felony or a misdemeanor].[14]

The significant breadth of this provision suggests that it could reach not only the providers themselves, but any party (including, for example, billing consultants, auditors and attorneys) with requisite knowledge of a proscribed event. Lest one count too heavily on the reasoned, and reasonable, discretion that federal prosecutors uniformly employ, the infamous case of *United States v. Anderson* needs to be reviewed carefully.

In *Anderson*, as New York's health care bar knows only too well, the government indicted not only physicians and hospital executives for an alleged violation of the Medicare Anti-Kickback Act and for criminal conspiracy in violation of Title 18, but also two well-known Midwestern health care attorneys. The indictment charged, in essence, that these two attorneys, as well as three "unindicted co-conspirators" who were well-known and well-respected health care attorneys in their own right, conspired in violation of the Anti-Kickback Act with the other defendants to develop sham agreements to paper over a scheme to pay physicians for the referral of Medicare and Medicaid patients. Those agreements, and the advice allegedly given to the administrators and the physicians by the attorneys, seemed to most dispassionate observers to be precisely the type which health care attorneys routinely give to their clients, informing them of the permissible as opposed to the impermissible grounds upon which such payments could be based, and crafting an agreement reflecting the parties' agreement to enter into a lawful transaction. Nonetheless, both defendant attorneys were forced to go to trial and to defend their actions, and the "unindicted co-conspirators" were forced to file a series of motions with the court in an attempt to clear their names. While the court ultimately dismissed the charges against the defendant attorneys at the close of the government's case and chastised the government for its treatment of the unindicted co-conspirators, that came at a cost of several hundred thousand dollars in legal fees, and for the defendant attorneys, virtually full time away from their law practices for an extended period. In granting the dismissals, the court observed:

> The court is firmly convinced from the evidence presented that the only reasonable inference a jury could draw is that the lawyers, each in their own turn, attempted to advise their clients to engage in legal transactions and that these two [lawyer] Defendants did not prepare sham agreements to paper over a fraud but, rather, tried their best to prepare agreements that would reflect what they intended to be legal transactions into which their clients desired to enter . . . What the evidence unassailably demonstrated is that they steadfastly maintained to their clients that if fair market value was paid for the doctors' practice or for legitimate consulting servvices, the relationship passed legal scrutiny. Nothing in the evidence or the law suggests otherwise.[15]

While this turned out to be an "easy" case for the court insofar as the lawyer defendants were concerned, the cost to those lawyers and to their "unindicted co-conspirators," in terms of money, time, career damage and reputational injury, was horrific. Moreover, to the extent that one is tempted to dismiss this case as an aberration created by an overzealous renegade prosecutor, it is important to note that the case was tried by assistant United States attorneys from both the Kansas City office and from Main Justice in Washington, suggesting that the indictment as drafted and the prosecution of the lawyers as pursued was sanctioned at a very high level within the Department of Justice.[16]

Despite the fact that federal enforcement authorities have taken center stage in this area, both due to the above developments and to the increased focus on health care fraud and overpayment issues as a result of the renewed vitality of the False Claims Act on the civil side,[17] one cannot ignore, nor should one underestimate, the potency of state enforcement provisions or the focus of state authorities charged with their administration. The primary source of the criminal authority for New York's 62 district attorneys and for the assistant attorneys general tasked to the Medicaid Fraud Control Unit is found in New York's Penal Law. Prosecutions regularly are pursued against providers for health insurance fraud,[18] which ranges from a class A misdemeanor up to a class B felony, depending upon the amount at issue;[19] aggravated insurance fraud;[20] offering a false instrument for filing in the first degree;[21] and grand larceny, which again ranges from a class E to a class B felony, depending on the amount obtained unlawfully.[22] Punishment for these various offenses ranges from a fine of $1,000 and up to one year imprisonment for a

class A misdemeanor, to a potential fine of twice the defendant's gain from the commission of the offense and a prison term of six to twenty-five years for a class B felony. In addition, providers and others should not overlook the perjury prohibitions in state and federal law, which long have been, and which remain, favorites of prosecutors and investigators in this area.[23] State officials and law enforcement personnel also have not exactly shunned the limelight when the opportunity presents itself, as demonstrated by several recent media releases.[24] In short, the enforcement climate currently shows no sign of relaxing and for the reasons discussed below it actually looks to get significantly worse before it gets better.

The Reasons Underlying the "Criminalization" of Health Care

Although there has been a significant expansion in the number and scope of available criminal enforcement tools over the past decade on both the federal and the state side, even at the outset of the Medicare and Medicaid programs in the mid-1960s there existed the statutory bases for prosecutions involving mail and wire fraud, embezzlement, false reporting, filing of a false instrument, larceny and insurance fraud. The Medicare Anti-Kickback and fraud provisions, moreover, followed directly on the heels of the passage of Medicare Act. That being the case, one must wonder why there has been such an explosion in both the number and the visibility of health care prosecutions in New York and elsewhere. We believe several converging circumstances account for this trend.

A. **Health Care Providers Are Now Just Another Business**—Historically, hospitals and the physicians that staffed them occupied a special, cherished place in our society. Hospitals as institutions, particularly in New York where not-for-profit and public hospitals predominate, were above the cutthroat infighting and competition that was thought necessary to survive in the for-profit arena, and the physicians were learned healers who came to community residents in need of care, and were key leaders in the communities they served so well and so faithfully. Not any more. Hospitals are perceived as part of just another industry, one alleged by the business community to be (and largely perceived by the public to be) a costly, inefficient industry at that. They advertise for "customers," they compete on cost and on "product lines," they attack each other in their advertisements, they lay people off and they close down—just like every for-profit employer. The physicians in our communities, similarly, no longer are thought of as dedicated professionals serving a grateful public, but rather as calculating technicians paid an extraordinary sum for little direct interaction with their patients. One need only look at the malpractice verdicts, and the ease with which plaintiffs find receptive jurors in many areas of our state, to conclude that both literally and figuratively, Marcus Welby is gone, and for good. The trend toward knocking providers off their pedestals, of course, began long before the current enforcement climate took hold, but that trend created a receptive environment for the stepped-up criminal enforcement initiatives we recently have seen.

B. **The Payors and the Regulators Are Now Adversaries**—"Bank robbery is small change compared to the losses we suffer from health insurance fraud." Is this mere rhetoric from some fringe group looking to sensationalize its position? Guess again. It is a direct quote from the opening text message in an advertisement jointly sponsored by the National Health Care Anti-Fraud Association and the New York Health Plan Association. The former organization, NHCAA, numbers among its Executive Committee members a host of officers from health care insurers across the country (including the upstate New York Blue Cross plans), as well as a senior OIG official.[25] NYHPA is a trade association consisting of virtually every HMO in New York.[26] Similarly, our Federal Bureau of Investigation warns that "Many of the players in health care fraud schemes are people you'd never expect to be criminals: doctors and pharmacists, nurses and physical therapists." The FBI also puts the "price tag" for this criminal conduct at "upwards of $95 billion a year."[27] New York State's Department of Health announces that "Every dollar lost to fraud is one less dollar available for someone in need."[28] Fraud reporting hotline numbers, like 800-IC-FRAUD, 800-HHS-TIPS and 877-87FRAUD, accompany virtually all communications from third-party insurers and governmental payors, and are on every relevant Web site. Of course, there are providers and beneficiaries involved with each of these programs who are unethical, and who do commit criminal fraud. Each payor and governmental organization also admits, somewhere in its literature, that the majority of providers are not criminals, but honest and ethical practitioners. That hardly is the message that gets communicated to the public, however, as a result of this barrage of advertising and "tip solicitations." The fact of the matter is that the current relationship between providers and payors is largely an adversarial one, with very high stakes on the table. The tenor of the discourse is harsh, and the primary underlying tension (in addition to the economic struggle) appears to be which group, providers or payors, will control the future of health care. Not coincidentally, many third-party payors also are entering the provider ranks as well, by sponsoring, controlling or seeking to control home health agencies, long-term care programs, health care institutions and groups of physicians. As the line between

provider and payor is permitted by regulators to be blurred or erased, this adversarial posture will continue, and if anything, will intensify. For its part, the regulators have largely turned a blind eye, since the net short-term effect in their view is the containment of costs and the streamlining of the delivery of services, systemwide. That the foxes may be among the chickens is deemed largely irrelevant. Finally, for investigators and prosecutors, the message is clear—increasing the "take" from fraud and abuse initiatives is good press[29] and good business. The HIPAA legislation, for instance, has expanded the resources appropriated to the Medicare Integrity Program by tens of millions of dollars every year during the last five years,[30] and Congress is slated to look at the issue again in its upcoming session. Just like in the case of Barry Bonds, the smart money says that the investigative and prosecutorial efforts will be stepped up during this upcoming "walk year," and the nature of the relationship with providers is therefore certain to further deteriorate.

C. **Health Care Providers Are Under a Microscope**—As one easily can glean from the above, prosecutors and payors are incentivized to look carefully at the health care industry. The FBI alone, over the past five years, has expanded the number of agents assigned to health care investigations from 112 to more than 500, and notes that many of its field offices rank health care fraud as the top white collar crime problem.[31] In addition, the burgeoning business in whistle-blower cases, and the potentially lucrative *qui tam* recoveries,[32] has recruited for the government an army of "inside agents," whose information can lead not only to the discovery of significant civil liability, but to the potential existence of criminal wrongdoing to be pursued. Coupled with "hotline" tips from beneficiaries who are urged to report irregularities "toll free," prosecutors and investigators do not lack for information or issues to pursue.

D. **Providers Are Vulnerable**—No rational individual or entity fails to take a government investigation or inquiry seriously. Indeed, the failure to cooperate often is accompanied by a heavy price tag. For hospitals and physicians, however, there are particular vulnerabilities and sensitivities. In this environment of shrinking budgets, shrinking reimbursement dollars and intense pressures to manage within strict dollar limits, not-for-profit organizations look to charitable contributions as a lifeline. Nothing will sever that lifeline as quickly as a charge (even a defensible charge) of fraud or criminal conduct. Similarly, all providers rely on their ongoing ability to treat Medicare, Medicaid and third-party payor patients in order to earn a livelihood. The threat of prosecution under any of the criminal provisions set forth above, or under the False Claims Act on the civil side, also raises the specter of exclusion from the Medicare or Medicaid programs, or dismissal from the authorized provider lists maintained by third-party payors. Finally, the elements of a civil False Claims Act matter are strikingly similar to the elements of certain criminal claims,[33] and often a given set of circumstances will be argued to support both a civil recovery and a criminal prosecution. The net effect of all of the above is to strongly influence providers to settle claims or complaints before they become public, even where the provider in good faith believes her or his actions to have been totally lawful. Conversely, the investigators and prosecutors well understand the leverage they have if they can unearth even a colorable claim of criminality, and therefore potential criminality is the first and foremost focus of investigators and prosecutors in this area. As a result, the criminalization of health care is an inevitable result.

Good or Bad?

As with virtually all else, one cannot characterize the criminalization of health care as all good or all bad. A key "pro" is that the threat of criminal and of draconian civil consequences has substantially spurred expanded enforcement efforts, and the accompanying corporate compliance activities that have arisen across the health care industry mean that much greater care is being given to the way in which providers go about their business. Billing and coding are improved, payment is more often justified and adequately supported, and many improper claims are wrung out of the system. An important dividend is that many truly unethical or incompetent providers are identified in the process, which at least in theory leads to the improved quality of care.

The damage caused by the increased criminalization of our health care system is in three primary areas. First, the antagonistic enforcement climate has caused all key parties to the health care delivery equation—governmental payors and regulators, third-party payors, and providers—to lose sight of the fact that the system works best when there is cooperation among them. The reality is that neither the government, nor the payors, can deliver sufficient health care services to the citizenry without both individual and institutional providers, and providers in turn cannot provide adequate care, or even continue in the field, absent reasonable support from the government and the payors. As the pressures caused by these dramatic shifts in our system result in the collapse of facilities, their closure through so-called "mergers" and a decline in the numbers of medical students or qualified residents willing to pursue medicine as a career, we are facing a serious shortage of competent practitioners and services in the not-so-distant future.

Second, the increased criminalization of health care has created certain voids, as cash-strapped providers turn

away from various initiatives or consider previously unattractive, Faustian bargains with the payors in order merely to survive. In turn, as the payors morph into providers, one must realistically question their commitment to quality care. Alternatively stated, there are, and historically have been, contrasting pressures between the providers (seeking to ensure the delivery of adequate and effective care) and the payors (who seek to limit the cost of that care). Payors who provide the care (albeit through a separate affiliate they control) may seek to choose cost limitations over the most effective and appropriate care. Similarly, payors inevitably may be tempted to support their own sponsored programs, which effectively limits patient choice and in the long run threatens the quality of available providers, communitywide.

Finally, the publicity accompanying ongoing enforcement activities has suggested to the public that their doctors are, or could well be, modern day "bank robbers," to borrow an analogy ineptly made by certain payors. Medicine is, and should continue to be, a noble profession, and the skilled and well-trained women and men needed when a patient's life is on the line should not be a demoralized lot scorned as common thieves by the public. While initiatives to control unnecessary and unauthorized billing are important and valid, labeling each procedure where a detailed chart entry may not be sufficient to support payment as an act of "fraud," or suggesting that providers are vultures preying on an innocent public, is grossly unfair and does serious and unjustified long-term damage to us all.

Criminal enforcement therefore certainly has and warrants its place in the health care world, but the public will best be served when the pendulum finds a more centered, reasonable position. One hopes that our legislators, law enforcement authorities and payors recognize that fact before it is too late.

Endnotes

1. *See* 18 U.S.C. § 24.
2. 18 U.S.C. § 669; *see United States v. Riza*, 267 F.3d 757 (8th Cir. Oct. 2, 2001).
3. 18 U.S.C. § 24(b).
4. 18 U.S.C. § 1036.
5. 18 U.S.C. § 1347; *United States v. Vining*, 2000 WL 1015919 (S.D.N.Y. 2000).
6. 18 U.S.C. § 1518.
7. *See* 18 U.S.C. § 1347.
8. 18 U.S.C. §§ 286, 287, 371, 664, 666, 1001, 1341, 1343, 1954; *see United States v. Jaramillo*, 98 F.3d 521 (10th Cir. 1996); *United States v. Calhoon*, 97 F.3d 518 (11th Cir. 1996); *United States v. White*, 27 F.3d 1531 (11th Cir. 1994); *United States v. Laughlin*, 26 F.3d 1523 (10th Cir. 1994); *United States v. Catena*, 500 F.2d 1319 (3d Cir. 1974).
9. *See* 18 U.S.C. § 24(a)(2).
10. 42 U.S.C. §§ 1320a-7b(a)(1)-(6); *see United States v. Vining*, 2000 WL 1015919 (S.D.N.Y. 2000).
11. 42 U.S.C. § 1320a-7b(b)(1)-(3); *United States v. Addis*, 1998 U.S. App. LEXIS 31072 (7th Cir. 1998); *United States v. Shaw*, 106 F. Supp. 2d 103 (D. Mass. 2000).
12. 42 U.S.C. § 1320a-7b(c).
13. 42 U.S.C. § 1320a-7b(d)(1), (2)
14. 42 U.S.C. § 1320a-7b(a)(3).
15. *United States v. Anderson*, 55 F. Supp. 2d 1163, 1170-71 (D. Kan. 1999).
16. *See United States v. Anderson*, 85 F. Supp. 2d 1084, 1089 (D. Kan. 1999). It also is important to note that while the lawyers escaped conviction, neither the individual physician defendants nor two of the administrator defendants fared as well, being convicted by the jury after nine weeks of trial. *Id.* at 1090.
17. 31 U.S.C. §§ 3129 *et seq.* In the last year alone, a constant stream of media releases from the federal enforcement authorities trumpeted a series of high-dollar, high profile settlements and investigations. *See, e.g.*, *KPMG is Paying $9 Million to Settle Fraud Case*, N.Y. Times, Oct. 24, 2001, at C2; *2 Drug Makers to Pay $875 Million to Settle Fraud Case*, N.Y. Times, Oct. 4, 2001, at C1; *Quorum Health Group Settles Medicare Fraud Case*, N.Y. Times, Apr. 24, 2001, at C4 ($82.5 million); *Yale Hospital Faces Inquiry on Fraud*, N.Y. Times, Mar. 31, 2001, at B1. *U.S. to Seek $400 Million More at HCA*, N.Y. Times, Mar. 16, 2001, at C5; *Court Papers Depict Scheme in Drug Billing*, N.Y. Times, Feb. 20, 2001, at C1; *Bayer to Pay $14 Million to Settle Charges of Causing Inflated Medicaid Claims*, N.Y. Times, Jan. 24, 2001, at A16.
18. N.Y. Penal Law § 176.05(2).
19. Penal Law §§ 176.10, 176.15, 176.20, 176.25, 176.30.
20. Penal Law § 176.35.
21. Penal Law § 175.35; *see People v. Rubin*, 96 N.Y.2d 548 (2001).
22. Penal Law §§ 155.30, 155.35, 155.40, 155.42; *see Rubin*, 96 N.Y.2d 548; *People v. Alizadeh*, 87 A.D.2d 418 (1st Dep't 1982); *People v. Strogov*, 216 A.D.2d 424 (2d Dep't 1995).
23. 18 U.S.C. §§ 1621-1623; Penal Law §§ 210.05-210.15; *United States v. Addis*, 1998 US LEXIS 31072 (7th Cir. 1998); *People v. Kenny*, 100 A.D.2d 554 (2d Dep't 1984).
24. *See, e.g.*, *Medicaid Fraud Control Unit Finds Overbilling by Hospitals*, Crain's N.Y. Bus., July 23, 2001, at 4; *Man to Pay $48 Million in Medicaid Fraud Scheme*, N.Y. Times, Apr. 7, 2001, at B3; *Physician Assistant Faces 3 Years in Scam*, N.Y. Daily News, Feb. 16, 2001, at 6; *Mastic Woman Jailed for Medicaid Fraud*, N.Y. Newsday, Feb. 6, 2001 at A45, *S.I. Hospital Sets Payback of $45 Million*, N.Y. Times, Sept. 22, 1999, at B1.
25. *See* National Health Care Anti-Fraud Association Web site, http://www.nhcaa.org.
26. *See* New York Health Plan Association Web site, http://www.nyhpa.org.
27. FBI Health Care Fraud Unit Web site, http://www.fbi.gov/hq/cid/fc/hcf/hcf.htm.
28. New York State Department of Health Web site, http://www.health.state.ny.us/home.htm.
29. *See* text notes 18, 25, *supra*.
30. Pub. L. No. 104-191 § 201(b).
31. About the Health Care Fraud Unit, http://www.fbi.gov/ha/cid/fc/hcf/about/hcf_about.htm.
32. 31 U.S.C. § 3730(b)–(d).
33. *Compare* 31 U.S.C. § 3729(1) *with* 18 U.S.C. § 287.

Thomas D'Antonio and Joseph Curran are colleagues at Ward Norris Heller & Reidy LLP in Rochester. Mr. D'Antonio assists numerous health care providers, primarily in New York State, with an array of legal matters, and Mr. Curran also devotes a substantial amount of his practice to health care clients, after spending more than a decade as a senior prosecutor.

The "Step-Up" in Enforcement of Nursing Homes: Recent Survey Trends

By Patrick Formato

I. Introduction

The care and safety of the elderly and infirm is of the utmost importance. To this end, ensuring quality of care and quality of life for those individuals who reside ("residents") in New York's nursing homes is, and should be, a high priority of our state and federal governments. Over the last several years, there has been what some call an increase in enforcement of the laws and regulations that govern nursing homes in New York. Owners, operators and advocates of nursing homes have characterized the enforcement activities of the New York State Department of Health, as well as the New York State Attorney General, as an "attack" on nursing homes and its operators and describe the industry as one that is under "siege."

The Department of Health and the Attorney General's Office are only two of the many government agencies responsible for oversight of the nursing home industry. The Office of the Inspector General of the Department of Health and Human Services, the Centers for Medicare & Medicaid Services of the Department of Health and Human Services, the FBI, US Attorney, the Department of Labor, the Occupational Safety and Health Administration, the Food and Drug Administration and the Centers for Disease Control are just a few of the other agencies responsible for enforcing the laws and regulations that govern nursing homes.

Although there has been an increase in enforcement on all fronts and by all agencies, this article will be limited to the increased enforcement by the New York State Department of Health. This article will explore the reasons behind the increased enforcement and whether or not the current enforcement policies and practices of the Department of Health (DOH) are actually achieving their stated goal of ensuring quality of care and quality of life of our elderly nursing home residents.

II. Overview of the Survey Process

As a result of the birth of the Medicare and Medicaid programs in 1965, the federal government became the primary payor for nursing home care. Nursing homes desiring to participate in the Medicare and Medicaid programs were required, pursuant to the Social Security Act, to enter into Provider Agreements with the Health Care Financing Administration (HCFA) now known as "Centers for Medicare and Medicaid Services" or "CMS." Furthermore, nursing homes electing to participate in the Medicare and Medicaid programs were required to meet specific requirements set forth in the Social Security Act (the "Act") and the federal regulations set forth in 42 C.F.R. § 483.

In order to monitor nursing home compliance with the federal regulations, HCFA contracted with the states to inspect/survey nursing homes periodically. The state agencies responsible for oversight of the facilities are required on the average to survey facilities at least once every 12 months. Furthermore, the largest period between surveys for any given facility cannot exceed 15 months. In New York, the agency responsible for surveying facilities is the Department of Health (DOH).

In 1987, Congress passed the Omnibus Budget Reconciliation Act or, as it is known, the "Nursing Home Reform Act" which provided dramatic changes to improve the quality of care and the quality of life for residents of nursing homes. Passage of the Nursing Home Reform Act was due in part to numerous scandals in the nursing home industry in the 1970s.

The Nursing Home Reform Act established new requirements for nursing homes, as well as new enforcement provisions. The new enforcement provisions gave state agencies greater power to impose a "remedy" on a facility for noncompliance with federal requirements. Remedies include, but are not limited to, termination from the Medicare and Medicaid programs, denial of payment for new admissions, ban on admissions and civil monetary penalties.

In New York, the DOH is charged with the oversight of nursing homes. In addition, to standard surveys conducted by the DOH, the DOH may conduct a complaint survey, which is often referred to as on "abbreviated survey" and is prompted by a complaint of a violation.

Survey results that include findings of noncompliance (referred to as "deficiencies") are documented on a CMS-2567 form called a "Statement of Deficiencies." Deficiencies are assigned a scope and severity level. The scope is intended to indicate the extent to which the deficiency affects the resident population. Scope is broken down into three (3) levels, as follows:

1. isolated;
2. pattern; and
3. widespread.

Severity is intended to reflect the harm caused the residents as a result of the deficient practice. Severity has four (4) categories which are as follows:

1. no harm with potential for minimal harm;
2. no actual harm, but has potential for more than minimal harm;
3. actual harm that is not immediate jeopardy; and
4. immediate jeopardy to residents' health or safety.

Each deficiency is assigned a scope and severity. Scope and severity are used to determine the remedies to be imposed against a facility. Survey results are public information. In fact, facilities are required to post their survey results in the facility.[1]

Generally, if a federal remedy is imposed, a facility will be entitled to a formal appeal. Appeals are heard by an administrative law judge who sits on the Departmental Appeals Board of the Department of Health and Human Services. Adverse decisions may be appealed to the Departmental Appeals Board.

In addition to the formal appeal process, each state is required to have an informal dispute resolution process. Generally the process includes a Stage I review, which is a paper review of the deficiencies that a facility disputes. The facility is required to provide exhibits supporting its position. A Stage II review includes a meeting with DOH representatives.

III. Recent Survey Trends

A. Number and Level of Citations

There is no question that over the past several years there has been a dramatic increase in the number of deficiency citations received by nursing homes in New York, as well as the level (i.e., scope and severity) of the citations. For example, in 1998, 17.25 percent of New York State skilled nursing facilities surveyed were cited with G level (severity—actual harm; scope—isolated) or above deficiencies. In 1999, 27.32 percent of all New York State facilities surveyed were cited with G level or above deficiencies (an increase of 58 percent). In just the first three quarters of 2000, the number of facilities cited with G level deficiencies rose another 25 percent to 34.16 percent of all facilities surveyed.[2]

In addition to the dramatic increase in G level deficiencies there has also been a sharp increase in the citations for substandard quality of care. Substandard quality of care is defined as:

> *One or more deficiencies* related to participation requirements under 42 CFR § 483.13, resident behavior and facility practices, 42 CFR § 483.15 *quality of life*, or 42 CFR § 483.25 *quality of care* that constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or widespread potential for more than minimal harm but less than immediate jeopardy, with no actual harm.[3]

In 1998, less than 1 percent of all New York nursing homes surveyed were cited with deficiencies that rose to the level of substandard quality of care. In 1999, the number of facilities cited with deficiencies that constituted substandard quality of care rose by 255 percent over 1998. In the first three quarters of 2000, there was an increase of 9 percent over 1999.[4]

In addition, there has been a sharp increase in the number of nursing homes that have been cited for abuse, neglect or mistreatment. In 1998, less than 1 percent of all New York homes were cited for abuse, neglect or mistreatment. In the first three quarters of 2000, 19.8 percent of New York nursing homes were cited for abuse, neglect or mistreatment.[5]

B. Strict Liability

In addition to the increase in the number of deficiencies cited, as well as the scope and severity, there is a trend to hold facilities strictly liable for the acts of their employees regardless of the apparent, and stated, intent of the regulations. For example, 42 C.F.R. § 483.13(c) provides: "The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect and abuse of residents and misappropriation of resident property."

It is apparent from a plain reading of the regulation that the intent of same is to require facilities to adopt and implement policies and procedures to avoid occurrences of mistreatment, neglect and abuse. Furthermore, CMS's Guidance to Surveyors (Appendix PP of the State Operations Manual)[6] clearly sets forth the intent of the regulation as follows: "the purpose is to assure that the facility is doing all that is within its control to prevent occurrences."

Although it may not be unreasonable to infer a failure to develop and implement policies if there are several incidents of neglect or abuse, recently the DOH has been citing facilities for a failure to develop such policies based on isolated acts. This is clearly not the intent of the regulation. In fact, just recently an administrative law judge of the Departmental Appeals Board of the Department of Health and Human Services addressed the issue of strict liability. In *Oakwood Manor Nursing Center, Petitioner v. Centers for Medicare and Medicaid Services*, CMS asserted "that wherever a single instance of abuse has occurred, the resident's right to be free from abuse has been violated and the facility has not complied with the requirement of 42 C.F.R. § 483.13(b)."[7] Basically, CMS argued that no matter what steps the facility took to avoid abuse, the facility is strictly liable if abuse occurs. However, Marion T. Silva, Chief

Administrative Law Judge, held against CMS, finding that the regulation

> does not impose a strict liability standard on a facility for any and all instances of resident abuse without regard to the surrounding circumstances. The regulation instead imposes a requirement on a facility to take all necessary steps to prevent a violation of a resident's right to be free from abuse.[8]

C. Mistake or Neglect

Neglect is defined in the State Operations Manual as "a failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness." Although the definition is quite broad, nursing home owners, administrators and staff have complained that surveyors are citing facilities with neglect for mere mistakes, misjudgments and accidents. To the general population, neglect connotes some kind of willful failure. However, an increasing number of facilities are being cited with a violation for a failure to implement policies to prohibit neglect, as well as a failure to report suspected neglect, when no such willful failure exists.

For example, one facility was cited for neglect based on an allegation that the facility failed to monitor a resident's glucose for a period of ten days, despite the fact that the attending physician, in his professional judgment, determined that such monitoring was not necessary. Furthermore, the physician had seen the resident just about every other day during such time period. Is this a case of neglect on the part of the nursing home? Should nursing home staff question a physician's professional judgment? If in fact the glucose monitoring should have been performed, would not the failure to do same be a mistake/misjudgment of the physician and not neglect on the part of the nursing home?

D. Trivial Findings

Over the last couple of years, nursing home owners and administrators have complained about the DOH citing the facilities for violations of federal law for trivial matters. For example, set forth below are two examples of reports made by owners and administrators which were included in a 2001 report prepared by the New York Association of Homes and Services for the Aging, an association representing over 560 not-for-profit and government-sponsored nursing homes, home care agencies, adult care facilities, assisted living programs and housing providers.[9]

The report included the following examples:

1. In one facility a deficiency was cited because residents were served only one pat of butter with dinner; and
2. another facility was cited because it served cream of wheat rather than oatmeal.

The important thing to remember when considering the foregoing is the fact that the facilities were cited for violating both federal and state law. Furthermore, each facility was required to take the time and effort to prepare and submit a "Plan of Correction" to address the alleged violations. It is highly questionable whether focusing on such trivial and isolated matters is consistent with the intent of the federal regulations. Would not the time spent to address these issues be better utilized to ensure quality of care and life?

E. Failure to Follow Applicable Time Frames

Both the federal regulations and the State Operations Manual include specific time frames to be followed by the State Survey Agency in connection with the survey process. For example, 42 C.F.R. § 488.110 which sets forth the procedural guidelines to be followed by surveyors, states that the Statement of Deficiencies (CMS Form 2567) is to be provided to the facility ***no later*** (emphasis added) than ten days after the survey. Despite such regulatory requirement, the DOH has often failed to meet its applicable time frames.

Failure of the DOH to meet such time frames results in hindering the facilities' ability to correct alleged violations before certain mandatory penalties are imposed. For example, pursuant to 42 C.F.R. § 488.412(c), the remedy of a Denial of Payment for New Admissions (DOPNA) must be imposed if a facility has not corrected the alleged deficiencies within three months of the survey date. Therefore, if the DOH provided the facility with the SOD within the ten-day time period, the facility would still have approximately 80 days to make all necessary corrections. When the DOH does not timely provide a facility with the SOD, the facility's ability to make timely corrections is prejudiced.

In addition to affecting the facility's ability to make corrections before a DOPNA is imposed, it obviously has an effect on the residents. It is in everyone's best interest, specifically the residents', that any violations be identified and corrected as soon as possible to ensure that they do not re-occur and to further ensure that residents receive quality care and quality of life. Whether or not the DOH's failure to comply with the time frames is due to its increased enforcement, including time spent on trivial matters, is an issue that should be reviewed.

IV. Is the Appeals Process Adequate?

As briefly mentioned above, there is a formal federal appeal process; however, a facility is not entitled to an appeal unless an enforcement remedy giving rise to an appeal has been imposed. In other words, if a facility

is cited for deficiencies, but no enforcement remedy is imposed by CMS, the facility will not be entitled to a federal appeal.

On the state level, there is no formal appeal process to challenge deficiency citations, however, each state is required to have an Informal Dispute Resolution (IDR) process.[10] IDR is a two-stage process. Stage I consists of a paper review. Facilities have ten days from the date of the survey to submit their request for an IDR which must include the facility's arguments and supporting documents. The facility's request is then reviewed by the DOH's area office. Pursuant to DOH Memorandum 95-11, the DOH is supposed to respond to the Stage I request within ten calendar days. If the facility is not satisfied with the DOH's Stage I determination, it has two calendar days to request a Stage II review. The Stage II review is supposed to be scheduled within five calendar days of the request and consists of a conference call or face-to-face meeting with the area administrator, long-term program director and/or their designees. Within two calendar days, the DOH is required to notify the provider of its determination.

Many facility owners and administrators have complained that the process is arbitrary and capricious. The same agency that is citing the facility with a deficiency is also determining whether that citation was appropriate. It is important to remember that deficiencies represent an alleged violation of law; however, the individuals reviewing the validity of such violations are not lawyers or otherwise trained in law.

The end result is that if a facility is cited with deficiencies and CMS does not impose any federal remedy, the facility will be left without a meaningful appeal process. Although no formal remedy/penalty is imposed, since the results are public, the facility's reputation is tarnished. Furthermore, nursing homes have become targets of plaintiff attorneys and the SOD can be used as a means of identifying causes of action against a nursing home. Just recently, in *U.S. ex rel. Foundation Aiding the Elderly v. Horizon West,*[11] the U.S. 9th Circuit Court of Appeals refused to dismiss a "*qui tam*" (whistle-blower action) under the Federal False Claims Act[12] which was based on deficiencies set forth in a SOD. The action was brought by a resident advocacy group accusing a nursing home operator with defrauding the government by submitting reimbursement claims for services it knew were substandard based on alleged deficiencies set forth in a SOD. Generally, the Federal False Claims Act makes it illegal for any person to knowingly present a false or fraudulent claim for payment of services to the federal government (e.g., Medicare and Medicaid). The False Claims Act provides for treble damages. Furthermore, it allows private individuals to bring a case on behalf of the government and share in the proceeds of any recovery, provided that the underlying allegations are not based on public information. In *Horizon West*, the court held that although the plaintiff's case was based on the allegations set forth in a SOD, which is public, same did not disqualify the plaintiffs from bringing the action. Accordingly, when a facility is cited for deficiencies and no remedy is imposed, it becomes vulnerable to civil actions without any meaningful appeal process to challenge the validity of the alleged deficiencies.

Another recent trend in enforcement activity is for the DOH to seek fines pursuant to Public Health Law § 12 (PHL) for survey deficiencies. PHL § 12 gives the DOH the authority to impose a fine of $2,000 per violation of a term or provision of the Public Health Law. Since New York's laws and regulations governing nursing homes mirror federal regulations, when a facility is cited for a deficiency, it is cited for violating both federal and state law. Recently, there appears to have been a sharp increase in the number of facilities that the DOH has sought fines from pursuant to PHL § 12. In fact, some facilities have been put on notice of the DOH's findings and intent to impose fines for deficiencies which are more than two years old. If a facility becomes the subject of enforcement under PHL § 12, it will then be entitled to a hearing. The hearing proceedings are governed by 10 N.Y.C.R.R. Part 51. The hearing is before a DOH administrative law judge. It is important to point out that the scope of the hearing is limited to whether or not the facility violated the New York State Public Health Law and not whether or not a violation of the federal regulations giving rise to the deficiencies cited on the SOD existed. Most of the cases settle before ever going to a hearing.

V. Reasons for Increased Enforcement

There have been several reports addressing the effectiveness of nursing home enforcement in New York. One report prepared by Rep. Louise M. Slaughter and Rep. Carolyn B. Maloney dated March 12, 2001, describes New York's nursing home enforcement as inadequate.[13] The report points to the results of "comparative" and "observational" surveys. Comparative surveys are surveys conducted by federal surveyors after the state has surveyed a facility, after which the results are compared. During "observational surveys" federal surveyors accompany DOH surveyors and then rate the performance of the state. The report prepared by Reps. Slaughter and Maloney points to poor results on comparative and observational surveys, as well as the fact the New York, on average, cited fewer violations than other states, as a basis for its conclusion that New York's enforcement is inadequate.

The foregoing report is only one of several reports addressing New York nursing homes and the adequacy of state inspections. Considering that New York is paid hundreds of thousands of dollars to conduct nursing

home surveys, there is a great deal of pressure on the DOH to maintain its contract with CMS. Many have speculated that reports such as the Maloney report, as well as pressure from resident advocacy groups and negative publicity, have led to the so-called "step-up" in enforcement activity. Whatever the reason, the increases in enforcement activity are readily apparent to those in the nursing home industry and their advocates.

VI. Do the Means Justify the Ends?

If the end result of increased enforcement activity is improved quality of care and quality of life for nursing home residents, it can be argued that the means do justify the ends. However, it is questionable whether current enforcement policies of the DOH are, or will, actually improve quality of care. For example, facilities are required to report suspected abuse, neglect and/or mistreatment to the DOH.[14] These reports are made through the DOH Hotline which accepts all calls regarding suspected abuse, neglect or mistreatment, not just those made by the nursing homes themselves. In 1998, the total number of calls to the hot line was 1,118. In 2000 the total number of calls jumped to 1,930. In addition, the percentage of the calls made by nursing homes in 1998 was 67 percent compared to 81 percent in 2000.[15] It appears obvious that facilities are making many more reports of suspected abuse, neglect or mistreatment. However, is this the result of increased awareness resulting in better care and quality of life, or a result of fear of being cited with a deficiency for failure to call in an occurrence, even though the facility does not actually believe that same constituted abuse, neglect or mistreatment? Based on the numbers, it appears the latter may be true. Although the number of hot line calls increased by 73 percent from 1998-2000, the total number of calls in which credible evidence of abuse, neglect or mistreatment was found decreased by 44 percent.[16] Of the 1,930 hot line calls made in 2000, in only 123 (11 percent) was credible evidence found to support the complaint.[17]

When a facility calls the hot line to report suspected abuse, neglect or mistreatment, it is also required to conduct a thorough investigation, including interviewing staff members, family members and the resident, if possible, as well as a review of medical records. Such investigations take up a considerable amount of time and effort by staff members. If in fact the increase in hotline calls is a result of fear of receiving a deficiency, despite having no reason to believe an injury was the result of abuse, neglect or mistreatment, then the question is whether the time spent on investigating such matters could be better spent rendering care to residents.

Furthermore, would the time spent by staff on Plans of Corrections to address trivial issues or isolated occurrences that do not represent facility practices or the quality of care rendered by the facility be better spent on rendering care, training and other means to improve quality of care and the quality of life of residents?

VII. Conclusion

While it is obvious there has been a "step-up" in enforcement by the DOH, the question remains as to whether such increased enforcement is actually improving the quality of life of New York's nursing home residents. Nursing homes and their advocates will tell you that current enforcement activities may actually have a negative effect on quality of care, while those advocating for the elderly will tell you that even more enforcement is necessary. In any event, it appears as though the entire process should be scrutinized and amended, if necessary, to further the goals of the federal regulations and ensure that members of our most vulnerable population receive the care and treatment they deserve.

Endnotes

1. *See* 42 U.S.C.A. § 1396r(c)(8).
2. *See Quarterly Report on the Progress of Nursing Home Initiative* to Senator Grassley by HCFA Calendar Year 2000 Fourth Quarter.
3. *Id.*
4. *See id.*
5. *Id.*
6. The State Operations Manual is a manual produced by CMS setting forth guidelines that state survey agencies must follow.
7. *See Oakwood Manor Nursing Ctr., Petitioner v. Centers for Medicare & Medicaid Services.*
8. *Id.*
9. *See Bad Medicine; How Government Oversight of Nursing Homes is Threatening Quality of Care*, a report from New York Association of Homes and Services for the Aging, Aug. 2001.
10. *See* 42 C.F.R. § 488.331.
11. *See U.S. ex rel. Foundation Aiding the Elderly v. Horizon West* 01 C.D.O.S. 8084.
12. *See* 31 U.S.C. § 3279.
13. *See New York's Nursing Home Enforcement Has Been Inadequate*, report prepared for Reps. Louise M. Slaughter and Carolyn Maloney Minority Staff, Special Investigations Division Committee on Government Reform, U.S. House of Representatives, Mar. 12, 2001.
14. *See* 42 C.F.R. § 483.13(c)(2).
15. *See NYSDOH Resident Abuse and Complaint Investigation Data Report* 1998-2000 Annual Report.
16. *Id.*
17. *Id.*

Patrick Formato is a partner at Abrams, Fensterman, Fensterman & Flowers, LLP and is Director of the firm's health law practice group.

Subpoenas to Health Care Organizations

By David E. Steckler

Subpoenas to health care organizations are becoming increasingly common. As a result, attorneys representing health care providers need to be prepared to advise their clients regarding what to do when they are served with a subpoena.

This article will present a step-by-step approach to enable providers and their counsel to deal with issues that arise as compliance with a subpoena goes forward.

The attorney representing the subpoenaed health care provider has a number of initial considerations to balance. For example, what type of subpoena was served (criminal or civil), what investigative entity served the subpoena, and what document or witness production is required. Throughout the investigation, it is vitally important that the provider's counsel keep very careful records of the documents produced (with due regard for attorney-client privilege issues) and be aware of potential conflicts of interest with the health care provider's employees.

Sources and Types of Subpoenas

In the health care setting, subpoenas may come from several sources. Typically, a subpoena will come from the U.S. Attorney's Office, the state Attorney General's Office or local law enforcement agencies. A subpoena may require a person to appear as a trial witness or before a grand jury; or, the subpoena can be a subpoena *duces tecum,* which requires the health care provider to produce the records called for in the attachment to the subpoena.

The U.S. Attorney General (AG) has the authority to issue subpoenas requiring production of records relevant to a "Federal health care offense" investigation.[1] The AG also has authority to issue administrative subpoenas under the False Claims Act[2] and the Racketeer Influenced and Corrupt Organizations Act.[3] Enforcement of these "Civil Investigation Demands" may be by order of a federal district court, which is limited to determining whether the administrative agency has satisfied the statutory prerequisites to issuing and enforcing the subpoena, and whether the agency has satisfied the judicially created standards for enforcing administrative subpoenas.[4] In other words, the agency request must be reasonable, and will be approved by the judiciary so long as it "is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant."[5]

The Inspector General of the Department of Health and Human Services is also authorized to investigate civil, criminal and administrative violations pertaining to fraud in federal and state health care programs and may issue subpoenas for both documents and testimony.[6] Noncompliance with such subpoenas are also subject to enforcement by federal district courts.

In New York State, the Attorney General's Medicaid Fraud Control Unit can issue civil subpoenas or subpoenas in support of grand jury investigations. In addition, the Attorney General and the Department of Health may also demand that providers produce records to substantiate their billings submitted to Medicaid.[7] Indeed, many 504.3 "audits" can evolve into administrative or grand jury inquiries. Moreover, although 18 N.Y.C.R.R. 504.3 does not on its face authorize the Attorney General or Department of Health to interview employees, the typical provider will, along with producing records, allow interviews when such are demanded. Even though this is a less formal fact-gathering process, counsel should react in the same manner as a formal subpoena. Therefore, we recommend that the suggestions set forth below apply to 504.3 audits as well.

"A subpoena may require a person to appear as a trial witness or before a grand jury; or, the subpoena can be a subpoena duces tecum, *which requires the health care provider to produce the records called for in the attachment to the subpoena."*

A grand jury subpoena is used by investigative agencies to investigate criminal cases. A grand jury "can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not."[8] Although grand juries are "not licensed to engage in arbitrary fishing expeditions, nor may they select targets of investigation out of malice or an intent to harass,"[9] they do enjoy wide latitude; thus, challenges to grand jury subpoenas based on relevancy are exceedingly difficult to win. A motion to quash the subpoena will be denied unless the district court determines that there is "no reasonable possibility that the category of materials the government seeks will pro-

duce information relevant to the general subject of the grand jury's investigation."[10]

The Purpose of the Subpoena

The typical grand jury or administrative subpoena issued to a health care provider will not, on its face, provide any clues to the purpose of the inquiry, and, in many situations, the attorney for the issuing authority will be reticent to predict whether the health care provider is a "subject" or "target" of the inquiry. Whether the subpoena appears to be a "simple" subpoena for testimony or a more complicated subpoena *duces tecum*, counsel for the provider should always call the issuing authority immediately to attempt to learn why the subpoena was issued. When the attorney speaks to the issuing authority (Assistant United States Attorney, Special Assistant Attorney General in the New York Attorney General's Medicaid Fraud Control Unit, etc.), the attorney should ask the most simple and basic of questions: Why did my client get subpoenaed? Can you tell me what this inquiry is about? The attorney must quickly become familiar with the documents subpoenaed *before* contacting the issuing authority.

Negotiate the Terms

As a general proposition, grand jury and/or administrative subpoenas can be challenged on a motion to quash. This motion can be brought if production of the subpoenaed documents would be unduly over-broad and burdensome for the provider. However, the U.S. Supreme Court has suggested that the parties attempt to reach a reasonable accommodation before a court holds an administrative subpoena overly burdensome.[11]

Counsel can request an extension of time to respond to the subpoena; such extensions are routinely granted. In extreme circumstances, when the attorney for the issuing authority refuses an extension, a motion to quash can be made if there is a good faith belief that the recipient cannot gather the records in time for the production date. This motion must be made before the return date of the subpoena. In grand jury subpoena situations, a representative of the provider can also appear before the grand jury on the production date with those records that have been reviewed and explain to the foreperson of the grand jury that all of the records are not available, given the shortness of time.

Although subpoenas typically call for original records, most prosecutors will agree to accept copies. If the prosecution demands original records, the attorney should request to produce the documents in stages, so that they may be photocopied and returned to the provider before the next round of production occurs. Alternatively, the case agents can be invited to the health care provider's law firm to review originals and designate which are to be photocopied. Health care providers are required to maintain originals, and Joint Commission rules frown upon maintaining "photocopied originals" where patient care is ongoing. The provider will have a difficult task separating original treatment records from photocopied records, when originals are returned (often months or even years later). While most providers are reluctant to go to court, most—if not all—judges will require that a prosecutor return original records within a reasonable period of time.

The attorney representing the provider needs to closely review the documents prior to their production in order to gain a firm understanding of the issue under review. The documents must also be reviewed to cull out irrelevant materials, as well as materials covered by the attorney-client and work product privileges.

A Subpoena Protocol

A formal "protocol" should be developed and followed by health care providers when responding to subpoenas. The advantage of having such a protocol is that it creates a predictable format for document review and enables the provider and counsel to assert forcefully that they have been careful and professional in the review of the subpoenaed documents. Unfortunately, an investigation can go from neutral into high gear quite suddenly and the attorney for the issuing authority will, at times, take the health care provider to court on a motion to compel or even try to hold the health care provider in contempt if the investigating/prosecuting attorney believes that relevant documents have been withheld. Having a protocol will enable the health care provider's counsel to argue more credibly before the presiding judge that the health care provider's conduct has been both professional and in good faith.

The first mandate of the health care provider's subpoena protocol should be to ensure that all staff are made aware that they are not to disclose any corporate documents or information in response to a subpoena unless instructed to do so by a supervisor. Moreover, staff must be informed that all responses to subpoenas must be accurate and complete, without any alterations, and that destroying or altering documents which are subject of the subpoena will result in termination of employment, and indeed may result in a separate criminal prosecution.

Set forth below is a sample subpoena protocol.

- **Issue Memorandum Regarding Collection of Records**. Upon receiving a subpoena, the health care provider should contact legal counsel. Under counsel's direction, the health care provider should issue a memorandum to all relevant personnel advising them of the receipt of the subpoe-

na and of the documents required to be produced. The memo should instruct those personnel to review their work areas and provide, to a central location, any documents which they may have in their possession that they believe are called for by the subpoena.

- **Gather, But Do Not "Commingle" Documents to Be Produced.** Next, all records presumptively covered by the subpoena need to be gathered in this central location. The documents should *not* be commingled with each other. This means that all clinical records should be kept separate from financial records, which should be kept separate from marketing records, etc. These records should then be placed in the central location for review, and photocopied. Federal and state court rules often permit a subpoenaed party to produce records *either* as originally kept or in the order in which they were maintained as business records. Records should always be produced in the *original* order, so as to avoid any suggestion that they were "reorganized" to make their review more difficult. Helping the investigation by organizing documents "out of order" can backfire. The attorney for the provider should review the records and remove any which are not responsive. The best example of nonresponsive documents would be documents which are dated either before or after the time frame set forth in the subpoena. Once all nonresponsive records are removed, all remaining records should be photocopied—two sets should be made.

- **Creating the Privilege Log**. The first photocopied set should be labeled "Original records photocopied *with* attorney-client and work-product documents." The second set should be bates-stamped from 00001 to the end of the documents. The bates-stamped documents should now be reviewed for attorney-client/work-product materials. The federal rules of civil procedure and many state court local rules require that the recipient of a subpoena produce a "privilege log." The privilege log is simply a columnar table setting forth the bates-stamp number of the withheld documents, a description of the sender and receiver, and a simple description of the document sufficient to explain why the documents have been withheld. By way of example, the privilege log might read:

Once all attorney-client privileged and work-product materials have been removed, this "bates-stamped redacted set" should be photocopied and prepared for production to the subpoenaing authority, along with the privilege log.

The Internal Investigation

Simultaneous with the document review, the health care provider's counsel must act quickly to "get ahead" of the inquiry and gain an understanding of the issues under review and any possible concerns that the health care provider may have. The attorney-client privilege permits counsel for the health care provider to interview employees regarding the issues which may be under inquiry, in order to provide legal advice to the health care provider.

Generally, New York institutional health care providers are corporations. Under New York law, while a corporation is a person, it is also an "entity" which does not possess a Fifth Amendment right against self-incrimination. However, the entity is presumptively liable for the conduct of its employees within the ordinary course of their employment undertaken for the benefit of the corporation. At the same time, however, the health care provider does not wish to be guilty of "corporate condonation"—in other words, once the health care provider comes to learn of illicit or questionable conduct, the corporation must not be placed in the position of condoning that illicit conduct.

Typically, besides reviewing the documents under subpoena, as well as other relevant documents, health care counsel will interview employees to gain an understanding of how the conduct began, how it was undertaken, how it proceeded, and what damage it may have caused. In *Upjohn Co. v. United States*,[12] the Supreme Court upheld the existence of the attorney-client privilege for a corporation whose counsel had conducted an in-house investigation in order to learn if or how its employees had broken the law. The Court ruled that the communications concerned matters within the scope of the employees' corporate duties, and the employees themselves were sufficiently aware that they were being questioned in order that the corporation could obtain legal advice.[12] The lesson of *Upjohn* is that the attorney-client privilege is a very powerful defense tool. If senior employees/executives working for the health care provider—the internal auditors or compliance officer, for example—conduct an internal inquiry, *their* work

Document No. 00513-518: from David Steckler, Esq. to Steven Smith, Purchasing Director	Dated 1/15/01	Subject: Legal analysis of proposed purchasing agreement

product is wholly unprotected and is simply a road map for government regulators, if subpoenaed.

Conflict of Interest Issues

When interviewing employees during the internal inquiry, they should be informed that the attorney represents the health care corporate provider and not the individual, and that any information the individual imparts will not be privileged between the attorney and the individual, since the attorney has the legal obligation to pass on the information to the Board/Senior Officers of the health care provider. If an employee refuses to speak to corporate counsel or tells counsel that he or she has information which would be self-incriminatory, corporate counsel should advise the employee to contact independent representation to discuss their concerns.

As health care counsel learns more about the information contained in the documents and, indeed, the status of the inquiry (through continuing phone calls and/or meetings with the investigating authority), issues will arise and decisions will need to be made. The status of the investigation must be reported often to both senior officers and the board.

Other Issues

The article cannot cover all issues which may surface as an investigation continues. For example, what steps should a provider take if it appears that employees have violated laws, rules or regulations? Other key issues that may come up include: how best to stop *ongoing* misconduct discovered in the midst of an inquiry, or when it may be appropriate to do a retroactive review.

Business as Usual During the Inquiry

As is all too obvious, a health care provider immersed in an investigation has to contend with significant legal issues, *even* as it labors to conduct business as usual. Rumors can race though a provider's work force, and can be quite destructive. If the investigation is well known—the subject of news media reports, for example—employees must be kept advised of the provider's intent to cooperate, and to conduct business as usual. Employees should be told that they may choose to be interviewed by the investigators without counsel, but that interviews on the employer's premises are not to occur without approval of management, to avoid disruption of patient care, staffing, etc.

In sum, in today's health care environment, it is important that health care providers be prepared to react to what has become almost inevitable—the receipt of a subpoena. By providing a road map for their clients, health care counsel will go a long way toward assuring that the provider is able to respond completely and efficiently to the subpoena's demands, while simultaneously not being diverted from its day-to-day operations.

Endnotes

1. *See* 18 U.S.C. § 3486.
2. 31 U.S.C. § 3729, *et seq.*
3. 18 U.S.C. § 1968.
4. *See Administrative Subpoena John Doe, D.P.M. v. United States*, No. 00-MD-00053 (6th Cir. June 14, 2001).
5. *United States v. Morton Salt Co.*, 338 U.S. 632, 652-53 (1950).
6. 42 C.F.R. § 1006.
7. 18 N.Y.C.R.R. § 504.3.
8. *Morton Salt Co.*, 338 U.S. 632.
9. *United States v. R. Enterprises, Inc.*, 498 U.S. 292, 299 (1991).
10. *Id.* at 301.
11. *Morton Salt Co.*, 338 U.S. at 653.
12. 449 U.S. 383 (1981).
13. *Id.* at 394-95.

David E. Steckler chairs the Compliance and Defense Practice Group at Garfunkel, Wild & Travis P.C. He was a Special Assistant Attorney General in the New York Attorney General's Medicaid Fraud Control Unit.

Criminal Liability for Failing to Disclose Improper Medicare or Medicaid Payments: Exposure to Clients and Their Lawyers

By Ross P. Lanzafame

As you are opening your morning mail, the phone rings. On the line is the distressed billing manager for one of your physician clients. She just returned from a coding conference with the office biller. The biller, a relatively new employee, has been with the practice and submitting claims for approximately three years. At the conference, they learned that the biller had misinterpreted or misunderstood prior coding instructions regarding submission of a particular series of codes. As a result of this misunderstanding or misinformation, the biller had upcoded some or all of the claims for one particular service. The business manager and the biller have tried to determine how many claims were submitted improperly, as well as the dollar value of the incorrect payments received to date. They believe that somewhere between 800-1000 claims were submitted over the past three years under the questionable code. However, they can only guesstimate the dollar amount because the error is of such a type that each patient medical record and each claim submission would have to be manually reviewed in order to determine whether or not all of the qualifiers had been met for proper submission of the code claimed. The biller went through all of the claims awaiting submission on his desk and, based upon what he learned at the conference, is prepared to submit all current and future bills using only the proper coding criteria. The business manager explains that the effort involved in manually reviewing each claim submitted for the past three years would be inordinate in relation to the dollar amount of any "overpayment" that the provider might have received. They believe that even if every claim had been upcoded, the "overpayment" would not exceed $12,000. The business manager's questions to you are simple:

- Isn't it enough that we just correct our practices and code/bill properly on a going-forward basis?
- If we need to go back, can't we just correct and re-bill the erroneously coded claims submitted since January 1, 2001?

Is There a Legal Obligation to Disclose?

Although your client may want to look the other way, or try to limit liability for repayment of overpayments, such an approach may open the door to criminal liability. It is a dangerous world for health care providers. Gone are the days when providers could look the other way and evade repayment until asked by a carrier or payor. With the increased criminalization of health care errors, as well as increasingly frequent health care fraud allegations and investigations, it is clear that overpayments pose both a financial and a legal challenge. Failing to disclose a known overpayment can convert what might have been a simple error into the basis for a criminal complaint against the provider and its employees and advisors.

The Social Security Act contains a little-cited provision, often referred to as the "duty to disclose," that makes concealing or failing to report overpayments a felony.[1] Pursuant to 42 U.S.C. § 1320a-7b(a)(2), a provider

> having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in greater amount or quantity than is due or when no such benefit or payment is authorized [is guilty of a felony.][2]

Anyone other than the provider who engages in such activities is guilty of a misdemeanor.[3] The broad reach of the "duty to disclose" provision extends to the health care provider, its employees, its auditors, and *any others* who "with knowledge of the occurrence of any event" "conceal or fail to disclose" an event or overpayment. Such individuals may be subject to criminal prosecution.[4]

In general, in order for criminal liability to attach under the "duty to disclose," an individual must (1) have knowledge, (2) conceal or fail to disclose the error or overpayment, and (3) intend to defraud.[5] In our example above, the billing manager and biller clearly have knowledge that an error has occurred and overpayments have been received. Their solution to correct on a going-forward basis is an absolute necessity. However, in and of itself, elimination of the problem on a

going-forward basis does not relieve them of criminal liability, because of their knowledge of the historical billing errors. Failure to disclose the historical problem/overpayment could constitute concealment with the requisite intent under the statute, giving rise to potential felony prosecution. As a result, the answer to the first query posed by the client must be "No." You cannot simply forget the past and correct the problem on a going-forward basis.

Likewise, trying to limit financial liability to a discrete period of time (e.g., going back only to January 1, 2001, as opposed to when the upcoding in fact began) does not relieve the client from potential criminal liability. Again, the client knows that there are more overpayments beyond those the client proposes to disclose and correct and intends not to disclose or correct the full overpayment. Failure to disclose and correct the entire historical problem could constitute concealment with intent to defraud under the statute, giving rise to potential felony prosecution. Thus, the answer to the client's second query must also be "No." You cannot simply correct the problem on a going-forward basis, disclose and correct back to some past point in time that is convenient, and forget the remaining overpayments.

Can an Overpayment Be Forgiven or Forgotten?

Not all overpayments are created equally; some overpayments are "Overpayments"—with a capital "O"—that must be reported and repaid, while others are "overpayments" that may be forgiven.[6] In providing advice to clients, it is important to analyze the facts and circumstances giving rise to the particular overpayments to determine if they are "Overpayments" that must be repaid, as well as the clients' proposed repayment plans.

Overpayment That Must Be Repaid:

Medicare considers an overpayment to exist whenever Medicare funds are received in excess of the amounts due and payable under the statutes and regulations.[7] CMS, as part of the voluntary disclosure program, has identified 17 different causes of overpayments,[8] all of which are capital "O" Overpayments that must be repaid. Although the list is not by any means exhaustive, it is instructive. CMS-identified overpayments include those arising from any of the following broad categories:

1. Claims submitted based on insufficient documentation,
2. Duplicate service claims,
3. Claims for services not rendered,
4. Claims that lack medical necessity,
5. Claims billed in error,
6. Incorrect CPT coded claims,
7. Medicare secondary payor/other payor involvement, and
8. Claims submitted without proper assignment.[9]

There are many other instances when an overpayment may occur. For example, base period or capital cost report errors may result in improper computation of the Medicaid rate for nursing homes or other cost-based providers. Such errors arise for a variety of reasons—some innocent and some not. Examples of cost reporting errors include: (1) claiming receivables as bad debts without engaging in proper collection activities; (2) use of inaccurate statistics for square foot or cost allocation; (3) characterizing operating expenses (e.g., maintenance costs) as capital expenses; (4) shifting costs from above ceiling to below ceiling centers; and (5) cost report entries for non-allowable or non-reimbursable expenses. Regardless of the cause, overpayments based on cost reporting errors are capital "O" overpayments[10] that must be repaid and are subject to recoupment by Medicaid.[11]

Overpayments may also arise as a result of excess periodic interim payments (PIP) received by acute care facilities from the Medicare program. The OIG has taken a greater interest in scrutinizing Medicare Intermediary computation and payment of PIP amounts.[12] An acute care facility that receives PIP in excess of the amount justified by its costs and Medicare utilization is being overpaid. Such overpayments are capital "O" Overpayments that must be repaid and are subject to recoupment by Medicare. Continued receipt of known excessive PIP amounts could pose serious liability for the provider and those who fail to disclose or halt the overpayment.

In addition, claims billed and paid where the underlying transaction is a violation of either the Stark Law[13] or the Anti-Kickback Statute[14] may be deemed to be overpayments. Similarly, payments for claims submitted during the time that DOH or HCFA surveyors have determined that substandard quality of care is being provided by a certified facility may be deemed overpayments. In each of these situations, the payments were for services that were not consistent with Medicare/Medicaid rules. The basis for this contention may be the CMS 855 signed by Medicare participating providers. The CMS 855 contains a certification by the provider that each claim for payment "is conditioned on the claim underlying the transaction complying with [Medicare] laws, regulations and program instructions (including the anti-kickback statute and the Stark

law)."[15] Receipt of payment for a claim that violates the Stark Law or the Anti-Kickback Statute or while substandard of care survey citations are in force, are at the very least a violation of the provider agreement. Whether the provider can be shown to have the requisite intent is a factual determination.[16] If in fact a willful intent to violate either the Stark Law or the Anti-Kickback Statute exists, identification and disclosure of the overpayment may be the least of counsel's and the client's concerns.

Overpayments That May Be Forgiven:

Medicare law permits overpayments to be waived or retained in certain very limited circumstances. Generally, where a provider is "without fault,"[17] Medicare will waive liability for the overpayment. Pursuant to the *CMS Carriers Manual*, a physician is liable for overpayments he receives *unless* he is found to be without fault. Actual determination of fault is the responsibility of the carrier. Carriers are instructed to consider a physician "without fault" if he has exercised reasonable care in billing for and accepting payments.[18] A physician is always "without fault" if the overpayment was due to an error with respect to the beneficiary's entitlement to Medicare (i.e., the payment was made during a time SSA records showed the beneficiary was not entitled to Medicare benefits)[19] or due to the carrier's failure to apply the appropriate deductible.[20]

The *Medicare Carriers Manual* expressly identifies each of the following instances of overpayment as examples of situations in which a physician is deemed at fault and, as a result, is liable for overpayment received:

A. Incorrect reasonable charge determination

B. Duplicate payments

C. Physician was paid by Medicare but did not accept assignment

D. Physician billed for item or services which he should have known were not covered

E. Items or services were furnished by a practitioner or supplier not qualified for Medicare reimbursement

F. Overpayment due to a mathematical or clerical error

G. Physician does not or did not submit documentation to substantiate the service billed

H. Overpayment was for the rental of durable medical equipment and a supplier billed for the equipment.

The *Medicare Carriers Manual* contains a time limit for recovery of overpayments. Section 7100.1 instructs carriers not to recover an overpayment not reopened within four years after the date of payment "unless the case involves fraud or similar fault." In addition, carriers are instructed not to recover an overpayment discovered later than three calendar years after the payment unless there is evidence that the physician or beneficiary was at fault with respect to the overpayment. As a cautionary note, this *Carriers Manual* section should not be read to give providers the right to forget "older" overpayments. The *Carriers Manual* does not negate the criminal penalties or the "duty to disclose" (found in 42 U.S.C. § 1320a-7b(a)) discussed above.

Repayment or Recoupment

Often, providers who determine that an overpayment has occurred will retain those overpayments—or even continue to receive overpayments—until a carrier or payor expressly asks that the funds be returned. For example, a skilled nursing facility may discover as a result of an internal audit that a cost reporting error occurred in its base period cost report which has resulted in excessive payments by Medicaid for a number of years. Believing that the Department of Health will exercise its audit authority and, upon audit, catch the error and levy a recoupment, the facility may elect to sit by and wait for the course of the audit. While awaiting the audit and subsequent recoupment, the facility may continue to submit claims and receive reimbursement based on a Medicaid rate that is computed on erroneous cost data.

Providers sometimes ignore or are casual about resolving "credit balances." Although the term "credit balance" includes a variety of items, it generally refers to incorrect or excessive payments made as a result of billing or claim processing errors. A "credit balance" may result from an accounting error, errors in calculating co-insurance amounts,[21] or duplicate payments received from other insurers or payors. As with cost reporting errors, providers often retain these funds until the carrier or payor identifies that an overpayment was made and either asks for a refund or levies a recoupment.

Moreover, the CMS 855 signed by participating providers contains a certification statement signed by the provider indicating that the provider understands that overpayments made may be recouped through withholding of future payments.[22] Although the provider may prefer to wait for the carrier or payor to discover the overpayment and institute a recoupment, once the provider has knowledge that an overpayment exists, the obligations under the "duty to disclose" would seem to take precedence.

Other Bases for Criminal Liability

Although many providers over the years have waited for the audit, recoupment or request for repayment to arrive before returning the "credit balance" or cost reporting error overpayment, that practice today is a risky one. The threshold question as to potential criminal liability with respect to each of these overpayments is whether or not the provider had knowledge of the error giving rise to the overpayment and, with intent to improperly retain the funds, concealed or failed to disclose the error. For counsel, liability could attach if you are deemed to have aided the client in a scheme to defraud the payor through concealment of the error or through development of the mechanism that caused the overpayment.

Providers who fail to disclose and to refund known overpayments may be prosecuted under any of the following criminal statutes:

1. Health Care False Statements. This statute prohibits knowingly and willfully making false statements or misrepresentations of a material fact in connection with any application for payment of a Medicare or Medicaid claim. This statute provides for a $25,000 fine and/or five years in prison.[23]

2. Violation of Assignment Terms. This statute prohibits knowing, willful and repeated violations of the terms of assignment or reassignment of Medicare benefits.[24]

3. Health Care Fraud. This statute prohibits knowing and willful execution (or attempted execution) of a scheme or artifice to defraud any health care benefit program or to obtain remuneration from a health care benefit program by false pretense, representations or promises.[25] Unlike many of the other statutes cited, this statute applies to all health benefit programs, not just Medicare and Medicaid.

4. Health Care Theft or Embezzlement. This statute prohibits knowing and willful stealing, embezzling, wrongful conversion, or intentional misapplication of the money or assets of any health care benefit program.[26]

5. Health Care False Statements. This statute prohibits knowingly and willfully falsifying or concealing any material fact or making materially false or fraudulent statements or representations in connection with the delivery of or payment for health care services or benefits.[27]

6. A variety of general criminal statutes including the False Claims Act,[28] RICO,[29] and Conspiracy to Defraud the Government.[30]

Identifying Overpayments

As noted above, not all overpayments are created equal. Some are the result of isolated errors, while others evidence a systemic problem. It is important early on to determine whether the identified overpayment is the result of an isolated error or something greater. Overpayments from an isolated error are discrete occurrences. Once identified, the amount at issue can be readily determined, the problem corrected, and the overpayment returned. If the audit identifies an overpayment that is the result of a systemic problem, the provider has knowledge that the overpayment is much greater than that identified in the sample. Again, once the provider has knowledge of the overpayment, unless the overpayment fits within the narrow "without fault" exception, the provider should return all overpayments or face the real possibility of criminal prosecution.

Can You, as Counsel, Face Any Criminal Liability?

In the example that opened this article, your client has disclosed improper billing practices to you and is seeking your legal advice and counsel on what to do. But can you be drawn into any possible criminal prosecution?

Even as legal counselor and advisor, you may be subject to prosecution if it is deemed that you aided or conspired with the provider in concealing the overpayment or error.[31] In the example that began this article, the client has admitted to you that improper billing occurred and, at most, only wants to disclose and correct the error from January 1, 2001, forward. You clearly have knowledge that the client received funds to which it is not entitled, as well as the client's intention to conceal at least a portion of the overpayment. Although the client's communication to you is information that can and is likely to be protected by the attorney-client privilege, the privilege is not absolute.

By its very nature, the attorney-client privilege results in the protection from release to or withholding from a fact-finder of pertinent information. However, courts have limited the attorney-client privilege so that it ***does not apply*** "where the client consults an attorney to further a crime or fraud."[32] The attorney-client privilege is forfeited where "the client sought the services of the lawyer to enable or aid the client to commit what the client knew or reasonably should have known to be a crime or fraud."[33] Failing to instruct the client to identify and return the entire overpayment could be deemed your participation in a scheme to conceal the overpayment and defraud the payor.

As counsel, we all should be aware that the possibility exists that our legal advice may be sought for improper purposes. Prosecutors in the past have been

interested in, and pursued, attorneys for their roles in health care schemes. Perhaps the most famous instance was the 1998 *Anderson* case, in the U.S. District Court for the District of Kansas, where two attorneys were indicted in the criminal prosecution of anti-kickback charges.[34] The charges against the attorneys arose from their transactional and employment advice to the provider rendered as part of a typical attorney-client relationship. Prosecutors claimed the attorneys were involved in developing the scheme used to defraud the government. In its decision dismissing the case against the lawyers based upon a lack of evidence, the court noted that the lawyers had reasonably believed their advice was sought in order to ensure that the provider complied with the Anti-Kickback Statute.

It is unlikely that the *Anderson* case will be the only prosecution of counsel for advice given to health care clients. Granted, the *Anderson* attorneys did not face prosecution for legal advice given with respect to the handling of overpayments. However, the lessons of the case and its ramifications on advice given to clients that reasonably may be subject to prosecution are clear. Prudence dictates advising clients of their exposure to criminal prosecution under the "duty to disclose" and the necessity to return any and all known or discovered overpayments. We would all be wise to implement within our practices the often-heard health care mantras: "Document. Document. Document" and "If it isn't documented, it didn't happen."

Endnotes

1. 42 U.S.C. § 1320a-7b(a)(3).
2. 42 U.S.C. § 1320a-7b(a). The criminal penalty set forth in the statute is a fine of not more than $25,000 and/or imprisonment for up to five years.
3. 42 U.S.C. § 1320a-7b(a). The criminal penalty set forth in the statute is a fine of not more than $10,000 and/or imprisonment for up to one year.
4. *Id.*
5. *Id.*
6. Medicare Carriers Manual § 7100 *et seq.*
7. *Id.*
8. HCFA Transmittal No. AB-33 (June 1, 1999) *Tracking and Reporting Procedures for Unsolicited/Voluntary Refund Checks from Providers/Suppliers Interim Instructions*; *reprinted in* CCH Medicare Medicaid Guide ¶ 150,401.
9. *Id.*
10. 18 N.Y.C.R.R. § 518.3.
11. 18 N.Y.C.R.R. § 518.5 *et seq.*
12. *See* "Review of Mutual of Omaha's Oversight of Medicare Inpatient Acute Care Providers Periodic Interim Payments" (A-07-02616), *at* www.hcfa.gov/progorg/oas/reports/region7/70102616.pdf.
13. 42 U.S.C. § 1395nn.
14. 42 U.S.C. § 1320a-7b.
15. CMS 855, *at* http://www.hcfa.gov/medicare/enrollment/forms/.
16. It must be noted that prosecutions against facilities for substandard care have been pursued under the civil False Claims Act. *See United States v. GMS Management—Tucker, Inc.*, 96-1271 (E.D. Pa. 1996).
17. 42 U.S.C. § 1395g(g); *see also* 42 C.F.R. § 405.358.
18. "Reasonable care" is defined as the physician having made "full disclosure of all material facts and on the basis of the information available to him, including, but not limited to, the Medicare regulations, he had a reasonable basis for assuming that the payment was correct or, if the physician had reason to question the payment, he promptly brought the question to the carrier's attention." CMS Carriers Manual § 7103.
19. CMS Medicare Carriers Manual § 7116E.
20. CMS Medicare Carriers Manual § 7103.
21. Co-insurance miscalculations may also be deemed to be assignment violations by Medicare. (*See* Upstate Medicare Fraud Bulletin, Fall 2001.) Providers who accept assignment are bound by all Medicare rules and regulations. Among these rules is the requirement that the provider only accept the payments (including co-insurance amounts) allowed by Medicare, even if the provider's billed amount is more.
22. *See* 42 C.F.R. § 405.371.
23. 42 U.S.C. § 1320a-7b(a).
24. 42 U.S.C. § 1320a-7b(e).
25. 18 U.S.C. § 1347.
26. 18 U.S.C. § 669.
27. 18 U.S.C. § 1035.
28. 18 U.S.C. § 287.
29. 18 U.S.C. § 1961-1963.
30. 18 U.S.C. § 286.
31. *See generally* 42 U.S.C. § 1320a-7b(a). It is a misdemeanor for "any other person" to "knowingly and willfully" "conceal or fail to disclose" an overpayment with the requisite intent to defraud.
32. *In re Grand Jury Proceedings*, 857 F.2d 710, 712 (10th Cir. 1988).
33. *United States v. Rakes*, 136 F.3d 1, 4 (1st Cir. 1998).
34. *United States v. Anderson et al.*, CR 98-20030-JWL 1998.

Ross P. Lanzafame is a partner in the Rochester office of the law firm of Harter, Secrest & Emery LLP. He counsels and represents acute and long-term health care clients on corporate and regulatory matters with a focus on Medicare and Medicaid issues.

The One Purpose Rule of *United States v. Greber*: Is It the Law? Is It Fair?

By Gregory J. Naclerio

The short answers to the questions posed by this article's title are "Probably yes" and "You make the call." The "one purpose test" announced in *United States v. Greber*[1] is indeed the prevailing rule when it comes to the Medicare/Medicaid Anti-Kickback Statute[2] (hereinafter the "Statute"). Nevertheless, a discussion of the evolution of the one purpose test, as discussed in subsequent cases, may give the practitioner some insights which may be used to challenge that test in future cases.

As amended in 1977, the Statute makes it a crime to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to refer or in return for referring an individual for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program; or in return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item, for which payment may be made in whole or in part under a federal health care program.

The presumption underlying the Statute is relatively simple: if a physician stands to gain financially each time he or she makes a referral for a service which Medicare or Medicaid pays, the physician most likely will (1) overutilize medical services and thus have the government's health plans pay for unnecessary medical services (usually tests) or (2) be more concerned with the amount of kickback received from the vendor of medical services than the quality of care rendered to the patient. While there may be no empirical studies on the subject, the author's experience has been that vendors who pay kickbacks tend to provide lower quality care in part to recoup the "cost" of the kickback or because the patient is not "really sick," i.e., did not need the test in the first place. In short, when a "financial gain" is the motivating force in a physician's decision to make a referral, both the patient and the government stand to lose.

Congress was so committed to keeping financial considerations out of a physician's referral practice that in 1977 it, *inter alia*, increased the penalty for violating the Statute from a misdemeanor to its present status as a felony, punishable by five years in a federal penitentiary, a fine of $25,000 or both. Providers and their counsel should be aware that a conviction under 42 U.S.C. § 1320a-7b triggers the Federal Sentencing Guidelines,[3] making incarceration a distinct possibility. Moreover, seeking to stem what it perceived to be a pervasive fraud problem in the health care industry, Congress penned the Statute with broad language in an effort to cover an endless variety of fact patterns.

It was not until a Pennsylvania osteopath and board-certified cardiologist, Dr. Greber, decided to venture outside of the practice of medicine into the business world that the courts would get the chance to opine on the breadth of the amended Statute. In addition to practicing as a board-certified cardiologist, Dr. Greber was the president of Cardio-Med Inc.—a business which provided other physicians with diagnostic services. One of these services involved the Holter monitor. Essentially, when a primary care physician felt his patient needed a Holter monitor, Cardio-Med would be contacted and the patient would be fitted with the monitor. The monitor recorded the patient's cardiac activity for approximately 12 hours and correlated with an activity log kept by the patient. By interpreting the tape and the activity log, a cardiologist could get a better profile of his patient's heart function. This type of test was "patient friendly," as it was non-invasive and did not require any out of pocket payment by the patient. Rather, Cardio-Med billed Medicare directly at a fee "not to exceed $65 per patient."

If our story had stopped here, Dr. Greber would not be a famous name in the lexicon of health care practitioners. Nevertheless—for reasons left for the reader to discern—Dr. Greber felt it was incumbent upon him to pay the primary care physicians (who referred the patient to Cardio-Med and who thereafter explained the results of the Holter monitor to the patient) an "Interpretation Fee." The interpretation fee paid by Dr. Greber, ironically enough, was equal to exactly 40 percent of the payment he received from Medicare. The government thought it was quite curious that Dr. Greber would pay primary care physicians an interpretation fee, when in truth and fact, the interpretation was done by Dr. Greber himself! Moreover, a fastidious Assistant U.S. Attorney found that Dr. Greber had testified in a prior civil proceeding as to what the government believed was the true nature of the "interpretation fees." During this civil case, Dr. Greber was heard to say: "If the Doctor didn't get his consulting fee, he wouldn't be using our service. So the Doctor got a consulting fee."[4]

At Dr. Greber's trial, the district court judge charged the jury that the government was required to prove, *inter alia*, that (1) Dr. Greber paid money to the physician customers of Cardio-Med to induce the physicians to use Cardio-Med services and (2) "even if the physicians interpreting the test did so as a consultant to Cardio-Med, that fact was immaterial if a *purpose* was to induce the ordering of services from Cardio-Med."[5] The jury found Dr. Greber guilty of violating the Statute and when his appeal went to the Third Circuit, not only was the conviction affirmed, but the "one purpose test" was born.

While the Ninth, First and Tenth Circuits purport to follow the one purpose test, a close reading of their decisions may prove otherwise. In *United States v. Kats*,[6] Yan Kats had the unfortunate occasion of buying a 25 percent interest in a community clinic that engaged in a kickback scheme with David Smushkevich of the infamous "Rolling Labs" scam. As part owner of that clinic, Kats received kickbacks for referrals of lab tests to Tech Diagnostic Medical Labs consisting of 50 percent of the fee Medicare paid the lab. The Ninth Circuit apparently agreed with the one purpose rule holding: "As the Third Circuit recently explained, the Medicare Fraud Statute is violated if 'one purpose of the payment was to induce future referrals' even if payments were also intended to compensation for professional services."[7] The *Kats* court also noted that *Greber*'s interpretation is "consistent" with legislative history, stating that "the *Greber* court held '[e]ven if the physician performed some service for the money received, the potential for unnecessary drain on the Medicare system remains.'"[8] "We agree,"[9] concluded the panel, or did they? The jury charge the Circuit was asked to review in part stated:

> It is not a defense that there might have been other reasons for the solicitation of remuneration by the defendants, if you find beyond reasonable doubt that *one of the material purposes* for the solicitation was to obtain money from the services. It is entirely up to you to decide whether the solicitation or remuneration was at least in *material part* for the referral of services. [Emphasis added].

Hence, while the Ninth Circuit maintains it endorsed the "one purpose test," perhaps a closer reading of the case suggests that it really endorsed a "*material* purpose test"—a test presumably requiring a higher threshold for a conviction.

The First Circuit was next to address this nettlesome issue in *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*[10] In *Bay State*, the defendant was awarded a contract with Quincey City Hospital in part through the efforts of a Mr. Felci, a public employee who was also moonlighting as a "consultant" to Bay State. It was the government's theory that payments made to Mr. Felci (consisting of a Buick, a Mazda and checks) were primarily improper inducements to help Bay State obtain the 1984 hospital transportation contract, while it was Felci's position that the payments were reasonable payments for actual services provided. At the conclusion of the trial, Mr. Felci's attorney asked for a jury charge to the effect that the government had to show payments to Felci "were not as compensation for services performed . . . or were of substantially more value than the service performed or to be performed" and that Felci could not be guilty unless he was "substantially overpaid" for the services.[11] Rather than charging as requested, the trial court instructed

> [t]hat the government has to prove that payments were made with the corrupt intent, that they were made for an improper purpose. If you find the payments were made for two or more purposes, then the government has to prove the improper purpose is the *primary* purpose or was the *primary* purpose in making and receiving the payments. It need not be the only purpose but it must be the *primary* purpose for making the payments and for receiving them. You cannot convict if you find the improper purpose was incidental or a minor one in making these payments.[12]

Apparently aware that its decision was not on all fours with *Greber*, the First Circuit held that (1) the gravamen of Medicaid fraud is "inducement" and (2) the issue of sole vs. primary reason for payment is irrelevant since *any* amount of inducement is illegal.[13] The court further held, "we need not decide the exact reach of the Statute since in this case, the District Court instructed defendants could be found guilty if the payments were made *primarily* as inducements. At a minimum this comports with the Congressional intent."[14]

Thus, after *Bay State*, we have possibly three standards to consider in the anti-kickback context. The "one purpose rule" (*Greber*), the "material purpose rule" (*Kats*) and the "primary purpose rule" (*Bay State*). Although the First Circuit tried to walk away from its primary purpose rule, the promulgated trend of holding the government to a lower *Greber* burden appears to be continuing. So declared the Tenth Circuit in *United States v. LaHue, Anderson*[15] and *McClatchey*.[16] Here, osteopathic physicians Robert LaHue and Ronald LaHue were owners of Blue Valley Medical Group, a specialized medical practice providing care to patients who resided in nursing homes and other long-term care facilities. Commencing in 1995, Baptist Medical Center, through its President Dan Anderson and Senior Vice President Dennis McClatchey entered into a contract with the LaHues, making them co-directors of the hospital's gerontology services. According to the hospital's Chief Financial Officer, who testified on behalf of the government, the negotiations with the LaHue brothers "were backwards, establishing the fee first and only then agreeing to the services the LaHues would provide in return and, from his and Messrs. Anderson, McClatchey and Keel's perspective were grounded in the hospital receiving patient referrals."[17] From 1985 to 1993, Baptist paid each of the LaHues $75,000 annually for his directorship. Additional trial testimony described the services provided by the LaHues as "minimal to none." In short, it was the government's position that Baptist was

paying the LaHue brothers kickbacks carefully disguised as "consulting fees."[18]

On appeal to the Circuit Court, the defendants argued, *inter alia*, that the district court adopted an improperly broad construction of the Anti-Kickback Statute, thereby erroneously instructing the jury under the one purpose test which "effectively criminalized innocent conduct." This argument was soundly rejected, as the court adopted the "sound reasoning" of the *Greber* court and held "a person who offers or pays remuneration to another person violates the act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals."[19] However, it is worthy to note in *LaHue* that the district court also charged the jury:

> Robert LaHue and Ronald LaHue cannot be convicted merely because they received remuneration in return for services and also decided to refer the patients to the hospital. Likewise, the mere referral of patients because of oral encouragement or because of the belief that the place that the cases are to be referred is attractive does not violate the law.[20]

This statement is in accord with the Ninth Circuit decision of *Hanlester Network v. Shalala*,[21] which held that in order to sustain a finding that a party has violated the Statute, the court must find that the defendant knowingly and willfully engaged in prohibited conduct with specific intent to violate the Statute.[22]

In *Hanlester*, physicians were given the opportunity to invest as limited partners in a laboratory business called the Hanlester Network. The physician partners were told that the limited partnership depended on referrals from the limited partners; however, cash distributions made to the limited partners were based solely on ownership shares and not the volume of their referrals. The Ninth Circuit held that "the fact that a large number of referrals resulted in the potential for high return on investment or that the practical effect of low referral rates was failure of the labs is insufficient to prove the appellants offered or paid remunerations to induce referrals."[23] In short, the court stated that "mere encouragement does not violate the Statute."[24]

Have we now come full circle and we are back to the "one purpose rule"? The answer is "Probably Yes" until the Second Circuit or Supreme Court addresses the issue.

Fair or Unfair? That Is the Question

The Statute on its face is a fair and appropriate expression of congressional intent to protect the Medicare and Medicaid Programs—and the taxpayers who fund them—from predatory and unscrupulous health care providers and business people who see patients only as dollar signs. In an effort to protect the public fisc, Congress intentionally drafted the anti-kickback law in sweeping language. However, Congress, aware of the almost unlimited reach of the Statute, immediately excepted certain "remuneration" (such as bona fide employment relationship and payments to purchasing agents) from the Statute and further exempted any payment practices specified by the Secretary of Health and Human Services (HHS) from the Statute's grasp, thus, giving birth to what we today know as the "Safe Harbors."[25]

The so-called Safe Harbors specifically address various payment practices which, although potentially capable of inducing referrals of business under Medicare/Medicaid, are protected from both criminal prosecution and civil sanctions. Thus, Safe Harbors now protect certain investment interests, space and equipment rentals, personal services and management contracts, sale of practices and discounts, to mention a few.[26] Unfortunately, the Safe Harbors are so narrowly drawn that unless one meets each and every requirement of a Safe Harbor, a transaction's safety cannot be guaranteed. There exists a vast expanse of ocean between a Safe Harbor and the storms of illegality that will sink a health care transaction. There lies the rule. How can practitioners counsel their clients seeking to engage in cutting-edge deals in a health care industry that seeks to capture patient referrals? For without patient activity—and more importantly, the funds paid by the federal government—a profitable transaction is not attainable.

The first issue for counsel to remember about the Statute is that it has criminal penalties, and as a criminal statute the burden is upon the government to prove a person knowingly and willfully[27] gave or received remuneration in return for a patient referral. Hence, the transaction, and more importantly the "real transaction," needs to be diligently reviewed.

Perhaps history can be used as a teacher. What would you have advised Dr. Greber, Yan Kats, the Drs. LaHue, Dan Anderson or Dennis McClatchey? These cases seem clear in that the goal was to obtain Medicare referrals by paying for them. Whether it was the parties' "one purpose," "material purpose" or "sole purpose," the bottom line of each transaction was to "pay money for bodies." Thus, these facts, standing on their own, seem to justify the guilty verdicts. While the *LaHue* defendants were more sophisticated and tried to cover their tracks by the preparation of contracts and retention of counsel, one could almost see the "wink and the nod" as the "co-director" contracts were executed.

The problem, however, becomes more difficult when you are called to advise the principals of the Hanlester Network. Assuming you cannot fit into a Safe Harbor, can you put together a transaction where health care providers can have an interest in entities with which they have a financial relationship (assuming no violation of the Stark Law[28] and/or the State Health Care Practitioner Referrals Act[29]) or are all such deals "totally illegal"? That's where the "Devil meets the details." The Anti-Kick-

back Statute is written so broadly that it literally can mean whatever a U.S. Attorney wants it to mean. The Circuit Courts' interpretation of the Statute, as discussed above, permits overzealous U.S. Attorneys to scrutinize every aspect of a business transaction in an attempt to find the "hidden one purpose" which violates the law. The ability of a prosecutor to make the Statute mean whatever he wants (reminiscent of the Cheshire cat in *Alice in Wonderland*) is why the Statute is unfair.

This very argument was made in the *LaHue* appeal where counsel argued that the "one purpose test" makes "virtually every agreement between a hospital and physician unlawful because the hospital executive will always have patient referrals in mind, at least to some degree."[30] The Tenth Circuit disagreed and noted, "We do not perceive any such problem and conclude a fair hearing of the Act provides reasonably clear guidelines for law enforcement officials, juries and courts to evaluate and discern illegal conduct."[31] That may have been true of the *LaHue* matter, where the 10th Circuit refers to the dealings between the parties as a "pay-for-patients" scheme, but what about the *Hanlester Network*? Hanlester believed he was right and even though not a criminal case, fought the case to the HHS Department Appeals Board, to the district court where the government's motion for summary judgment was granted and then to the Ninth Circuit where Hanlester "won," but was bankrupt. How many clients have the resources and the perseverance to battle a crusade from March 1991 to July of 1994 to vindicate themselves? Yet that is what needs to be done to turn the tide. The government is on a winning streak and now seeks to extend that streak into more and more tenuous cases. Therefore, the gauntlet has been laid down to defense counsel to fight cases that seek to expand the Statute. That fight may extend to the U.S. Attorney personally, to Main Justice, or in the court, but it must be fought to bring the pendulum back to the middle.

The Statute is clearly too broad, hence, every effort should be made to come under the protection of a Safe Harbor or seek out an Advisory Opinion[32] before a deal that appears problematic is consummated. Just as importantly, a health care regulatory attorney should review any business deal which has referrals as an overtone. For what might be considered a "good deal" for a business lawyer can be an illegal deal to a health care lawyer. Health care fraud is still the No. 2 priority of the Justice Department. "Prudence" is the watch word. "Wink and a nod" deals should be avoided (recall in the *LaHue* case counsel was also charged with violating the law) and common sense must prevail over dollars.

Recall the words of Justice Potter Stewart in *Alberts v. California:*[33]

> I shall not today attempt further to define the kinds of material I understand to be embraced with that shorthand [hardcore pornography]; and perhaps I could never succeed in intelligibly doing so **but I know it when I see it** and the motion picture in this case is not that.

I trust counsel will know a deal which violates the Statute when they see it and will seek to avoid placing their client and themselves in harm's way.

Endnotes

1. 760 F.2d 68 (3d Cir. 1985).
2. 42 U.S.C. § 1320a-7b.
3. United States Sentencing Commission, *Guidelines Manual*, Guideline, 2B1.1, 2B4.1, 2F1.1.
4. 760 F.2d 68, at 70.
5. *Id.* at 71.
6. 871 F.2d 105 (9th Cir. 1989).
7. *Id.* at 108.
8. *Id.*
9. *Id.*
10. 874 F.2d 20 (1st Cir. 1989).
11. *Id.* at 29.
12. *Id.*
13. *Id.* at 30.
14. *Id.*
15. 261 F.3d 993 (10th Cir. 2001).
16. 217 F.3d 823 (10th Cir. 2000).
17. *LaHue,* 261 F.3d at 997.
18. Ronald LaHue was sentenced to 37 months imprisonment, Robert 70 months, and Anderson 51 months plus fines.
19. *LaHue,* 261 F.3d at 1003, citing *McClatchey,* 217 F.3d at 835.
20. *Id.* at 1007.
21. 51 F.3d 1390 (9th Cir. 1995). Although not a criminal prosecution, the Anti-Kickback Statute was implicated in the context of a permissive exclusion from Medicare/Medicaid.
22. *Id.* at 1400.
23. *Id.* at 1399.
24. *Id.* at 1398.
25. 42 C.F.R. § 1001.
26. *Id.*
27. *See United States v. Ratzlaff,* 114 S. Ct. 655 (1994); *United States v. Starks,* 57 F.3d 833 (11th Cir. 1998).
28. 42 U.S.C. § 1395nn.
29. N.Y. Public Health Law §§ 238 *et seq.*
30. *LaHue*, 261 F.3d at 1007.
31. *Id.*
32. 42 C.F.R. § 1008.47.
33. 354 U.S. 476.

Gregory J. Naclerio is Chair of the Ruskin, Moscou, Evans & Faltischek Health Care Regulatory Group, representing a wide variety of clients. Previously, he was the Regional Director with the New York State Special Prosecutor for Medicaid Fraud Control on Long Island.

A Defense Perspective on Administrative Proceedings

By Hermes Fernandez and Stuart Klein

Health care providers, be they licensed professionals or institutions, hold significant interests in their continued ability to deliver health care services. A licensed physician, for example, has pursued and received a bachelor's and medical degree, and most likely, has completed three to four years of residency. A skilled nursing facility may represent several million dollars of investment, care for several hundred residents and employ scores of individuals. When the government acts against these interests, typically it acts through administrative action, and the health care provider's interests are adjudicated through an administrative proceeding.

Administrative proceedings do not include the procedural protections traditionally applicable in a judicial proceeding. Typically, administrative proceedings include greatly truncated discovery, relaxed evidentiary rules and hearing officers employed by the prosecuting agency.

Virtually every lawyer is familiar with the legal axiom that the process due is dependent upon the importance of the interests at stake.[1] This article will describe certain administrative procedures applicable to the health care industry. It will also question whether the process that has been provided is sufficient to the interests at stake.

What Process Is Due?

Due process "considerations do not require the full panoply of procedural tools available to civil litigants in an administrative proceeding."[2] The Legislature and courts have ceded considerable authority to administrative agencies in the conduct of administrative proceedings, and in the results of those proceedings. Although administrative proceedings are adversarial, the rules established for judicial proceedings are generally inapplicable. In the administrative process, the administrative agency employs the prosecutor and judge, and selects the jury. The rules of evidence, if applicable at all, are greatly relaxed, allowing the administrative agency to rely on written reports prepared outside of the hearing. If an evidentiary hearing is held, there is a right to cross-examination, but an aggrieved health care provider is not always entitled to an evidentiary hearing.

Despite the important interests that have been charged to administrative adjudication, these proceedings are conducted with remarkably little judicial oversight. An aggrieved provider may invoke judicial review pursuant to Article 78 of the Rules of Civil Procedure, but the standards of review essentially yield a high level of autonomy to the administrative agency. Absent an error in the application of law, an agency's determination will be upheld if it is supported by substantial evidence.[3] The substantial evidence test essentially involves a sweep of the record. If there is evidence in the record sufficient for a reasonable person to reach the same conclusion reached by the agency, the agency's determination will stand.[4] Make no mistake, this is not a review as to whether the determination is supported by a preponderance of the evidence. A record review is limited to searching for items of evidence that support the agency's determination. Moreover, appellate courts are not allowed to disturb the administrative agency's findings as to witness credibility. Such issues are solely within the province of the administrative agency during the course of the hearing.[5]

The deference accorded the administrative fact finder is not unlike that afforded to a jury or trial court. But in the administrative proceeding, unlike the judicial arena, the administrative agency acts as prosecutor, judge and often jury. And, in an administrative hearing, the decision may be based upon hearsay.[6] Although issues of credibility are charged to the administrative fact finder, in at least some instances, hearing panel members may be absent from the hearing, left solely to read the hearing transcript prior to reaching a decision.[7] Those differences raise questions as to whether the near absolute deference is appropriate in the administrative setting.[8]

As for the imposition of penalties, the courts will only overturn an agency's penalty if it is considered "so disproportionate to the offense, in light of all the circumstances, as to be shocking to one's sense of fairness."[9] This "shocks the conscience" standard is violated only if the penalty "imposed is so grave in its impact on the individual subjected to it that it is disproportionate to the misconduct, incompetence, failure or turpitude of the individual, or to the harm or risk of harm to the agency or institution, or to the public generally visited or threatened by the derelictions of the individuals."[10]

In short, judicial oversight of the administrative process is minimal. The agencies have virtually a free hand. It is important, therefore, that the procedures employed by those agencies be fair to the subject health

care provider. Unfortunately, in too many instances, they are not.

This article will next examine several common administrative proceedings, as representative of those faced by health care providers. We will examine proceedings under the New York Medical Assistance program, professional discipline proceedings under the New York Education Law and physician discipline proceedings. We will also briefly discuss the survey process as applicable to skilled nursing facilities.

1. Medical Assistance Program

Pursuant to the rules and regulations promulgated under Title 18 of the New York Codes, Rules and Regulations, the New York State Department of Health (DOH) is vested with the power to sanction persons under the Medical Assistance (MA) program, recover overpayments due to unacceptable practices, and even seek restitution.[11] When exercising this power, DOH must follow certain procedural steps before instituting any penalty.

If DOH intends to sanction a provider or require restitution or repayment due to an overpayment of MA benefits, DOH must send a notice of proposed agency action.[12] The notice states the reasons for the intended action, the legal authority, nature and amount of overpayments, if any, and informs the MA provider that it has the opportunity to file written objections or submit documentation in support of its objections to the proposed action.[13] Although an MA provider may always be represented by counsel, DOH rules and regulations do not require that the provider be advised of that right.

Following the submission of any written objections or documentation by the provider, DOH is required to review such material and determine whether to issue a notice of agency action.[14] The agency action can include exclusion of the provider from the MA program for a specific period of years and restitution for overpayments.[15] DOH's determination to sanction a provider is entirely within DOH's discretion.[16] The notice of agency action includes such things as the date the sanction will take effect and the right of the sanctioned party to appeal the determination.[17] Invoking the right to appeal, however, does not stay the sanction. This is particularly significant. DOH makes and enforces its determination without the prior approval of even a putatively neutral person. Before the provider has any meaningful opportunity to appeal, the sanction takes effect. This is true whether DOH seeks the recoupment of funds, or even exclusion from the MA program. In other words, the sentence is imposed before the trial is held. Termination from the MA program can be a death sentence. Unless the provider has the economic wherewithal to survive termination, the right to appeal becomes meaningless.

Presumably, termination is reserved for the worst actors. With hearing rights only after the fact, the determination of who the worst actors are is largely ceded to the DOH. The process virtually takes on faith that DOH will exercise this authority appropriately.

Short of termination, the DOH can take significant action against a provider by stopping or limiting reimbursement of pending Medicaid claims. This "withhold" authority is an interlocutory remedy. A provider may challenge the "withhold," but there is no right to a hearing. Instead, the regulations provide that a provider may submit a written request for reconsideration of the withhold.[18] The request is reviewed by the same DOH personnel who put the withhold in place.

The procedures for the recovery of overpayments and the withholding of payments to providers under the MA program are detailed under 18 N.Y.C.R.R. § 518. Recovery of overpayments may be made in connection with an audit, review or investigation under Part 515 or 517 of Title 18.[19] DOH has the ability to obtain overpayments due to the submission of incorrect or improper claims or for the furnishing of inappropriate, improper, unnecessary or excessive care, services or supplies.[20] Those persons who furnish or supervise the furnishing of medical care, services or supplies are held jointly and severally liable for any overpayments.[21]

The power to withhold is a daunting authority. A continued flow of funds is the lifeblood to many a Medicaid provider. By cutting off those funds, a provider can be brought to its knees, causing its failure and closing before the provider ever has the opportunity to actually contest the DOH's underlying determination.

DOH may withhold current or future payments under the MA program, in whole or in part, when it has "reliable information that a provider is involved in fraud or willful misrepresentation involving claims submitted to the program, or has abused the program or committed an unacceptable practice."[22] What is reliable is charged to the discretion of the DOH. An unacceptable practice can include any billing alleged to be erroneous. Typically, a notice of withholding will be provided prior to or contemporaneously with the withholding; however, the withholding can continue for five days before the provider must receive any notice of it.[23] The notice of withholding must include, among other things, that the withholding is only for a temporary period, specify the claims to which the withholding applies, and advise the provider of the right to submit written arguments and documentation in opposition to the withholding.[24]

Unlike the sanctioning of a provider under this Title, the withholding of payments may occur prior to

the issuance of a draft audit report or notice of proposed agency action.[25] If such a withholding occurs, DOH has 90 days to issue a written draft audit report or notice of proposed agency action.[26] If either of these are issued, the withholding may extend until an amount reasonably calculated to satisfy the overpayment is withheld, pending a final determination on the matter.[27] If the withholding is initiated by DOH after the issuance of a notice of proposed agency action or draft audit report, the withholding cannot continue for more than 90 days unless a notice of agency action or final audit report is sent to the provider.[28] If such occurs, the withholding may continue until an amount reasonably calculated to satisfy the overpayment is withheld, pending a final determination on the matter.[29] Finally, if DOH initiates a withhold at the request of another agency, such as the Attorney General's Office, the withholding can continue until the agency in question determines that there is insufficient evidence to support an action against the provider or the proceedings are completed.[30]

As a condition of participation in the MA program, each Medicaid provider agrees to maintain books and records in accordance with the MA program's rules and regulations, and to be subject to periodic audits. Failure to comply with this regulation constitutes an unlawful practice and could result in exclusion from the MA program.[31] During the audit process, the DOH is not required to review all of a provider's records, but may utilize a statistically valid sample.[32] At the conclusion of the audit, DOH conducts an exit conference with the provider and presents the provider with a draft audit report.[33] The provider may submit written comments on the draft audit along with material or documentation the provider wishes to be considered in support of its objections. DOH considers such material in preparation of the final audit report.[34] The final audit includes DOH's final findings along with a demand for repayment of invalidated claims.[35] After the issuance of a notice of determination, interest begins to accrue.[36]

Recently, DOH has introduced an aggressive new wrinkle into the audit process, not reflected in the regulations. With the completion of the audit, DOH makes a demand for payment of a certain amount. However, DOH adds that if the provider asserts its right to appeal the final audit report, DOH will seek repayment of a greater amount. This practice is objectionable on its face, as the audit results are supposed to reflect DOH's best estimate of erroneous overpayments. Either DOH is inappropriately discounting its findings in order to discourage appeals, or it is inappropriately seeking to penalize those providers who have the audacity to challenge its methods and conclusions.

This bi-level demand is objectionable for several other reasons. It is an inappropriate manipulation of DOH's right to conduct its audits through statistical sampling. The use of statistical sampling allows the DOH to review a statistically valid sample rather than the entirety of a provider's claims. The DOH may then extrapolate results.[37] If the DOH is manipulating those results, as the use of alternate numbers suggests, its authority to use a sampling method must be questioned.

It is also inappropriate as an attempt to manipulate the proof burdens established for the administrative appeal. This arises from the fact, in the evidentiary hearing, that the Medicaid provider has the burden of proof if the DOH's final determination has invalidated any Medicaid payment. To prevail, the provider must show that the determination of the DOH "was incorrect and that all claims submitted and denied were due and payable under the program, or that all costs claimed were allowable."[38] By threatening to seek a higher amount on appeal, the DOH is relying on those presumptions to defeat a challenge to the higher number.

Finally, the possibility of a higher demand appears to be of questionable validity because it calls into question what is the DOH's final determination. That an administrative agency is bound by its final determination is a long held and meaningful protection to the administrative litigant. DOH cannot make its *final* determination a moving target. A "person is entitled to a hearing to have the department's final determination reviewed."[39]

The DOH's statistical sampling methodology is presumed to be valid.[40] The provider may challenge the statistical method used, but faces the burden of disproving the DOH's methods and conclusions, rather than the DOH supporting those methods.[41] As noted above, once the administrative hearing begins, the burden of proof generally falls upon the provider. If the DOH's final determination was to impose a sanction on the provider, the provider also bears the burden of establishing any mitigating factors that might affect the severity of the sanction imposed.[42] The burden of proof, however, falls upon the DOH if the determination was based upon an alleged failure of the provider to comply with generally accepted accounting, business, professional or medical practices or standards of health care.[43] In such cases, DOH also bears the burden of establishing that such practices or standards in fact actually exist.[44]

During the administrative hearing, the DOH faces minimal evidentiary foundation requirements. Besides the presumptive validity of its statistical sampling method, material such as computer-generated documents prepared by DOH showing the nature and amount of payments under the MA program are presumed admissible.[45] At the hearing, a provider does have the ability to introduce evidence and cross-exam-

ine witnesses. However, the ability to cross-examine witnesses is mitigated by the fact that hearsay evidence is admissible.[46] One of the fundamental deficiencies of hearsay evidence is that it is not subject to cross-examination.

In invoking its rights to an administrative hearing, the provider finds itself playing on the DOH's home court. The hearing officer "is a person who is employed by the department to conduct administrative hearings."[47] The fact that the administrative law judge is employed by DOH is not lost on clients. It creates real questions regarding the administrative law judge's impartiality. In writing this, we do not mean at all to suggest that the men and women who serve as administrative law judges do not strive for fairness. Indeed, our experience has been that they do.[48] Nevertheless, DOH's administrative law judges serve two masters—fairness and DOH. DOH controls their purse strings, their salaries and their career advancement. These ties create at least the appearance of a conflict of interest. These ties also should be contrasted against the ethical obligations applicable to attorneys generally, requirements such as the bar on representing adverse parties and avoiding even the appearance of impropriety.[49]

Besides playing on the agency's home court, the Medicaid provider also finds itself with greatly restricted discovery rights. There is no general right to discovery of relevant information, as in civil litigation. Instead, both parties are obligated to provide copies of the documentary evidence planned to be used at the hearing, if requested, at the pre-hearing conference.[50] Since the pre-hearing conference can be held as late as seven days before the hearing, DOH controls the agenda and the information. Since the provider's books and records have been open to DOH, DOH is much less interested in the provider's disclosure. Notably, by limiting pre-hearing disclosure to evidence intended to be introduced, DOH is able to shield other relevant information that the appealing provider might otherwise find useful. The appealing provider is left to surmise the testimony of DOH's witnesses. In these proceedings, cross-examination is not for the faint of heart.

2. Professional Discipline

Article 130 of the New York Education Law provides for the regulation of the admission to, and the practice of, numerous professions within the health care sector (e.g., physicians, nurses, pharmacists, etc.). This section discusses the procedures under the Education Law and Public Health Law for disciplining health care professionals.

i. Procedures for Professional Misconduct (Non-Physicians)

The procedures for non-physician professional discipline are set forth in Education Law § 6510. The State Education Department (SED) is required to investigate each complaint which alleges conduct which, if true, could constitute professional misconduct.[51] After investigation, SED must make a determination whether to prosecute.[52] Before pursuing charges, SED must first consult with a professional member of the applicable state board for the profession, such as the State Nursing Board.[53] Following an investigation of a complaint of professional misconduct, if the SED intends to pursue charges, it must prepare a statement of charges.[54] The statement of charges must state the statutes or regulations violated, and concisely state the material facts supporting each charge.[55] A copy of the charges must be served upon the licensee at least 15 days before the hearing.[56]

The investigation process itself can place a licensed professional at substantial risk. Licensed professionals are required to cooperate with SED investigations.[57] Many professionals fail to recognize that an investigation is the precursor to an adversary proceeding. We recommend that professionals obtain the assistance of counsel the moment an investigation has begun.

Professional misconduct violations involving a minor or technical nature may be resolved by expedited procedures which limit the use of the adjudicatory process.[58] However, contested disciplinary proceedings and other proceedings that are not resolved in an expedited manner must be tried before a hearing panel of the appropriate state board.[59] Like the defendant in a civil lawsuit, the licensee is afforded the opportunity to answer the charges against him or her, may be represented by counsel at the hearing, has the right to produce witnesses and evidence, can cross-examine witnesses and may issue subpoenas in accordance with the CPLR.[60] There is no right to discovery, however. Rather, the parties must disclose the evidence they intend to introduce at the hearing at least five days before the hearing. This is a distinct advantage to SED as prosecutor. SED has fully investigated the matter, with the cooperation of the professional. SED will also have reviewed the professional's records.

The hearing panel consists of three or more members, two of whom must be from the applicable state board for the health care profession at issue. The third must be a public representative, i.e., a consumer representative, or a member of another state board.[61] The executive secretary for the state board for the representative profession appoints the hearing panel and appoints its chairperson.[62] An administrative officer, who is designated by SED, is vested with the authority to rule on all motions, procedural issues and legal objections.[63] The administrative officer also drafts the hearing panel's report, which is subject only to the review and approval of the panel's chairperson.[64] In practice, the administrative officer who is appointed by

the SED, is also an attorney licensed in the state of New York who is employed by the SED.[65]

It has been our experience that the SED does not maintain a separation between attorneys employed as hearing officers and those acting as prosecuting attorneys. They work out of the same units, in the same office space. This writer has even experienced the situation where the administrative officer and prosecuting attorney shared a secretary.

The administrative officer plays a critical role in the hearing process. With the authority to rule on all evidentiary issues, the administrative officer can control the flow of the hearing, and the evidence that will be heard by the hearing panel. As the rules of evidence do not apply, the administrative officer is charged with great latitude.[66] In addition, as scrivener of the hearing panel's report, the administrative officer plays a key role in advising the panel of the applicable law and shaping its decision.

The panel is not bound by the rules of evidence. Thus, the hearing panel's decision can be based entirely on hearsay evidence.[67] In practice, this means that the SED can base its entire case on the report of its investigator. Although the licensed professional retains the right to cross-examination, the admission of hearsay testimony limits that right. It is also noteworthy that in the hearing process, a panel member may be absent for some part of the hearing. In those circumstances, the hearing panel member may simply provide assurances that he or she will read the transcript of the missed testimony.[68] This procedure, obviously meant for convenience, ignores the important credibility determinations that can only be made through the live viewing of a witness's demeanor.

At the conclusion of the hearing, the panel, by majority vote, reaches a conclusion on each charge. A professional's license can be lost by a 2-1 vote. These conclusions are then reflected in a written report. The report must include findings of fact, guilt determinations on each charge and a recommendation of the penalty to be imposed.[69] The penalties recommended can range from censure and reprimand to revocation of the licensee's professional license.[70]

Note that the panel's finding and conclusions are only recommendations. The final determination rests with the Board of Regents. Before the Board of Regents acts, however, the panel's report is reviewed by the Regents Review Committee.[71] That review is based upon the transcript and the report of the hearing panel.[72] Prior to the meeting of the Regents Review Committee, SED notifies the licensee of the meeting, his or her right to appear, the right to be represented by counsel and whether he or she is required to appear.[73] The Regents Review Committee submits its written report to the full Board of Regents.[74]

Board of Regents review is the third and final stage in the administrative review process. The Board of Regents considers the transcript of the hearing, report of the hearing panel and report of the Regents Review Committee, all before deciding whether the licensee is guilty on the particular charges, and what penalties, if any, should be imposed.[75] The ultimate decision of the Board of Regents requires an affirmative vote of a simple majority its members.[76] If a hearing panel has recommended a finding of "not guilty," and the Board of Regents disagrees with that finding, the Board must remand the matter to the original hearing panel or to a new panel for a new hearing.[77] An aggrieved professional can seek review pursuant to Article 78 of the CPLR. These proceedings are returnable before the Appellate Division, Third Judicial Department. The decision of the Board of Regents "shall not be stayed or enjoined except upon . . . a showing that the petitioner has a substantial likelihood of success."[78]

The single most important element in this process is the evidentiary hearing before the panel. But throughout, the process is controlled by SED. SED chooses the members of the hearing panel. SED chooses the administrative officer. An SED employee writes the hearing panel report. SED staff prepare the case for the Regents Review Committee and write its report. Ultimately, SED staff prepare the matter for the Board of Regents. The licensed professional is at the mercy of SED staff and the Board of Regents.

ii. Physician Misconduct

Discipline of physicians is charged to the New York State Department of Health (DOH), through the Board of Professional Medical Conduct (BPMC).[79] Public Health Law § 230 details the procedures that must be followed when instituting a disciplinary action against a physician. The procedures are largely similar to those under the Education Law, but there are significant differences.

Where the Commissioner of Health, after an investigation and a recommendation by a committee on professional medical conduct, finds a physician's conduct to constitute an imminent danger to the public health, the Commissioner may summarily suspend the physician's license. In such circumstances, the physician is entitled to a hearing commencing within ten days and ending within 90 days of the suspension.[80] Otherwise, the DOH may not act against a physician without the concurrence of a physician member of the Board of Professional Medical Conduct. In addition, a physician is entitled to be interviewed by a physician member of the BPMC before the DOH acts.[81] This is a meaningful protection, not shared by other professions. In addition, if

the investigation is to continue after the interview, the physician must be given written notice of the issues and an opportunity to respond in writing.[82]

Where an administrative delay has significantly and irreparably hindered a licensee in preparing his or her defense, the court reviewing the final administrative order may dismiss the proceeding.[83] However, absent a showing of actual prejudice, a simple delay will not be enough to annul an administrative agency's determination.[84]

Once the physician has received notice of the charges, he or she is entitled to file a written answer to each of the charges and allegations.[85] Like an answer in a civil proceeding, any charge or allegation not answered will be deemed admitted.[86] A physician may be represented by counsel, and produce witnesses and evidence on his or her behalf during the hearing.[87] Additionally, during the hearing, the licensee will have the right to cross-examine witnesses and have subpoenas issued requiring the production of witnesses and evidence as prescribed by the CPLR.[88] As in the SED proceeding, there is limited disclosure.

An administrative hearing pursuant to Public Health Law § 230 is conducted by a Committee on Professional Conduct. The Committee consists of two physicians and one lay member.[89] There is no requirement that the physicians on the Committee be of the same medical discipline as the physician under review. Overseeing the Committee is an administrative officer, appointed by the Commissioner of Health, who acts as the judge during the proceeding.[90] Any conclusions made by the Committee must be based on a preponderance of the evidence.[91] The Committee rules on guilt and imposes a penalty.[92] As in the SED process, if one member of the three person committee becomes incapacitated, or deceased, the outcome of the hearing is not affected as long as a new officer is appointed and avers that he or she has considered the evidence and transcript.[93] Unlike the SED process, the Committee renders a final decision, subject to further administrative appeal by either the physician or the DOH.

Appeals do not go directly to the courts. Rather, appeals of findings of the Committee on Professional Conduct go to the Administrative Review Board for Professional Misconduct (ARB), another Health Department entity.[94] The ARB consists of five members of the BPMC appointed by the Governor with the Senate's consent.[95] Of the five members on the ARB, three must be physicians, the remaining two are lay members of the BPMC.[96] Appeals to the ARB are not limited to questions of law, or even of determinations of guilt. Appeals can be limited to merely the penalty imposed. Although the concept of double jeopardy does not apply to administrative proceedings, DOH appeals, especially of penalties, have a certain Star Chamber quality to them. The DOH can continue to pursue its desired result despite the fact that the Committee charged with weighing live testimony has reached a different conclusion. One must question the fitness of the ARB to consider penalties when it is engaged in a mere record review.

As with the SED process, the physician discipline process is controlled by DOH. Especially at the ARB level, from the defense perspective, one must wonder how independent the process remains. It is a fair question whether the ARB responds to the Commissioner's general direction and remains cognizant of the Commissioner's overall goals for physician discipline as it considers the record before it.

An appeal of penalties (expect annulment or suspension without stay or revocation) to the ARB stays the penalties until the ARB has rendered its final determination.[97] The ARB is not bound by the Committee's determination as to penalty. Rather, the ARB may impose whatever penalty it deems just and proper.[98] The ARB needs only a majority to act.[99] Orders of the ARB, like decisions of the Board of Regents, are reviewable pursuant to the procedures under Article 78 of the CPLR.[100]

3. Nursing Home Surveys

Skilled nursing facilities, intermediate care facilities for the mentally retarded and other institutional providers are subject to an inspection process, commonly referred to as a survey.[101] The survey is a necessary process to the facility's continued receipt of Medicare and Medicaid funding. The purpose of the survey process is to ensure that facility residents are well cared for. Surveyors review a facility against the Medicare conditions of participation and standards of care. Where deficiencies are found, the facility may either challenge the surveyors' conclusions, or may develop a plan of correction for the deficiencies. Once the plan of correction has been accepted and implemented, the facility will be re-surveyed.[102]

A facility unhappy with the survey results may invoke its right to an administrative appeal, described in point 1, above. There are certain aspects of the survey process that can make the administrative appeal process particularly ineffective.

Facility deficiencies are graded on a scale. Several years ago, HCFA, now CMS, directed its surveyors to be harsher graders. As a result, surveyors are doing so, and are issuing grades of real consequence to facilities. This is quite serious. A sufficiently low grade prevents a skilled nursing facility from accepting any new Medicare or Medicaid admissions until a plan of correction has been accepted, and the facility has been re-sur-

veyed. In addition, a facility subject to a ban on new Medicare and Medicaid admissions is barred from training new nurse aides for 24 months. These are quite serious penalties and go to the fiscal stability of the facility. Skilled nursing facilities depend upon high occupancy levels to meet their expenses. Interference with new admissions can cost a facility tens of thousands of dollars per month, depending on the facility's size. Because of what has become chronic labor shortages in the health care industry, many providers conduct their own nurse aide training programs. The inability to operate such a training program interferes with a provider's ability to meet its staffing needs, thereby making the delivery of care more difficult.

We are not at all suggesting that poor care should be tolerated, but neither should the survey process interfere with the delivery of quality care. The survey process should not be punitive; its focus should be on improving the quality of care.[103]

In many ways, the survey process is subjective. The subjective nature of the process is underlined by the HCFA directive to increase the level of deficiencies. But even without that directive, the survey process includes numerous opportunities for subjective judgment. Is an open door a failure to maintain a resident's privacy? If so, what level of deficiency should be ascribed? Surveyors also interview residents. Those interviews are entirely appropriate and add to the value of the survey. Nevertheless, surveyors must be sensitive to the fact that not all resident's provide reliable statements. Some residents' physical or mental health may impair the quality of the information they provide the surveyor. Surveyors also must be sensitive to the statements of employees. Does the employee have an ax to grind?

The credibility of the surveyors' sources are critical. The administrative hearing process does not provide a good vehicle to challenge those sources. The survey report has a presumption of validity. It provides the basis for the agency's action.

Conclusion

The public deserves quality health care, delivered in an honest manner. When the quality of care is below acceptable standards, or when dishonest or erroneous claims for reimbursement have been made, the government has a duty to act. When acting to protect the governmental interest, however, there needs to be greater recognition of the important interests held by providers, be they individuals or institutions. A better balance needs to be struck, one that recognizes the importance of the provider interests at stake.

Endnotes

1. See *Mathews v. Eldridge,* 424 U.S. 319, 334-35 (1976).
2. *Sinha v. Ambach*, 91 A.D.2d 703, 457 N.Y.S.2d 603, 604 (3d Dep't 1982).
3. *See Freyman v. Board of Regents,* 79 A.D.2d 719, 720, 434 N.Y.S.2d 733, 735 (3d Dep't 1980).
4. *See Stroker v. Tarentino,* 101 A.D.2d 651, 652, 475 N.Y.S.2d 562, 564 (3d Dep't 1984).
5. *See Abraham v. Board of Regents*, 216 A.D.2d 812, 813, 629 N.Y.S.2d 299, 300 (3d Dep't 1995).
6. *See Eves v. Passidomo,* 121 A.D.2d 538, 538-39, 503 N.Y.S.2d 596 (2d Dep't 1986).
7. *See Dorsey v. Board of Regents*, 87 A.D.2d 728, 449 N.Y.S.2d 337, 338 (3d Dep't 1982).
8. The result of an administrative hearing cannot be challenged due to the lack of effective assistance of counsel. *See Allen v. Board of Regents,* 140 A.D.2d 824, 825, 528 N.Y.S.2d 211, 213 (3d Dep't 1988). A hearing may also proceed without the provider or provider's counsel present. *See Dorsey,* 87 A.D.2d at 728, 449 N.Y.S.2d at 338.
9. *Pell v. Board of Educ.*, 34 N.Y.2d 222, 233, 356 N.Y.S.2d 833, 841 (1974).
10. *Id.* at 234, 356 N.Y.S.2d at 842.
11. *See* 18 N.Y.C.R.R. § 515.1(a).
12. *See* 18 N.Y.C.R.R. § 515.6(a)(1).
13. *Id.*
14. *See* 18 N.Y.C.R.R. § 515.6(b). If DOH intends to take action following a provider audit, DOH will have provided the agency with a draft audit, and an exit conference. DOH will then consider and address provider's comments before issuing a final audit.
15. *See* 18 N.Y.C.R.R. § 515.3.
16. *Id.*
17. *See* 18 N.Y.C.R.R. § 515.6(b)(2).
18. *See* 18 N.Y.C.R.R. § 518.7(a).
19. *See* 18 N.Y.C.R.R. § 518.1(d).
20. *See* 18 N.Y.C.R.R. § 518.3(a-b).
21. *See* 18 N.Y.C.R.R. § 518.3(c).
22. *See* 18 N.Y.C.R.R. § 518.7(a).
23. *See* 18 N.Y.C.R.R. § 518.7(b).
24. *See* 18 N.Y.C.R.R. § 518.7(c)
25. *See* 18 N.Y.C.R.R. § 518.7(d)(1).
26. *Id.*
27. *Id.*
28. *See* 18 N.Y.C.R.R. § 518.7(d)(2).
29. *Id.*
30. *See* 18 N.Y.C.R.R. § 518.7(d)(3).
31. *See* 18 N.Y.C.R.R. § 515.2(b)(6).
32. *See* 18 N.Y.C.R.R. § 519.18(g).
33. *See* 18 N.Y.C.R.R. § 517.5(a).
34. *See* 18 N.Y.C.R.R. §§ 517.5(c), 517.6(a).
35. *See* 18 N.Y.C.R.R. § 517.6(b)(1-5).

36. *See* 18 N.Y.C.R.R. § 518.4(c).
37. *See* 18 N.Y.C.R.R. § 519.18(g).
38. 18 N.Y.C.R.R. § 519.18(d)(1).
39. *See* 18 N.Y.C.R.R. § 519.4(a).
40. *See* 18 N.Y.C.R.R. § 519.18(g).
41. *Id.*
42. *See* 18 N.Y.C.R.R. § 519.18(d)(2).
43. *See* 18 N.Y.C.R.R. § 519.18(d).
44. *Id.*
45. *See* 18 N.Y.C.R.R. § 519.18(f).
46. *See* 18 N.Y.C.R.R. §§ 519.8(e), (b).
47. 18 N.Y.C.R.R. § 519.3(d).
48. A party can request that the hearing officer remove himself or herself if they believe a bias exists, but the removal determination is ultimately made by the hearing officer whose removal is requested. *See* 18 N.Y.C.R.R. § 519.15(c)(4). If the hearing officer chooses not to remove himself or herself, the decision is automatically reviewable, but it is reviewed internally by DOH's general counsel. *See* 18 N.Y.C.R.R. § 519.15(c)(6-8).
49. *See* The Lawyers' Code of Professional Responsibility, DR 5-105 and 9-101.
50. *See* 18 N.Y.C.R.R. § 519.14.
51. *See* Education Law § 6510(1)(b).
52. *Id.*
53. *Id.*
54. *See* Education Law § 6510(1)(c).
55. *Id.*
56. *See* Education Law § 6510(1)(d).
57. *See* 8 N.Y.C.R.R. § 29.13.
58. *See* Education Law § 6510(2).
59. *See* Education Law § 6510(3).
60. *See* Education Law § 6510(3)(a).
61. *See* Education Law § 6510(3)(b).
62. *Id.*
63. *Id.*
64. *Id.*
65. *Id.*
66. *See* Education Law § 6510(3)(c).
67. The rule commonly referred to as the legal "residuum rule" which states that at least some quantity of evidence which supports the administrative decision has to be of a kind admissible in a court, is no longer recognized in New York.
68. *See* Education Law § 6510(3)(c).
69. *See* Education Law § 6510(3)(d).
70. *See* Education Law § 6511.
71. *See* Education Law § 6510(4)(a).
72. *See* Education Law § 6510(4)(b).
73. *Id.*
74. *Id.*
75. *See* Education Law § 6510(4)(c).
76. *Id.*
77. *Id.*
78. *See* Education Law § 6510(5).
79. *See* PHL § 230(1).
80. *See* PHL § 230(12)(a).
81. *See* PHL § 230(10)(a)(iii).
82. *Id.*
83. *See Lawrence v. DeBuono*, 251 A.D.2d 700, 701, 673 N.Y.S.2d 773, 774 (3d Dep't 1998).
84. *Id.*
85. *See* PHL § 230(10)(c).
86. *Id.*
87. *Id.*
88. *Id.*
89. *See* PHL § 230(6).
90. *See* PHL § 230(10)(e).
91. *See* PHL § 230(10)(f).
92. Where a physician has been disciplined in another state, the procedure on referral from the other state is limited to the question of penalty.
93. *See Freymann v. Board of Regents*, 102 A.D.2d 912, 477 N.Y.S.2d 494 (3d Dep't 1984); *see also* PHL § 230(10)(c).
94. *See* PHL § 230-c.
95. *See* PHL § 230-c(2).
96. *Id.*
97. *See* PHL § 230-c(4)(a).
98. *See* PHL § 230-c(4)(b).
99. *See* PHL § 230-c(4)(c).
100. *See* PHL § 230-c(5).
101. *See* 42 C.F.R. § 488.305.
102. *See* 42 C.F.R. § 488.110.
103. We would be remiss to raise concerns about what appears to be the punitive direction of the survey process without also mentioning available informal dispute resolution process. This process can be useful, but does rely on the provider working with the very surveyors who found deficiencies.

Hermes Fernandez is a partner in the firm Bond, Schoeneck & King, LLP, and a member of the firm's Health Care Group. He advises and represents health care providers in a number of areas, including transactional and regulatory matters, and related litigation. He is a *magna cum laude* graduate of Syracuse University College of Law.

Stuart Klein is an associate with Bond, Schoeneck & King, LLP, and a member of the firm's Health Care Group and Litigation Department. He is a *magna cum laude* graduate of Syracuse University College of Law.

Substandard Quality of Care Used as a Basis for False Claims Act and Criminal Liability in Nursing Homes

By Lourdes Martinez and Nora A. Colangelo

Residents of nursing homes across this country are entitled to receive the necessary care and services that will enable them to attain or maintain their highest practicable physical, mental and psycho-social well-being.[1] However, "quality of care" issues do exist. In recent years, both federal and state governments have begun to use substandard quality of care as a basis for False Claims Act cases and criminal liability in the nursing home industry. This practice is likely to continue given both the financial recovery that can be achieved and the government's commitment to seeing that the quality of resident care in nursing homes is enhanced.

The Federal False Claims Act

Enacted in 1863 to fight rampant over-billing of the federal government by opportunistic contractors during the Civil War, the False Claims Act[2] has become the federal government's "weapon of choice" in pursuing alleged fraud and abuse in the health care industry. According to a recent study, between 1986 and June 2001, the federal government recovered $8 for every $1 spent in fighting health care fraud and abuse using the False Claims Act.[3]

In 1986, the False Claims Act was strengthened. Amendments were added which strengthened the *qui tam* or "whistle-bower" provisions, by creating a cause of action against employers who retaliate against a whistle-blower who pursues a company engaged in fraudulent billing. Since then, *qui tam* cases have accounted for approximately 57 percent of the total civil fraud monies recovered. Altogether, as of fiscal year 2000, the government has recovered almost $7 billion in improperly paid funds from those accused of fraud since the 1986 amendment to the False Claims Act. In fiscal year 2000 alone, $840 million of total civil fraud recoveries was from health-related cases.[4]

The False Claims Act provides for a minimum $5,000 penalty—and as much as a $10,000 penalty—for *each* false claim submitted for payment to the federal government. In addition, the government can also collect double or triple damages. Health care entities that have violated False Claims Act provisions may also face exclusion from further participation in federally funded health care programs.[5]

In order to sustain a charge under the False Claims Act, the government need only prove that the defendant acted "knowingly" in submitting the claims. This means that the government must prove that the defendant either (1) submitted the claims with actual knowledge that they were false; *or* (2) submitted them with a deliberate ignorance as to their truth or falsity; *or* (3) submitted them with a reckless disregard for their truth or falsity.

Importantly, no specific intent to defraud is required. Although innocent mistakes are not actionable under the False Claims Act, the government will often presume recklessness if there is a *pattern* of billing errors or if the health care provider had *notice* through a prior Medicare audit or Medicare bulletin. For nursing homes, repeat deficiencies on state surveys that remain uncorrected could also develop into a pattern of reckless disregard that the government could use to develop an action under the False Claims Act.

To understand the scope and power of this statute, consider the following example:

Assume that a nursing home has incorrectly assessed the acuity of 300 residents and, that as to each claim, the nursing home received an overpayment of one single dollar. If the government was able to establish that these 300 claims were submitted knowingly or even recklessly, the nursing home could face potential liability not only for the $1 overcharge for each claim ($300), but would be potentially liable for treble damages ($900), and—most important—for $10,000 per false claim, leading to a potential $3 million False Claims Act liability.

The *size* of the false claim may become less important as the *number* of such claims increases. The number of claims routinely submitted by health care providers can create massive False Claims Act exposure!

Traditionally, in the health care context, the government has utilized the False Claims Act in pursuing monetary recovery from providers who have (1) billed for unnecessary medical services, (2) double-billed for services provided, (3) billed for a more expensive service when a lesser service was provided, or (4) falsified a diagnosis or other information to secure payment. Today, however, the government has expanded its application to include false claims action against those who provide substandard care, under the theory that when providers submit a claim to the federal government through Medicare or other federally funded programs, they certify that the services performed meet community standards. If the standard is not met (says

the government), the claim may be false! To date, the use of the False Claims Act in cases of substandard quality has been applied primarily to the nursing home industry.

False Claims Act Cases in Nursing Homes

The first instance occurred in Philadelphia in 1996, when the U.S. Attorney for the Eastern District of Pennsylvania filed a False Claims Act suit against the Geriatric & Medical Co., Inc. and its Tucker House Nursing Home (Tucker). The suit accused Tucker of submitting false claims for services that were alleged to be substandard. The government specifically charged that Tucker provided substandard nutritional and wound care to three residents. Tucker eventually settled this case with the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) for $600,000 and agreed to a comprehensive compliance program.

Pennsylvania again fell under the national spotlight in 1998, when a chain of Philadelphia area nursing homes settled False Claims Act cases with the OIG for $500,000 each in satisfaction of charges levied for allegedly presenting false claims to the government. One resident of the Chester Care Center ("Chester") died of injuries allegedly received when she was placed in a scalding tub of water by a nurse's aide (despite the nursing home's alleged knowledge that it had a malfunctioning boiler and despite a previous citation from the state for improper water temperatures). Three other Chester residents died, allegedly as a result of receiving inadequate diabetes care. Another resident of Bishop Nursing Home—another chain member—died because of the home's alleged failure to respond in an appropriate and timely manner to the resident's progressive weight loss and the failure to treat the resultant pressure sores properly. Again, in addition to the monetary penalties assessed, the nursing homes had to agree to the imposition of corporate compliance programs. Chester also agreed to pay for a temporary manager and monitor to oversee the provision of care.

Also in 1998, the Philadelphia Nursing Home agreed to a False Claims Act settlement. The home agreed to upgrade conditions to ensure that elderly and disabled residents are free from abuse and neglect and receive adequate psychiatric, medical and nursing treatment (including daily activities) that enable the residents to reach their highest practicable level of physical and mental well-being. The settlement further provided for the limited use of restraints, a federal monitor to implement the agreed-upon procedures, payment to the federal government of $50,000 and the creation of a special project fund to improve the quality of life for residents. Finally, a geriatric nurse practitioner was appointed by the government at the nursing home's expense to visit the home at least monthly to monitor its compliance with the terms of the agreement.

In July 2000, the U.S. Attorney's office announced the latest False Claims Act settlement in Pennsylvania; this time with Mercy Douglass Human Services Corp., a manager of two Philadelphia nursing homes. In the settlement agreement, the defendant denied any liability, but consented to two orders that provided for $160,000 in restitution to the government, the appointment of a temporary manager, federal monitoring of the facilities at the defendant's expense, and development of protocols for wound care treatment and pain management.

Criminal Liability

Along with its success in bringing False Claims Act suits against nursing homes for substandard or nonexistent care, the government has also generated a large number of criminal prosecutions against nursing home employees. Although difficult to measure exactly how many criminal actions have been brought, in one three-year period—between 1995 and 1998—the OIG excluded 668 nursing home workers from participating in Medicare and Medicaid programs as a result of a conviction related to patient abuse or neglect.[6]

In New York, where over 100,000 people live in 676 nursing homes throughout the state,[7] there has been an aggressive move to apply criminal sanctions to providers who neglect or abuse nursing home residents. In the past, reports received by the New York State Department of Health (DOH) were investigated and resolved by the DOH, often resulting in nursing homes receiving citations of deficiency on state surveys. More of these reports, however, are now turned over for investigation by the Medicaid Fraud Control Unit (MFCU), part of the Criminal Division of the Department of Law under the New York State Attorney General, and frequently result in criminal prosecutions.

But prosecuting criminal actions against those who abuse the frail elderly, who are often isolated and unable to voice their complaints, is difficult. Public Health Law § 2803-d provides an alternative means to impose criminal sanctions. The statute imposes strict reporting requirements on those involved in delivering health care services—from owners and administrators of residences to nursing staff, physicians, social workers, and others—and criminal sanctions for those found guilty of physical abuse, neglect, or mistreatment of a nursing home resident or for those who fail to report such abuse.[8]

Public Health Law § 12-b(2) authorizes the imposition of criminal penalties equivalent to a misdemeanor conviction (a crime punishable by imprisonment of up

to one year or a fine up to $2,000, or both) for anyone found guilty of "willfully" violating Public Health Law provisions. The Court of Appeals has equated "willful" with the term "knowingly," thus the prosecutor need not prove an evil motive or intent to injure, but must only show that a defendant was aware that the conduct complained of was illegal.[9] For example, in *Coe,* the Court held that the People amply established a knowing violation of the statute where the defendant admitted she received a copy of the resident bill of rights and attended lectures regarding its contents, which included mandates that residents must be free from having their personal privacy invaded, being physically or mentally abused, and being forced to do anything against their will. Moreover, the defendant admitted that she knew it was inappropriate to search a resident who physically resisted.[10]

In *People v. Spence*,[11] the appellate court upheld a conviction of willful violation of Public Health Law by a nurse who failed to administer medication to her nursing home patients. The court found that the People had introduced sufficient evidence to show that the nurse had participated in an orientation program at the nursing home that discussed appropriate medical care, the nursing home utilized a particular policy with regard to providing residents with their medication, and that the nurse failed to administer proper medication to her residents on three occasions.

Recent Criminal Cases

The following is a sample of recent announcements from the Attorney General's Office regarding prosecutions brought by the MFCU; most of these cases originated from complaints received by the DOH.

- **August 2001**: A nurse's aide pleaded guilty to endangering the welfare of a physically disabled person in satisfaction of charges arising from an incident at a skilled nursing facility in Montgomery County. The aide had been assigned to bathe a 94-year-old resident who suffered from kidney problems, osteoporosis, chronic heart failure and a history of strokes. Following the bath, the aide raised the woman, who was in a motorized chair, out of the tub and stopped the chair at approximately chest height. He then unbelted her and lowered the chair to waist height, where he left her without the safety belt and walked out of the room. The resident fell out and suffered a fractured right hip. She could not withstand surgery because of her advanced age and died within three weeks.
- **July 2001**: A licensed practical nurse pleaded guilty to Grand Larceny in the Fourth Degree following an undercover surveillance investigation at a nursing home in Orange County involving complaints that powerful narcotic pain patches had been removed from two residents. After his arrest, it was discovered that the aide had previous criminal convictions for first-degree robbery and second-degree rape.
- **June 2001**: A licensed practical nurse pleaded guilty to Willful Violation of Public Health Laws to settle charges that she withheld two prescribed blood pressure medications and one anti-seizure medication from a 69-year-old resident of a Long Island nursing home. The resident was suffering from congestive heart failure, hypertension and other ailments.
- **June 2001**: A licensed practical nurse pleaded guilty to Falsifying Business Records in the Second Degree. She had been charged with failing to change the wound dressing on the foot of an 84-year-old diabetic woman at a nursing home in Rochester and covering up her neglect. This was the nurse's second arrest by the MFCU. According to Attorney General Eliot Spitzer, "Shortly after being fired from an Ontario County nursing home for neglecting patients there, [the nurse] simply crossed the county line and took a similar position at a Rochester facility, where she did the same thing." The nurse had also been previously charged with failing to administer medication and treatment to three separate patients and falsifying medical records.
- **March 2001**: A nursing home resident in Queens suffered traumatic skin tears when he was roughly grabbed by a nurse's aide who eventually pleaded guilty to Willful Violation of Public Health Laws.
- **January 2001**: A licensed practical nurse pleaded guilty to Willful Violation of Public Health Laws, after giving an elderly male resident of a Westchester nursing home twice the amount of Xanax, a controlled substance, as prescribed by his physician.

Why Are Quality of Care Issues So Prevalent?

The OIG reports that despite efforts to monitor and promote quality of care in nursing homes, serious quality of care problems continue to "persist." Indeed, a recent study indicates that 13 of 25 "quality of care" deficiencies have actually increased in recent years, including lack of supervision to prevent accidents, improper care of pressure sores and lack of proper care

for activities of daily living. According to a DHHS Office of Evaluation and Inspections (OEI) Report, several areas that contribute to substandard quality of care in nursing homes have been identified, including, but not limited to, inadequate background checks, staffing shortages, and weaknesses in the state survey process.

First, there is no federal requirement—nor is there one in New York—that criminal background checks on nursing home employees be conducted. Nursing homes are only required to check with state registries of nurses' aides to see if prospective employees have previously been found guilty of patient abuse or neglect. The OEI report noted that because not all states systematically report to their respective state agencies, there is no assurance that individuals who pose a risk will be identified and barred from nursing home employment.[12] In New York, Attorney General Spitzer has twice submitted proposals to the state Legislature—the Nursing Home Quality Improvement Act—that would obligate nursing homes and home health agencies to screen new employees by obtaining criminal history checks.

Second, the OEI report concluded that staffing shortages and the lack of proficiency and training of available nursing home staff leads to chronic quality of care problems, such as failure to adequately treat and prevent pressure sores.[13] Indeed, short staffing has been cited as a possible contributing factor to events that led to the death of a 94-year-old woman who was exposed to 140 degree Fahrenheit water temperatures in her shower. The nursing home administrator had acknowledged before the incident that the facility was short-staffed and suffered from a high rate of nursing staff turnover.[14] Recognizing this pervasive problem, New York State recently provided $530 million to help recruit, retain and train health care workers.[15]

Third, the OEI report cited weaknesses in the state survey process as another contributing factor to the delivery of substandard care. For instance, the OEI found a great deal of predictability in survey methods. This allows nursing facilities to anticipate the arrival of the survey team and thus modify their daily procedures, including temporarily increasing staff, to reduce potential deficiencies. The OEI also reported weak enforcement through the survey process, including state surveyor offices having their own difficulties maintaining adequate staffing levels of appropriately experienced and trained individuals. Additionally, the OEI report found inaction on abuse complaints to be problematic. Of 4,707 abuses reported in ten states between January 1997 and July 1998, one-third were substantiated. But over 90 percent of all complaints concluded with no action, plans of correction or other remedy.[16]

What Steps Should Nursing Homes Take to Protect Their Residents (and Themselves)?

What steps should the nursing home industry take to raise the level of care? There are many tools available for nursing homes seeking to avoid criminal and civil penalties and improve the quality of services delivered to their residents.

Every nursing facility should establish a corporate compliance program and mandate employee adherence to its code of conduct. The program must establish standards through written policies and procedures, include staff training and education, provide for internal auditing, and provide methods for responding to and correcting problems. A compliance program will provide mechanisms for nursing home staff to report their concerns and questions—anonymously or not—and mechanisms for disciplining employees who do not abide by the code of conduct.

In March 2000, the OIG issued compliance program guidance for nursing facilities. It is one in a series of guidances issued by the DHHS to various sectors of the health care industry as part of its ongoing national initiative to engage the private health care community in combating fraud and abuse. It is the only guidance published thus far that identifies "quality of care" as a specific risk area and it lists the following special areas of concern:

- absence of a comprehensive, accurate assessment of each resident's functional capacity and a comprehensive care plan that includes measurable objectives and timetables to meet the resident's medical, nursing, and mental and psycho-social needs;
- inappropriate or insufficient treatment and services to address residents' clinical conditions, including pressure ulcers, dehydration, malnutrition, incontinence of the bladder, and mental or psycho-social problems;
- failure to accommodate individual resident needs and preferences;
- failure to properly prescribe, administer and monitor prescription drug usage;
- inadequate staffing levels or insufficiently trained or supervised staff to provide medical, nursing, and related services;
- failure to provide appropriate therapy services;
- failure to provide appropriate services to assist residents with activities of daily living (e.g., feeding, dressing, bathing, etc.);

- failure to provide an ongoing activities program to meet the individual needs of all residents; and
- failure to report incidents of mistreatment, neglect, or abuse to the administrator of the facility and other officials as required by law.

The Role of Quality Assurance Committees

In addition to implementing corporate compliance programs, all nursing homes are required by law—the Omnibus Budget and Reconciliation Act of 1987—to institute quality assessment and assurance (QA) committees, composed of a physician, the director of nursing, and at least three other staff members. The QA committee is required to meet at least quarterly to review quality indicators and to develop and implement appropriate plans of correction when deficiencies are identified. A strong QA committee, one which really looks at the issues, takes corrective action and ensures that the corrections are truly working will enhance the nursing home's ability to raise its quality of care.

State surveys are a good starting place. The QA committee should review current and past deficiencies to see what corrections need to be implemented, i.e., change in nursing home policy, re-education of staff, hiring more staff, etc. The committee should implement the necessary changes and then revisit the issues at regular intervals to make sure the corrective action has worked. A nursing home that has repeat deficiencies cited through the survey process has already done the government's job of proving the "knowing" element of the False Claims Act: awareness of the deficiency in care and reckless disregard in not correcting the problem.

Nursing homes can also help enhance the safety and well-being of their residents by taking steps to ensure that all employees are adequately screened. This entails checking the state registry, checking the OIG's and the state's online database of excluded individuals, and checking that those employees who are licensed or certified to perform their functions have valid credentials. As a condition of employment, nursing homes should require prospective employees to certify that they have no record of criminal convictions that would preclude employment in a nursing home and have not been excluded from federal health care programs. On an ongoing basis, there should also be a requirement that employees immediately report any criminal conviction or exclusion to the nursing home administrator.

Nursing homes have been put under a microscope by both federal and state regulators. Although this is due primarily to the misconduct of a few, the entire industry is suffering the consequences. Therefore, all nursing home operators should implement strict standards regarding quality of care as well as procedures to enforce these standards. There must also be a willingness to react quickly to any deviations from these standards. Given the government's recent actions, nursing homes that fail to take these necessary measures will undoubtedly heighten their risk of exposure to False Claims Act and criminal liability.

Endnotes

1. *See* 42 C.F.R. § 483.25.
2. 31 U.S.C. §§ 3729 *et seq.*
3. Jack A. Meyer & Stephanie E. Anthony, *Reducing Health Care Fraud: An Assessment of the Impact of the False Claims Act*, New Directions for Policy for Taxpayers Against Fraud, Sept. 2001, at 11.
4. *Id.* at 10-11.
5. *See* 42 U.S.C. § 1320a-7.
6. June Gibbs Brown, Inspector General, Department of Health and Human Services, Office of Inspector General, *Quality of Care in Nursing Homes: An Overview* (OEI-02-99-00060), Mar. 1999.
7. Antonia C. Novello, Commissioner, New York State Department of Health, Commissioner's Column, *Protecting Nursing Home Residents in New York State*, Jan. 2001.
8. Under 10 N.Y.C.R.R. § 81.1 (a), the term "abuse" is defined as: "inappropriate physical contact with a patient or resident of a residential health care facility . . . which harms or is likely to harm the patient or resident. Inappropriate physical contact includes, but is not limited to, striking, pinching, kicking, shoving, bumping and sexual molestation." Under 10 N.Y.C.R.R. § 81.1(b), "mistreatment" is defined as: inappropriate use of medications, inappropriate isolation or inappropriate use of physical or chemical restraints. Under 10 N.Y.C.R.R. § 81.1(c), the term "neglect" is defined as a failure to provide timely, consistent, safe, adequate and appropriate services, treatment, and/or care to a resident, including but not limited to: nutrition, medication, therapies, sanitary clothing and surroundings, and activities of daily living.
9. *See People v. Coe,* 71 N.Y.2d 852 (1988).
10. *Id.* at 855-56.
11. 232 A.D.2d 434 (2d Dept. 1996).
12. OIG Report, *Quality of Care in Nursing Homes: An Overview,* at 26.
13. *Id.*
14. Beth Quinn, *Elderly Woman Boiled Alive*, The Times Herald-Record, July 10, 2001.
15. DOH Commissioner's Column, *Protecting Nursing Home Residents in New York State, supra.*
16. OIG Report, *Quality of Care in Nursing Homes: An Overview, supra* at 23-24.

Lourdes Martinez is an associate with Garfunkel, Wild & Travis, and Nora A. Colangelo is a Compliance Specialist with the firm. Garfunkel, Wild & Travis represents a large and diverse group of health care clients.

Applying Old Laws in New Times: Fraud and Abuse Risk Areas for Medicaid Managed Care Plans

By Robert Belfort and Douglas Sansted

The legal framework governing health care fraud and abuse in this country was largely constructed during an era when nearly all medical services were paid for by government and private payors on a fee-for-service basis. It is not surprising, therefore, that these laws and regulations were primarily intended to discourage and sanction the traditional improprieties of fee-for-service medicine: providing medically unnecessary services, billing for services not performed, upcoding claims and participating in kickback schemes that contribute to increased utilization of health care services. The arsenal of fraud and abuse laws created by the federal government and replicated by many states, including the False Claims Act[1], the Anti-Kickback Law[2] and the Stark Law,[3] were mainly designed to enable regulators and prosecutors to more effectively investigate and prosecute these types of abuses.

Over the past 15 years, however, public health insurance programs have started to change. Although lagging behind the private sector, the federal government and the states have increasingly turned to managed care plans to coordinate the delivery of health care services for a fixed per-patient fee. In New York today, about 26 percent of all Medicaid beneficiaries are enrolled in managed care plans.[4] This percentage is expected to increase substantially over the next few years as New York continues to expand the geographic scope of its section 1115 waiver, under which most Medicaid recipients are required to enroll in a managed care plan. The newer public health insurance programs established by New York State—Child Health Plus and Family Health Plus—do not even offer a fee-for-service option and mandate managed care enrollment for all beneficiaries.

As the nature of Medicaid and the state's other public insurance programs changes, government officials have contemplated the extent to which traditional fraud and abuse laws make sense in the new managed care environment. By shifting risk for the cost of health care services to managed care plans, the state would have appeared to eliminate the incentive for over-utilization and created, instead, an incentive to restrict access to care. Given this reversal of incentives, state and federal regulators have been forced to understand and analyze the different way in which fraud and abuse manifests itself under Medicaid managed care and other capitated programs.

The reorientation process has been a slow one. New York Medicaid managed care plans, to date, have generally not received the same level of attention from fraud and abuse investigators as fee-for-service providers. Indeed, the 2000 annual report of the New York State Attorney General's Medicaid Fraud Control Unit (MFCU), the entity primarily responsible for combating Medicaid fraud in New York, indicates that only 3 percent of the MFCU's prosecutions last year involved managed care plans. However, this is likely to change in the next few years, as the MFCU gains greater understanding of managed care plan operations and a larger percentage of Medicaid recipients receive coverage through the managed care program.

"The newer public health insurance programs established by New York State—Child Health Plus and Family Health Plus—do not even offer a fee-for-service option and mandate managed care enrollment for all beneficiaries."

In prosecuting Medicaid managed care fraud and abuse, the MFCU will rely upon its traditional legal tools: the state's anti-kickback statute as well as laws of general applicability such as Grand Larceny, Offering a False Instrument for Filing and Falsifying Business Records.[5] The MFCU will also look to the provisions of the contracts prepared by the New York State Department of Health (DOH), which are entered into by each Medicaid managed care plan with New York City or the county governments. These contracts include detailed operational requirements in a wide range of areas, including enrollment, disenrollment, marketing, grievance resolution, emergency room treatment, reporting of encounter data, access to care and record retention. As the state's focus on Medicaid managed care intensifies, we expect the following issues to emerge as risk areas in future DOH audits and MFCU investigations and prosecutions.

- *Failure to Pay for Primary Medical Care*. The MFCU has already signaled its intention of developing cases in which plans fail to assign enrollees to a

primary care provider as required by their Medicaid contract and do not pay the standard monthly primary care capitation fee to a provider for these enrollees. In May 1999, the State Attorney General announced the indictment of a managed care plan and its owner for removing 6,700 enrollee names from its primary care physician rosters and failing to pay physicians for these members, while collecting $300,000 in premiums from the state. Although this violation appeared to be egregious, the MFCU may question far more ambiguous practices that arise as a result of the discrepancy between premium payments, which are made on a monthly basis, and Medicaid eligibility, which is determined daily. For example, an enrollee could lose Medicaid coverage just before the first of the month, not appear on the plan enrollment roster generated by the state, regain Medicaid eligibility at the end of the month, and be retroactively enrolled effective the first of the month. At the time the plan made its capitation payments to primary care providers—typically within the first ten days of the month—the individual was not listed as an enrollee and the plan did not pay a primary care provider to coordinate his or her care. If the individual is restored to the roster at the end of the month, is the plan obligated to make this payment even if the provider was never at risk for rendering services to the member? And is this a fraud and abuse issue or really a contractual dispute between the plan and the provider? These concerns should prompt Medicaid managed care plans to carefully review their capitation payment systems and determine whether the plan might be subject to claims that it failed to pay for primary care for members for which it received premiums.

- *Phantom Providers*. Even if a managed care plan properly reimburses physicians, the MFCU is likely to look at whether the services for which the plan was paid were truly accessible. In February 2001, the Attorney General's Office announced that it had entered into a settlement agreement with a managed care plan that had allegedly become aware of complaints from enrollees that two participating clinics would not provide patients with timely appointments and denied them access to care. The plan agreed to repay more than $2 million in premiums it had received for enrollees who were unable to access services from these clinics. Given the state's sensitivity to the potential for under-utilization in managed care, the MFCU may become even more aggressive in this area, targeting plans that may not have had actual knowledge of access problems but did not adequately monitor their providers to uncover these type of abuses. The threat of such liability should encourage plans to be proactive in identifying provider access problems. Plans are required to conduct appointment availability surveys under the state's Medicaid contract and these surveys could serve as part of a comprehensive program to monitor access to care.

- *Cherry Picking*. While the nature of fee-for-service reimbursement often rewards providers for treating the sickest patients, because Medicaid managed care premiums are not risk adjusted in a comprehensive and sophisticated manner, in theory, there is an incentive for health plans to enroll the healthiest individuals. In our view, this practice, referred to as "cherry picking," has been a far more significant issue in the Medicare program, where health plans have been accused of using subtle marketing techniques (bowling parties, marketing at health clubs, etc.) to avoid high risk enrollees. Most Medicaid managed care marketing, in contrast, takes place at government social services offices and provider sites. Nonetheless, we expect the MFCU to carefully analyze the type of provider locations used for marketing purposes and the nature of health plans' interactions with potential enrollees in an effort to determine whether cherry picking occurs in the Medicaid managed care program. Plans would be well advised to review their marketing plans, schedules and training regimens to evaluate whether they are susceptible to these types of claims.

- *Marketing Fraud*. The New York City or county contract entered into by each Medicaid managed care plan contains detailed requirements regarding the accuracy and completeness of marketing materials and the behavior of plan marketing representatives. MFCU and DOH investigators are likely to be particularly sensitive to claims that a marketing representative advised beneficiaries that they would lose their benefits if they did not enroll in the plan. Other abuses that the state may be looking to uncover include the failure to fully explain to the beneficiary that he or she has a choice of plans and that managed care enrollees must generally use only participating providers. Marketing is perhaps the most difficult aspect of a plan's operations to supervise because employees are dispersed outside the office in community-based locations. Training is critical in this area. Plans may also want to consider conducting post-enrollment verification interviews with new members to assess whether marketing representatives complied with all applicable protocols and procedures.

- *Kickbacks for New Enrollees*. In analyzing the application of the Anti-Kickback Law to managed care arrangements, as evidenced by the law's managed care safe harbor, the federal government has generally focused on the extent to which providers are improperly inducing patient referrals from managed care plans. The MFCU may begin to look, however, at inducements that run in the opposite direction. Given the reliance Medicaid managed care plans place on provider site marketing, the MFCU may scrutinize the reimbursement paid by plans to providers in an effort to determine whether any portion of such payments are intended to induce the referrals of a provider's patients to a plan. Concern over such inducements may cause the MFCU to carefully compare the reimbursement levels paid by a plan to different providers. Plans should be particularly wary of arrangements in which the rates paid to a provider are linked to the number of the patients the provider assists in enrolling into the plan.

- *Inaccurate Cost Reporting*. One might expect the MFCU to be looking for inflated costs in the books of cost-based providers, not Medicaid managed care plans that are paid a fixed monthly per enrollee fee, regardless of expenditures. This is not necessarily the case. In the mid-1990s, New York established premium rates through a competitive bidding process in which costs were truly irrelevant. Over the past few years, however, the state has moved to a negotiated rate-setting process, where plans submit premium proposals, and rates are set by DOH, in part, based on historical plan and industry-wide costs. Although there is no formulaic connection between prior costs and future rates, the MFCU is likely to argue that the submission of inflated cost data can influence the rate-setting process and lead to higher premiums. In particular, the MFCU may scrutinize the methodologies used by commercial managed care plans when they allocate a portion of their general administrative costs to their Medicaid product or enter into other arrangements whereby the plan's parent company provides goods or services. The MFCU may also conduct audits to ensure that the costs reported by plans were actually incurred. These types of investigations will be aided if federal Medicaid managed care rules proposed by the Department of Health and Human Services (HHS) in August 2001 are ultimately adopted.[6] Among other things, these rules provide that whenever state payments to a managed care plan are based on data submitted by the plan, including enrollment information and encounter data, the plan must certify the data. A false certification could presumably serve as the basis for a False Claims Act prosecution. In short, cost reporting still matters in a managed care environment.

- *Denial of Reimbursement for Emergency Services*. There are regular disputes between plans and hospitals over a variety of emergency treatment issues, including post-treatment notification mandates and authorization for post-stabilization services. This is particularly true when the care is rendered by a nonparticipating provider and there is no contract clearly spelling out each party's obligations. Plans and hospitals also argue frequently over whether an emergency room visit met the state's "prudent layperson" standard and should therefore be reimbursed at the full emergency room rate. The Attorney General's Office often intervenes in these disputes in response to complaints from hospitals, and we anticipate the MFCU will look carefully at the emergency treatment reimbursement policies of Medicaid managed care plans during routine audits. Although virtually all health plans have institutionalized practices to ensure that pre-authorization is never required for an emergency room visit, implementation of post-treatment notification rules and the prudent layperson standard are probably less consistent. Plans should be especially careful to avoid denying full reimbursement for emergency room claims based solely on diagnostic codes and without regard to presenting symptoms. Such an approach is arguably at odds with the prudent layperson rule and has already been cited by DOH as an area of concern.

- *Other Contract Breaches*. The Medicaid contract executed by managed care plans is extensive and complex, replete with demanding mandates relating to network access, enrollment and disenrollment, encounter data reporting and countless other issues. If the proposed HHS regulations referenced above are adopted, it would be easier for government officials to use breaches of these contractual requirements as the basis for prosecutions under the False Claims Act and similar state statutes. The regulations provide that, regardless of whether governmental payments are based on data submitted by a Medicaid managed care plan, each plan must certify that it is in substantial compliance with its state contract. These certifications would strengthen the legal basis for aggressive False Claims Act prosecutions, where the government could argue that any claim for premiums submitted by a managed care plan constitutes a false claim if the plan failed to comply with any of the material terms of its state contract. The precedent for this approach is a landmark 1996 prosecution by the U.S. Attorney's

office in Philadelphia in which a nursing home was charged under the False Claims Act for failing to satisfy federal quality of care standards.[7] Although the government did not allege the nursing home billed for services that were not actually provided, it argued that the nursing home submitted false claims when it wrongly certified that it was in compliance with federal quality standards. The nursing home settled the case for $600,000. The same prosecutors have filed other cases of a similar nature more recently. This legal theory could be employed against Medicaid managed care plans once the new certification requirements go into effect, making compliance with complex contractual requirements even more critical for these organizations.

* * * *

Because they have been largely insulated from fraud and abuse prosecutions, Medicaid managed care plans in New York have generally lagged behind hospitals and other institutional providers in developing and implementing corporate compliance programs. We expect this to change as MFCU investigatory and prosecutorial activity intensifies. In addition, the federal Medicaid managed care rules referenced above, if adopted, will require all Medicaid plans to adopt compliance programs.

A key element in any effective compliance program is the identification of appropriate risk areas that truly reflect the potential fraud and abuse vulnerabilities of the particular organization. Indeed, adopting an "off-the-shelf" compliance program that is not tailored to meet the individual organization's needs is often worse than having no compliance program at all. Each Medicaid managed care plan, therefore, will have to conduct its own assessment to determine the risk areas addressed in its compliance program. We hope the discussion above provides a good starting point for Medicaid managed care plans seeking to prepare themselves for the increased fraud and abuse scrutiny that is likely to come in the years ahead.

"Because they have been largely insulated from fraud and abuse prosecutions, Medicaid managed care plans in New York have generally lagged behind hospitals and other institutional providers in developing and implementing corporate compliance programs."

Endnotes

1. 31 U.S.C. § 3729 (civil); 18 U.S.C. § 287 (criminal).
2. 42 U.S.C. § 1320a-7b.
3. 42 U.S.C. § 1395nn.
4. *New York State Department of Health Medicaid Managed Care Enrollment Report*, Sept. 2001.
5. Offering a False Instrument for Filing in the First Degree involves offering or presenting a written instrument to a public office with knowledge that the instrument contains false information with the intent to defraud the state. CLS Penal Law § 175.35. The offense Falsifying Business Records involves the falsification of business records with the intent to defraud. CLS Penal Law § 175.110.
6. 66 Fed. Reg. 43090 (Aug. 17, 2001).
7. *United States v. GMS Management-Tucker Inc.* (E.D. Pa. 96-1271).

Robert Belfort is a partner at Kalkines, Arky, Zall & Bernstein LLP in New York City. He represents health care organizations in regulatory and transactional matters. Douglas Sansted is an associate at the firm.

Your Own Petard: The Danger of Inadequate Implementation of Compliance Programs

By Melissa M. Zambri

Introduction

As anyone reading this edition of the New York State Bar Association's *Health Law Journal* will be able to surmise, these are difficult times for providers of health care services. There is an ever-present pressure to do more with less, that is, to provide better care while revenue streams decrease. At the same time, government regulators have made the elimination of health care fraud a top priority. Health care providers in every sector of the industry have realized that not only ill-meaning providers can become subject to an investigation, any provider can easily be a target.

With strong encouragement from the U.S. Department of Health and Human Services Office of the Inspector General (OIG), many providers have correctly decided it is prudent to implement a compliance program. The benefits, many of which are discussed below, can be great for these health care providers. However, "effective" implementation of a compliance program can be a challenging endeavor, as it requires the commitment of management, staff and resources. In these times when providers are seeing financial viability challenged more than ever before, attorneys and consultants who assist providers embarking on the establishment of, or who already have, a compliance program, must continually emphasize the importance of effective implementation. This article will discuss the benefits of an effective compliance program, the meaning of the term "effective," and why having an ineffective compliance program is worse than having none at all.

The Benefits of an Effective Compliance Program

The easiest dangers to identify when an organization fails to adequately implement its compliance program are those associated with the organization failing to receive the benefits of the program. Compliance programs cost organizations a great deal of money, time and resources to formulate. There are numerous advantages to an effective compliance program. An inadequate program will fail to reap the benefits discussed below.

An effective compliance program will disseminate to organization employees, directors and business associates the importance to the organization of law-abiding behavior, thereby discouraging wrongdoing.[1] "A well-structured, widely disseminated, and strongly enforced compliance program encourages employees to think twice before engaging in questionable conduct."[2] An effective program can prevent potential criminal conduct through employee education or through the threat of discipline.[3] Such deterrence of misconduct can ultimately save a company money.[4]

Another advantage of an effective compliance program is the detection of wrongdoing. In this way, an organization can address problems as they arise and minimize adverse consequences.[5] Ideally, a corporate compliance program will detect misconduct before it becomes criminal or in the very least, before the government uncovers it.[6] The company can then pursue remedial action in a more flexible environment, and hopefully without a burdensome investigation by government regulators.[7] Many times, an investigative agency is less likely to pursue enforcement action if it "believes a company is engaged in good faith efforts to avoid and correct problems."[8]

"There is an ever-present pressure to do more with less, that is, to provide better care while revenue streams decrease."

An effective compliance program can also serve as a mitigating factor when dealing with government investigators and prosecutors.[9] Prosecutors have tremendous latitude when determining whether or not to prosecute an entity based upon the actions of corporate actors.[10] Corporations can be held liable for the criminal actions of agents acting within the scope of their corporate authority.[11] Often, a prosecutor will not prosecute a corporation because he or she determines that it would not be in the public interest.[12] A key factor in such a prosecutor's decision is whether the corporation acted responsibly in attempting to avoid the criminal conduct.[13] Organizations with compliance programs can "point to the program as evidence that it is a good corporate citizen and that the wrongdoing constituted aberrant behavior of rogue employees."[14]

By far, one of the most prevalent reasons for the adoption of a compliance program is that its presence at the time of an offense can help to significantly diminish an organization's exposure if sentenced.[15] The *United States Sentencing Guidelines Manual* reduces a convicted

organization's "culpability score" by three points if the offense occurred despite an effective compliance program.[16] A three-point reduction can decrease the fine imposed on the convicted entity by as much as 80 percent, which could save a company several million dollars.[17]

An entity convicted of a criminal offense can be subject to great government intrusion into its affairs.[18] For example, the government may be allowed to inspect the company's books and records, attend management meetings, and conduct audits and investigations.[19] Additionally, in many cases, a court will require a compliance program to be implemented under the direction and review of an applicable regulatory agency.[20] The existence of an effective company-sponsored compliance program can reduce the chances of having one imposed as part of an enforcement action by the government and can reduce the level of government intrusion.[21] In recent years, health care providers particularly have seen bold initiatives taken by the government to ensure compliance with laws and regulations.[22] Settlements with the OIG and the Department of Justice (DOJ) have required organizations to implement a corporate compliance program, including the retention of outside experts.[23] These plans, in many cases, are far more onerous than a voluntary plan, and thus, many providers have responded proactively by forming a plan of their own.

An effective compliance program can also reduce the risk of *qui tam* actions.[24] Financial incentives are only one reason for these suits.[25] Another factor behind these suits is a plaintiff's fear of personal liability for the corporate wrongdoing.[26] A corporate compliance program, effectively implemented, affords frustrated employees, directors and officers with a venue to resolve problems.[27] In addition, a *qui tam* plaintiff, to recover, must be first to report the action to the government.[28] An effective compliance plan reduces the opportunity for plaintiffs to report wrongdoing to the government before the organization has remedied the situation itself.[29]

Compliance plans can also protect a company's directors. An effective compliance plan may be necessary to comply with a director's duty of care and to avoid liability in shareholders' derivative suits.[30] The court in *In re Caremark International, Inc.*,[31] a case which involved fraudulent Medicare billing practices, stated that directors have a duty to assure "that information and reporting systems exist in the organization that are reasonably designed to provide to senior management and to the board itself timely, accurate information sufficient to allow management and the board, each within its scope, to make informed judgments concerning both the corporation's compliance with the law and its business performance."[32] Thus, there is some evidence that an effective compliance program might be necessary to protect directors from potential liability.[33]

The Emphasis on "Effective"

Not all compliance programs reap the benefits outlined above.[34] To receive benefits, a compliance program must be "effective."[35] An effective compliance plan is one "that has been reasonably designed, implemented and enforced so that it generally will be effective in preventing and detecting criminal conduct."[36] Measuring effectiveness can be a difficult but worthy endeavor. The *United States Sentencing Guidelines Manual* has established minimum requirements that must be met to label a program "effective."[37] In summary, compliance programs must

- establish compliance standards that are "reasonably capable of reducing the prospect of criminal conduct";[38]
- assign the responsibility of overseeing the program to specific high level personnel;[39]
- assure that due care is exercised not to delegate discretionary authority to those who were or should have been known to have a "propensity to engage in illegal activities";[40]
- assure that standards and procedures are effectively communicated to employees and agents;[41]
- assure that reasonable steps are taken to comply with the standards;[42]
- consistently enforce standards through disciplinary mechanisms;[43] and
- assure reasonable steps are taken after offense detection to prevent further similar offenses.[44]

Providers should also look to the model compliance guidances set forth by the U.S. Department of Health and Human Services for various health care sectors to ensure that their compliance program has the elements outlined in those guidances.

Of utmost importance is due diligence.[45] There should be unwavering support from top management to establish the importance of the program and to stress that deviations may lead to discipline.[46] An effective compliance program must have teeth. It must be very far from just a "paper" program.[47] There must be constant monitoring and review, plus comprehensive audits.[48] Compliance should be part of every employee's duties and responsibilities.[49]

No matter how carefully a compliance plan is drawn, gray areas undoubtedly will arise.[50] Periodic adjustments may be needed to the plan to reflect changes in the organization's business and regulatory environment or to eliminate any confusion in the plan.[51]

"Any successful program must be a dynamic one—an ongoing process and not a static document."[52] An organization's compliance program should address prior misconduct of the organization and, as such, should be revised as issues arise.[53]

A program should be tailored to an organization's culture, which can only be achieved by a commitment from those at the top of the organization.[54] However, the plan itself should be written so that all employees who need to understand parts of the plan can indeed understand.[55] The plan should be written in plain English rather than legalese or organizational jargon.[56] Employees should feel that the compliance officer is available to hear complaints and suggestions without fear of retribution.[57] Thorough investigations of complaints should be made and documented.[58]

"[A] compliance program that effectively uncovers information but then fails to take appropriate steps to remedy problems can lead to much bigger issues for the entity."

The U.S. General Accounting Office (GAO) looked at indirect indictors to determine compliance program effectiveness including: refunds of provider-identified overpayments, self disclosure of potential misconduct, and increased employee awareness of proper billing rules and other compliance policies and procedures (including awareness of reporting mechanisms and risk areas).[59] The OIG has looked at other items to determine effectiveness including: baseline, or initial, audits; proactive audits based upon an organization's identification of certain risk areas; and audits to quantify the breadth and depth of a suspected or identified problem.[60] The OIG stated that it would look beyond a program's written representations to see how the plan performed during a provider's daily operations. For example, rather than look to see how many training sessions were held, the OIG would look to whether employees retained information from the training.[61] The OIG also stated that it would look for evidence of management's commitment and good faith efforts to implement the program, including funding to the program and the background of the compliance officer.[62]

Why an Ineffective Compliance Program Is Worse Than No Compliance Program at All

In many instances, the establishment of standards of conduct that are then ignored can be far worse than having no standards at all.[63] Says the OIG in many of its compliance guidances:

> Implementing an effective compliance program in a . . . facility may require a significant commitment of time and resources by all parts of the organization. However, superficial efforts or programs that are hastily constructed and implemented without a long term commitment to a culture of compliance likely will be ineffective and may expose the . . . facility to greater liability than if it had no program at all.[64]

As discussed above, benefits come to those who are making a "good faith effort" to correct problems. A poorly implemented compliance program may go to show the opposite intent, that is, a government agency might look at an ineffective plan as a sign of bad faith.[65] For example, the government might argue that corporate officials knew the standards of appropriate conduct, how to respond to inappropriate conduct, were on notice that inappropriate behaviors were going on in the organization, and just chose not to respond, either because of indifference or because of the profit being made from the inappropriate activity.[66] Worse yet, the government could try to prove that the existence of the compliance program was actually a smoke screen to make regulators and investigators believe that the provider was making an attempt at detecting inappropriate conduct.

> The fact that high-level personnel "participated in, condoned, or [were] willfully ignorant of the behavior resulting in the conviction increases the culpability score." On the other hand, the score of organizations with an "effective program to prevent and detect violations of law" is reduced. Further, if the organization reported the violation, cooperated in the investigation, and accepted responsibility for its actions, its culpability score is again reduced.[67]

To have a compliance program and fail to implement it effectively could be interpreted as "willfully ignorant" behavior by investigatory officials. Additionally, a compliance program that leads to an organization failing to report or cooperate might again show an improper intent. As such, all parts of a compliance plan must be properly implemented.

Additionally, an ineffective plan may uncover information that is then inappropriately used.[68] This type of information can be damaging in litigation or in an investigation.[69] For example, internal investigations can be used as road maps for the government or private plaintiffs.[70] Additionally, employee complaints may not be privileged.[71] As such, a compliance program that effectively uncovers information but then fails to take

appropriate steps to remedy problems can lead to much bigger issues for the entity.

A plaintiff's lawyer or prosecutor may try to use the compliance plan as the standard by which employee conduct should be judged.[72] Clearly, should the compliance plan be ineffective, employees will likely fall short of these standards leading to an increased risk of civil and/or criminal liabilities.

"The benefits of a compliance plan in this time of increased scrutiny for providers makes the development of one a necessity."

Conclusion

Once an organization establishes a compliance program, the company must abide by it.[73] In some circumstances, this may force a company to make difficult decisions, such as changing profitable business practices, terminating long-standing business relationships, and/or firing employees.[74] Many times, providers will complain that it is difficult to maintain the corporate determination, dedication and resources necessary to sustain the compliance program under the day-to-day pressures of providing health care.[75] However, once damaging information is discovered, it cannot be disregarded.[76] While remedial action may prove unpleasant, the discovery of it with an appropriate response is a test that will help an organization to prove its dedication to legal compliance.[77]

"Many unsuccessful compliance programs are drafted with great fanfare, promise, and expense only to be quickly relegated to the shelf to collect dust."[78] A program collecting dust is not just a representation of money ill spent, but should be the cause of great concern for the organization as it may go a long way at showing the exact opposite of that which a provider seeks to show by formulating a compliance plan. The benefits of a compliance plan in this time of increased scrutiny for providers makes the development of one a necessity. Providers should beware, however, of not doing a thorough job of implementation and creating their own petard.

Endnotes

1. Dan K. Webb & Steven F. Molo, *Some Practical Considerations in Developing Effective Compliance Programs: A Framework for Meeting the Requirements of the Sentencing Guidelines*, 71 Wash. U. L.Q. 375, 376 (1993); Steven M. Kowal, *Corporate Compliance Programs: A Shield Against Criminal Liability*, 53 Food Drug L.J. 517, 520 (1998).
2. Webb & Molo, *supra* note 1, at 376.
3. Kowal, *supra* note 1, at 518.
4. Webb & Molo, *supra* note 1, at 377.
5. *Id*. at 376; Kowal, *supra* note 1, at 520 ("Reducing the time period when illegal conduct can occur is very important. The calculation of the fine often will depend on the loss by or the gain derived from the criminal conduct."); Greg Radinsky, *Making Sense of the Federal Sentencing Guidelines: How Health Care Corporations Can Manage Risk By Adopting Corporate Compliance Programs*, 30 Am. Health Law. Ass'n, J. of Health L. 113 (1997).
6. Webb & Molo, *supra* note 1, at 377.
7. Kowal, *supra* note 1, at 522.
8. *Id*.
9. Webb & Molo, *supra* note 1, at 376.
10. *Id*. at 377.
11. *Id*. at 377-78; Jonathan C. Poling & Kimberly Murphy White, *Corporate Criminal Liability*, 38 Am. Crim. L. Rev. 525, 528 (2001).
12. Webb & Molo, *supra* note 1, at 378.
13. *Id*.
14. *Id*. at 376. *See also* Kowal, *supra* note 1, at 520.
15. Webb & Molo, *supra* note 1, at 376.
16. U.S. Sentencing Guidelines Manual § 8C2.5(f) (2000). *See* Webb & Molo, *supra* note 1 at 379.
17. Webb & Molo, *supra* note 1, at 379; Kowal, *supra* note 1, at 519.
18. Kowal, *supra* note 1, at 519.
19. *Id*.
20. *Id*.; Radinsky, *supra* note 5.
21. Kowal, *supra* note 1, at 519-20.
22. Gabriel L. Imperato, *Internal Investigations, Government Investigations, Whistleblower Concerns: Techniques to Protect Your Health Care Organization*, 51 Ala. L. Rev. 205, 207 (1999).
23. Thomas E. Bartrum & L. Edward Bryant, Jr., *The Brave New World of Health Care Compliance Programs*, 6 Ann. Health L. 51, 55 (1997); Kowal, *supra* note 1, at 520.
24. Radinsky, *supra* note 5; Bartrum & Bryant, *supra* note 23, at 56.
25. Radinsky, *supra* note 5.
26. *Id*.
27. *Id*.
28. *Id*.
29. *Id*.
30. Kowal, *supra* note 1, at 522.; Imperato, *supra* note 22, at 208-09.
31. *In re Caremark Int'l Inc.*, 698 A.2d 959 (Del. Ch. 1996). *See also In re Oxford Health Plans, Inc.*, 192 F.R.D. 111, 117 (S.D.N.Y. 2000).
32. *See Caremark*, 698 A.2d at 969. *See also* Kowal, *supra* note 1, at 522; Naomi Ono, *Boards of Directors Under Fire: An Examination of Nonprofit Board Duties in the Health Care Environment*, 7 Ann. Health L. 107, 124-25 (1998) ("Directors may be held personally liable for losses caused by a breach of the duty of care either by failing to maintain reasonable information and reporting systems, or by failing to monitor and improve suspect practices which have been brought to their attention.")
33. Kowal, *supra* note 1, at 522.
34. *Id*. at 523.
35. *Id*.
36. U.S. Sentencing Guidelines Manual § 8A1.2 n.3(k) (2000). *See* Bartrum & Bryant, *supra* note 23, at 59-60.
37. U.S. Sentencing Guidelines Manual § 8A1.2 n.3(k) (2000). *See also* Kowal, *supra* note 1, at 523; Poling & White, *supra* note 11, at 548-51.

38. U.S. Sentencing Guidelines Manual § 8A1.2 n.3(k)(1) (2000). *See also* Kowal, *supra* note 1, at 523.
39. U.S. Sentencing Guidelines Manual § 8A1.2 n.3(k)(2) (2000). *See also* Kowal, *supra* note 1, at 523.
40. U.S. Sentencing Guidelines Manual § 8A1.2 n.3(k)(3) (2000). *See also* Kowal, *supra* note 1, at 524.
41. U.S. Sentencing Guidelines Manual § 8A1.2 n.3(k)(4) (2000). *See also* Kowal, *supra* note 1, at 524.
42. U.S. Sentencing Guidelines Manual § 8A1.2 n.3(k)(5) (2000). *See also* Kowal, *supra* note 1, at 524.
43. U.S. Sentencing Guidelines Manual § 8A1.2 n.3(k)(6) (2000). *See also* Kowal, *supra* note 1, at 524; Radinsky, *supra* note 5; Bartrum & Bryant, *supra* note 23, at 73 (noting that discipline must be consistent no matter how high a violator ranks on the corporate ladder).
44. U.S. Sentencing Guidelines Manual § 8A1.2 n.3(k)(7) (2000). *See also* Kowal, *supra* note 1, at 524.
45. Kowal, *supra* note 1, at 524; Poling & White, *supra* note 11, at 548.
46. Kowal, *supra* note 1, at 524.
47. *Id*. at 525.
48. *Id*.
49. *Id*.
50. Bass, et al., *Corporate Compliance: Design and Implementation of an Effective Program,* Tenn. Health L. Update, Dec. 1995.
51. *Id*.
52. *Id*.
53. Bartrum & Bryant, *supra* note 23, at 61.
54. Bass, et al., *supra* note 50.
55. *Id*.
56. *Id*.
57. Bartrum & Bryant, *supra* note 23, at 72; Jamie R. Welton, *In the Wake of the Columbia/HCA Investigations: Plotting a Course for Medicare Compliance*, 7 Elder L.J. 217, 258 (1999).
58. Bartrum & Bryant, *supra* note 23, at 72.
59. U.S. General Accounting Office. *Early Evidence of Compliance Program Effectiveness is Inconclusive*, GAO/HEHS-99-59, at 14, 18.
60. U.S. Department of Health and Human Services Office of the Inspector General. *Building a Partnership for Effective Compliance*, Apr. 2, 1999, at 4.
61. *Id*. at 5.
62. *Id*.
63. Kowal, *supra* note 1, at 523; Bartrum & Bryant, *supra* note 23, at 62.
64. Publication of the OIG Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14289, 14290 (2000).
65. Kowal, *supra* note 1, at 523. *See Stender v. Lucky Stores, Inc.*, 803 F. Supp. 259, 330 (N.D. Cal. 1992) (using company's affirmative action plan to establish discriminatory intent).
66. Kowal, *supra* note 1, at 523.
67. Bartrum & Bryant, *supra* note 23, at 58. U.S. Sentencing Guidelines Manual § 8C2.5(g) (2000).
68. Kowal, *supra* note 1, at 523.
69. *Id*.
70. *Id*.
71. *Id*.
72. Webb & Molo, *supra* note 1, at 379; Kowal, *supra* note 1, at 523.
73. Webb & Molo, *supra* note 1, at 379; Kowal, *supra* note 1, at 523.
74. Webb & Molo, *supra* note 1, at 379.
75. Kowal, *supra* note 1, at 523.
76. *Id*.
77. *Id*.
78. Bass, et al., *supra* note 50.

Melissa M. Zambri is an associate in the Health Care Services and Technology Group of Hiscock & Barclay, LLP, chaired by David P. Glasel. She received her J.D., *cum laude*, from Albany Law School, her M.B.A. in Health Systems Administration from Union College's Graduate Management Institute and her B.S. in Finance, *summa cum laude*, from Siena College.

Bad Medicine

How Government Oversight of Nursing Homes Is Threatening Quality Care*

New York Association of Homes & Services for the Aging

Foreword

The nursing home survey process has become an exercise in both circular logic and turning opinions into truths.

State and federal regulators and consumer groups have been drawing attention to recent increases in survey deficiencies and alleged instances of abuse, concluding that care levels are declining. Fewer numbers of deficiencies cited in New York state in recent years resulted in a call for more stringent surveillance to stop the decline. Yet it is widely known that deficiencies and abuse reports have increased mainly because it was decided that they *should* increase.

In fact, most abuse reports come from nursing homes themselves because they have been told to report everything to the abuse reporting hot line or risk being cited for not doing so. On the subject of surveys, a 1998 White House directive to federal regulators made citing more deficiencies the measure of success for federal and state surveyors. So it is no surprise that the survey process cites more problems or that there are more abuse allegations. In fact, issues that used to be findings are now survey deficiencies, and incidents that clearly do not involve abuse are now abuse. Is care better or worse? Given these scenarios, one is unable to tell.

Some consumer groups claim that more reports of abuse and deficiencies mean worse care. They also "know" that more surveyors are needed so that even more citations can be found. This then will "prove" that care is even worse and in all likelihood more surveyors will be needed, who will find even more problems. This is clearly circular logic. Apparently, in spite of the spirit and intent of federal law, the main purpose of the survey is to find deficiencies rather than measure quality of care and quality of life.

Some opinions are now accepted truths; in math class, these are called "givens." Is it a given that fear of fines and penalties will motivate facilities to improve care? Or the corollary: Is it a given that in the absence of penalties, good care won't happen as a result of its own inherent value?

***This is an excerpt from an August 2001 report by the New York Association of Homes & Services for the Aging, and is reprinted here with that organization's permission. For a copy of the full report—including NYAHSA's recommended reforms—visit www.nyahsa.org.**

Most nursing home operators do not need a "kick in the pants" to behave. How can regulators think that the Little Sisters of the Poor, the Jewish Philanthropies or the United Methodists don't instinctively want to do the right thing? This is a bizarre and crazy notion. Restraint reduction, pain management, injury prevention, incontinence programs, rehabilitation, expanded resident rights—did all these happen because facilities were dragged kicking and screaming to implement them, or were they done because providers learned of their importance? It was knowledge that taught us that restraints were not generally a good thing. Twenty years ago, restraints were the state of the art in "protecting" residents. Indeed, providers often still have to persuade family members that using restraints is not in the resident's best interest. Even issues like residents' rights take a simple raised awareness for change to happen. Facilities want to do the right thing!

An effective survey process is essential. Members of the New York Association of Homes & Services for the Aging (NYAHSA) agree with this given; however, it begs the question as to what is an "effective survey process." Public and private sector evaluation models that seem to work should be explored and incorporated into a new nursing home survey paradigm. What currently exists is a 100 percent dose of negative reinforcement: a list of errors. Who would buy a car when the salesman says this fine car has only one major problem and two minor ones? Is that how anyone would define quality?

Foreword by G. Neil Roberts, CEO/Administrator of Wesley Health Care Center in Saratoga Springs, New York. Mr. Roberts is Chairman of the New York Association of Homes & Services for the Aging and a member of the Association's Nursing Home Survey and Quality Task Force

I. Executive Summary

This report, *Bad Medicine: How Government Oversight of Nursing Homes Is Threatening Quality Care,* attempts to tell the real story about nursing home services in New York state, a perspective that has not been articulated or presented to the state's citizens and consumers of nursing home care. Until recently, what little news New Yorkers heard about nursing homes was mostly negative and in many cases erroneous. In more recent months, the volume of news has increased, but the negativity and inaccuracy has become overwhelming and more damaging. Even the state health department's monthly press releases about nursing home survey results have been inaccu-

rate, unclear and incomplete (and the department has acknowledged these shortcomings).

Founded in 1961, NYAHSA represents over 560 not-for-profit and government-sponsored nursing homes, home care agencies, adult care facilities, assisted living programs, and housing providers. Our nursing home members have reached a point of zero tolerance for a flawed, ineffective, adversarial and egregious surveillance process.

Ironically, as this report will demonstrate, the process in place to ensure quality—the punitively administered survey process—is contributing to a loss in quality, monopolizing limited resources and slowly destroying our service system. It has gradually become an end unto itself rather than a means to the real goal of quality assurance and improvement.

This report is based on the work of the NYAHSA Nursing Home Survey and Quality Task Force, a group of nursing home CEOs, administrators, clinicians and media experts convened in 2001 to study critically important issues around nursing home surveillance and quality. The report:

- identifies a series of key issues surrounding the nursing home survey process, measuring and improving nursing home quality and media coverage;
- factually discredits the existing survey process and demonstrates how the process itself is leading to compromised care of nursing home residents;
- provides the reader with unpublicized but highly relevant information about nursing home care, such as resident and family member perspectives, staff quality, viewpoints of surveyors themselves and quality indicator data; and
- recommends over 40 constructive and achievable strategies to change the ineffectual survey process and focus on measuring and improving quality of care.

New Yorkers and consumers throughout the country deserve to hear the truth about the current flawed survey process. They also deserve a credible process for the future that is properly focused on outcomes, rather than process; on reinforcing success, rather than emphasizing failure. NYAHSA hopes this report will draw attention to the inadequacies of the current process and focus all stakeholders—government, consumers and providers—on an agenda for change, with the end goal of preserving and enhancing nursing home quality of care and quality of life.

II. Introduction and NYAHSA Research

Many of New York's nursing homes are beginning to be caught in an inexorable downward spiral. They cannot find the staff they need; they cannot adequately compensate people even if they could find them because their reimbursement is inadequate; they have great difficulty innovating and improving quality when they are straight jacketed by an incoherent and inflexible regulatory system; they are victimized by misleading negative media coverage; and they cannot hope to fare well in a subjective and process-oriented survey system. As a result, they also cannot hope to improve their public perception and develop an effective constituency to change any of these circumstances.

New York's policymakers have systematically failed to acknowledge and take meaningful steps to address growing work force shortages and these other very real obstacles to maintaining and improving the quality of nursing home care. Worse yet, the proffered government "solutions" for quality improvement proposed minimum staffing ratios without accompanying reimbursement and work force strategies; narrow criminal background check proposals which will further stigmatize careers in nursing homes; espousing "zero tolerance" for error; focusing the survey process exclusively on punitive tactics; and delegating communications about quality of care to the media, are only making a difficult situation worse.

* * *

III. The Survey Process Fails to Meet Its Original Intent

The Nursing Home Reform Act of 1987, which was enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1987, dramatically changed the regulation of nursing home care. The OBRA 87 law called for sweeping nursing home reforms, including mandated training and certification of nurse aides, an emphasis on residents' rights and major changes in the survey process. In spite of an apparent and well-reasoned focus on the outcomes of resident care and quality of life in OBRA 87, the survey process in New York and other states is:

- riddled with inconsistencies, surveyor subjectivity and over-citation of trivia;
- process and paperwork oriented, rather than outcome-based;
- lacking in recognizing or improving quality of care; and
- an abject failure in providing adequate information to consumers and providers.

NYAHSA has repeatedly raised many of these concerns directly with DOH and officials from the Centers for Medicare and Medicaid Services' (CMS) (formerly the Health Care Financing Administration). Based on the statutory and regulatory framework underlying nursing

home surveillance, we believe the federal government bears ultimate responsibility for addressing these concerns through regulatory and policy changes. However, leadership and a willingness to change are also needed at the state level.

The OBRA philosophy is reflected in New York State regulations found in Title 10 N.Y.C.R.R. § 415.1(a). The following passages are excerpted from that regulation:

> A code intended to assure the highest possible quality of care and most meaningful quality of life for all residents must not only accept, but in fact invite variety in nursing home environments, policies and practices, and encourage creativity among nursing home managers and staff.
>
> In order to meet obligations to nursing home residents, this set of requirements, to the extent possible, expresses expectations for facility operation in terms of performance and outcomes rather than by dictating structure and process. It is the intent of these requirements to grant a high degree of latitude and flexibility to administrators and staff while insisting upon conformance to fundamental principles of individual rights and to accepted professional standards.

These expectations are clearly not reflected in the current survey process, as evidenced by many examples discussed later in this report.

NYAHSA and its members support a properly structured and consistently administered regulatory and enforcement system to protect vulnerable residents and ensure high quality care. Part of ensuring quality is dealing forcefully with providers that seriously or repeatedly fail to correct problems. The state and federal governments should take strong actions against providers that fail to correct serious deficiencies, including banning new admissions and closing facilities when appropriate.

The survey process, as currently designed and administered, is a poor proxy for measuring quality of care, and in fact compromises quality. It is replete with subjectivity and inconsistencies in its application, largely fails to focus on outcomes and is devoid of any positive incentives or recognition for a job well done. The survey process is consistently inconsistent in its application.

Furthermore, the surveillance language itself belies what is supposed to be a focus on outcomes. For example, one of the levels within which survey citations are categorized is called "potential for harm." A potential for harm exists for us all—at all times of the day, at work, in our homes and elsewhere—and this hardly speaks to an outcome. To place this in context, a facility could be cited at a level denoting potential for harm because of a wall that needs repainting.

* * *

The increasingly negative climate surrounding the long-term care survey and enforcement process has repercussions beyond the statement of deficiencies and any remedies that may be imposed. The damage to employee morale emanating from such a system makes it far more difficult for long-term care providers to recruit and retain qualified staff at a time when they are already experiencing a staffing crisis at all levels.

Is this destructive process what the original architects of OBRA 87 had in mind? Based on the wording and intent of the law, the answer is "no."

IV. Specific Survey Process Issues

This section of the report discusses a series of problems with the current nursing home survey process. Major areas that are covered include: (a) abuse reporting/citations; (b) intent of regulations/trivia; (c) inconsistency of the process; (d) time frames; (e) adversarial and punitive focus; (f) lack of due process; (g) inappropriate and ineffective punishments; and (h) misuse of quality indicators.

A. Abuse Reporting/Citations

NYAHSA and its members recognize the paramount importance of protecting the safety and well-being of nursing home residents. In fact, nursing homes themselves are probably the most frequent reporters of potential abuse situations. However, many nursing homes have found themselves in "no man's land" either because they properly reported a potential abuse situation or didn't report such a situation, even if it was determined not to be abuse.

The federal survey and enforcement system finds the facility out of compliance for abuse even if an employee committed the abuse against facility policies, the facility promptly investigated the abuse, the facility took appropriate action against the employee, and the facility reported the abuse, its investigation, and its actions to the appropriate state office. This is an area where the federal system is inadequate, unless the only goals are to blame and punish the provider, regardless of its culpability.

Clearly, facilities are being inappropriately cited for abuse, neglect or mistreatment. Some actual examples follow.

1. *Issue:* A facility resident was injured when she fell from the toilet. Staff were not in attendance but the resident had no history of falls, had requested to be left in private, and the care plan did not call

for staff supervision while in the bathroom. The facility was cited because the resident sustained an injury.

Question: Is every injury reportable as abuse and neglect even when there is no relationship to staff action(s), no violation of the care plan, and no reasonable cause exists for abuse or neglect? We assert that such injuries are not reportable.

2. *Issue:* A facility had an incident in which a resident was found in bed with a fractured leg and the incident hadn't been reported within the facility. During the internal investigation, no staff admitted to having witnessed the incident or knowledge of how the injury occurred. The facility had notified DOH appropriately. DOH conducted an on-site investigation and reportedly found no systems problems with respect to employee screening or abuse prevention protocols, but cited the facility because, it concluded, abuse had occurred.

   Question: Must it be assumed that an injury of unknown origin is solely attributable to staff abuse, neglect or mistreatment? We maintain that it does not.

3. *Issue:* A facility investigated what it quickly determined to be a "non-incident," and did not call it in to DOH as a result. During a federal follow-up survey, the facility was cited for not reporting. The rationale as reported by the federal surveyor to the administrator was, "Any time a facility documents an investigative process, the issue must be called in."

   Question: Is this consistent with regulation? We do not believe so. If this is the case, every incident, whether or not there is reasonable cause to suspect abuse, mistreatment or neglect, must be called in, and the receiving end of the reporting system (i.e., DOH) would find it impossible to investigate each report.

4. *Issue:* A number of facilities have called in some issues that they investigated and took appropriate actions to address. During the standard survey, DOH conducted its follow-up on these issues and cited the facilities for abuse. Rationale: Even though there were no systems problems and the facility had self-reported and acted appropriately, abuse had allegedly occurred.

   Question: Does every instance of either an accident or misjudgment on the part of a staff member constitute abuse, neglect or mistreatment? We maintain that it does not, and that citing as such conflicts with the regulatory intent.

   Question: Why does a facility get cited for abuse when it has self-identified issues and taken the proper actions? (Example: A certified nurse aide (CNA) transfers a resident by herself when the care plan calls for assistance of two. The resident falls and sustains an injury. The facility calls in the incident and takes remedial action with the CNA. The CNA had been properly screened prior to hire and received appropriate in-servicing regarding resident transfers.)

5. *Issue:* New York requires that all nursing home staff applicants (not just certified nurse aides) be checked with the nurse aide registry.

   Question: Is this requirement applied in all states? We have reason to believe that it is not. While we don't oppose the requirement in concept, it nevertheless is an unfunded mandate and we question the fairness of this process being imposed inconsistently among states.

The current climate of "zero tolerance" for human error and unfortunate, not preventable accidents is unacceptable and contrary to regulatory intent. It also results in reporting "non-issues" to DOH, since facilities fear reprisal for "failure to report" these non-issues. This diverts facility resources into additional paperwork and process, and consumes DOH resources that should be used to thoroughly and more timely investigate those cases of actual abuse or mistreatment.

The situation can be likened to the role of parenting. Even the best parent's child will inevitably sustain cuts, scrapes—perhaps even broken bones—in the course of growing up. If nursing home surveillance standards and enforcement concepts were to be applied, then nearly every parent in the country would be labeled as, and punished for being, a "non-compliant, substandard" parent.

B. Intent of Regulations/Trivia

We hear all too frequently of instances when deficiencies are unreasonably cited and do not address regulatory intent. The time and effort that goes into writing such citations divert surveyors' attention from other areas that may have more impact on resident care or quality of life. Similarly, facilities are required to submit plans of correction for these citations just as for other deficiencies, and the time and effort they must devote to developing and writing these plans of correction diverts them away from focusing, again, on more important areas. While certain sharing with a facility, citing these types of issues as deficiencies only serves to compromise resident care by diverting limited resources away from patient care.

* * *

Sixteen percent of the statewide respondents to NYAHSA's member survey said their facilities had been cited for deficiencies based on one-time occurrences (e.g., a CNA who did not remove a restraint as care planned, one significant medication error, etc.). This figure ranged as high as 29 percent in the Westchester region.

* * *

Fifty-eight percent of statewide respondents' deficiencies fell into the "isolated" category, meaning that only an isolated number of residents or situations contributed to the citation.

One actual example of a deficiency cited outside of the intent of the regulations involves a facility that sought to establish a more homelike, dignified dining experience for residents. As part of this effort, they developed an alternative system for assuring accuracy of the meal (e.g., consistency, caloric restrictions) and eliminated including meal tickets with meals. During the survey, although there were no errors in meals, the facility was cited solely based on the fact that meal tickets did not accompany the meals. How does this square with the previously cited state regulations (10 N.Y.C.R.R. § 415.1(a)) that, "invite variety in nursing home environments, policies and practices, and encourage creativity among nursing home managers and staff?"

Additional examples of egregious deficiency citations and inappropriate surveyor behaviors are provided later in this report.

* * *

E. Adversarial and Punitive Focus

The survey process has deteriorated into an adversarial and punitive exercise that pits surveyors against nursing homes rather than allowing all parties to work together to improve quality of care and quality of life.

It is a process that anticipates and presumes negative outcomes; one that distinguishes only between compliance and noncompliance, never recognizing excellence. A perfect survey merely means the absence of observed violations or deficient practices. It says nothing of the positive initiatives the facility is taking for its residents or any innovative programs it may have put in place for residents and clients or staff. A deficiency-free survey is perceived less and less as a marker of good care, and more as an indication that the surveyor is not applying the appropriate level of scrutiny to the facility. The result is an environment in which it is almost impossible for a good surveyor and a good facility to coexist.

The punitive nature of this process and information conveyed to the public can be likened to a school which only records the C's, D's, and F's on students' report cards, and totally ignores the A's and B's. How would you feel if you were a student (i.e., a nursing home) in this school? What family and others (i.e., the general public) think of you when they saw your grades?

Recently, a state surveyor in one NYAHSA member facility was heard to say to a colleague, in the presence of (and overheard by) facility staff, the words, "Happy hunting" as the survey inspection began. This clearly typifies the "gotcha" mentality that has overtaken the process, with no regard to positive outcomes.

We have been advised that CMS considers it a conflict of interest for surveyors to act in a consultative manner with facilities. This is an unproductive approach. One needs only to look to communities in which police work closely with the area residents in collaborative and proactive ways. While CMS is a "policing" agency, it would do well to model such programs. There is no reason why state or federal survey agencies should be discouraged from sharing "best practices" and conducting similar activities if CMS agrees that the end goal of the survey process is to improve resident quality of care and quality of life.

F. Lack of Due Process

The survey process does not allow for a fair and impartial means of contesting deficiencies. Federal regulations dictate that each state establish a means for an informal dispute resolution (IDR) process.

IDR is a process of informal administrative appeals that allows facilities to attempt to settle disputes over survey citations. IDR provides an opportunity for providers and surveyors to resolve disputed citations and save the time and costs of a formal appeal. IDR that is fair and equitable to all parties is critical to the integrity of the survey and enforcement process. However, the current IDR process has serious flaws.

This system allows two opportunities (Stage I and Stage II) for facilities to attempt to contest any cited deficiencies. If the IDR is rejected on Stage I, then the state is required to meet either in person or via a phone conversation with the provider. If the Stage II determination is unsuccessful for the facility, it may then request a review by CMS in cases where monetary penalties have been imposed.

While this sounds reasonable on the surface, in reality it is not. New York includes the very same surveyors who were responsible for the facility's survey on the team that reviews and makes determinations on the IDR requests. This is akin to "letting the fox into the chicken coop" and poses an obvious and significant barrier to an impartial review.

* * *

CMS does not allow facilities to use the IDR process to challenge the scope and severity of survey deficiencies, except in cases of substandard quality of care and

immediate jeopardy. Similarly, facilities cannot use IDR to challenge remedies such as fines. Since the scope and severity determination, rather than the actual deficiency, is what leads to the imposition of a remedy, prohibiting challenges to scope and severity or enforcement remedies denies providers due process rights under the IDR process.

G. Inappropriate and Ineffective Punishments

Those facilities that undergo an extended survey and/or are cited with substandard quality of care (SQC) or immediate jeopardy (IJ) temporarily lose their ability to conduct their own CNA training programs. This is true even for deficiencies unrelated to CNA competence. This is a grossly unfair and inappropriate "remedy" which only serves to: (1) make it more difficult to staff the facility; (2) reduce the quality of CNA staff (most providers assert that training within the facility enables the organization to ingrain its value systems and standards throughout the training program); and (3) promote higher CNA turnover rates.

In such facilities, the administrator's name must be reported to the state Board of Examiners for Nursing Home Administrators (BOENHA), which potentially subjects the administrator to disciplinary actions. While this may be appropriate in some circumstances, it is inappropriate in most others. A good example is an administrator who knowingly takes on and tries to improve a troubled facility, only to have a bad survey occur shortly after his or her arrival. This is not only a duplicative process (as there is already a means for BOENHA to take actions against administrators), but is extremely intimidating and contributes to the declining numbers of licensed and aspiring administrators.

While some would argue to the contrary, fines are not always an appropriate "punishment" either. A typical sanction imposed on facilities is Denial of Payment for New Admissions (DOPNA). This means that facilities will not be paid for any newly admitted Medicare/Medicaid residents for a period of time. Under certain circumstances, this "remedy" is imposed without the facility being afforded an opportunity to correct the alleged deficiency(ies). As a result, many individuals needing nursing home care remain languishing in hospitals or their homes, deprived of the care they need. One must ask what this accomplishes other than punishing ill, frail individuals by depriving them of necessary services and a place to call home.

* * *

VI. Egregious Survey Citations and Process Issues

The following are examples of serious issues reported by NYAHSA members, which clearly indicate survey process flaws and shortcomings and divert caregivers' attention away from patient care:

- In one facility, a deficiency was cited because residents were served only one pat of butter with the meal.
- In another facility, a deficiency was cited because cream of wheat was served instead of oatmeal.
- Despite the Department of Health's requirement to deliver the SOD within ten calendar days of the exit survey (42 C.F.R. § 488.110(h) and CMS State Operations Manual (SOM) § 7316), the facility did not receive its SOD for 39 days.
- A CNA went to put a resident to bed and noticed two red areas on the resident's back. The CNA called the nurse who looked at the blouse the resident had been wearing and noticed that the buttons on the back of the blouse lined up with the reddened areas. An incident and accident report was made out, and the facility reported it to DOH. On survey, they were cited because they hadn't interviewed staff for the 24 hours prior to when the reddened areas were detected.
- A facility was imposed with Denial of Payment for New Admissions (DOPNA) and was seeking to be resurveyed in a timely fashion so that the DOPNA could be lifted. The CEO spoke with a CMS official and questioned whether he should call the DOH local area office and request the resurvey. The CMS official told the CEO that he "shouldn't press too hard" or he "may not like what happens."

* * *

- One administrator wrote and told us the true version of cited deficiencies:
  - "A housekeeping attendant noticed a fresh food spill on the wheel of a resident's chair as she was being removed from the dining room. He wiped it off quickly. The surveyor's judgment was this insulted the resident's dignity."
  - "A resident was admitted with very swollen legs. She was placed on physical therapy and medication to reduce the swelling. In two weeks her condition improved dramatically and she returned to her home in the community, very happy with her rehabilitation. In reviewing the closed record, the surveyor's opinion was that we should have formulated a separate care plan for the weight loss recorded from her admission to discharge. This issue had been addressed in several other areas, but not with a separate document."
  - "One tube-fed resident had a small amount of vomitus after a feeding at 11:30 p.m. The nurse

recorded the event in the communication book for the attending physician to note the next day. The surveyor's opinion was that the doctor should have been called that night even though an experienced nurse assessed the situation and in her professional opinion, immediate notification was not justified."

* * *

VII. Countering Negative Publicity

The public's perception of nursing homes is worsening by the day. These increasingly negative perceptions are being fueled by sensationalistic journalism, political pressures cascading down from Capitol Hill to CMS to New York and other states, the menacing terminology used in the survey process, fraud and abuse allegations, and chronic labor shortages. Nursing homes and their employees are being held to unreasonable and, in many cases, unattainable standards.

Over time, negative public attitudes are progressively depriving nursing homes of the work force needed to provide high quality care and undermining financial support for a much-needed service setting. We are already seeing caregivers and administrators exiting the field entirely, without adequate numbers of new applicants coming in to replace them. It has literally reached the point where some caregivers are ashamed to even talk about the fact that they work in nursing homes. This is an alarming trend that all of us—the provider community, policymakers, residents, families and consumer advocates—ought to be doing something about.

New York's health care providers, in particular its long-term care providers, are faced with many challenges, including inadequate reimbursement rates, deteriorating finances and burdensome regulations, while also coping with a severe staffing crisis caused in part by negative media coverage of continuing care issues.

While not all responsibility for the staffing crisis can be placed at the feet of the media, their lack of familiarity with continuing care has resulted in many instances of information being reported inaccurately without challenge. In addition, certain segments of the media have decided their agenda regardless of the validity of their position. Other parties responsible for negative press coverage of long-term care are those, such as DOH, that provide information that is most often damaging and fail to promote positive aspects.

In October 2000, DOH instituted a new policy of issuing nursing home survey inspection results via press release. NYAHSA acknowledges that DOH has made some improvements in the way the information is disseminated. However, there have been several instances in which either the department has issued incorrect information or the media misreported survey results based on correct DOH information.

- A facility that was listed in a DOH press release as having provided "sub-standard quality of care" had never received such a ranking in its more than 100-year history.
- Members of the media have been repeatedly provided with incorrect information regarding deficiencies. In some cases, the deficiencies at one facility were attributed to a different facility, and in other cases deficiencies were reported that were not known to have occurred at any facility.
- A Central New York newspaper carried a wire service story on the October release, highlighted local homes, combined the conflicting data from the versions of the DOH press release and erroneously upgraded the deficiency finding for several nursing homes from "potential for harm" to "actual harm."
- A Buffalo television station incorrectly upgraded the deficiency finding for several nursing homes from "potential for harm" to "actual harm."
- In an apparent attempt to justify proposed Medicaid cuts, DOH released a five-year, retrospective report on industry profits, which maintained that, "over the past five years nursing homes have realized $1.8 billion in profits." New York City's tabloid media seized on the issue and tarred the voluntaries with the same brush used on the proprietary facilities. News reports failed to mention that the last three of those five years have seen a negative trend for providers, and that the average not-for-profit facility lost money on operations in 1999, the most recent year for which data were available.

In these and other unfortunate episodes, the providers nearly always sustain the brunt of the bad publicity and damage, not the policymakers, regulators or the media. NYAHSA has and will continue to play a visible role in insisting on accurate and unbiased coverage in the media. For this to happen, the media must be educated, one reporter, one editor or one photographer at a time, as to the value of long-term care and the impact of negative press coverage.

This educational responsibility is one that regulators and advocates, and the media itself, must also take on.

* * *

XIII. Bad Medicine Is Threatening Quality

Ironically, as this report has demonstrated, the process in place to ensure quality—the punitively administered survey process—is threatening quality, monopolizing limited resources and slowly destroying our serv-

ice system. It has gradually become an end unto itself rather than a means to the real goal of quality assurance and improvement.

A potent mixture of government action and inaction is directly threatening nursing home quality of care and quality of life. Examples that have, for the most part, already been discussed include the following:

- establishing deliberate policies aimed at increasing the number of deficiency citations, which consume provider and regulator resources;
- promoting over-reporting of incidents that do not constitute abuse or neglect;
- citing trivia as deficiencies, rather than as findings;
- espousing zero tolerance, suspending nurse aide training programs and highlighting survey findings to the media, which compromise providers' ability to recruit and retain sufficient staff in the wake of a labor shortage;
- failing to adhere to reasonable time frames for issuing statements of deficiencies, acting on plans of correction and investigating complaints;
- inappropriately imposing large fines and even more costly sanctions, such as denial of payment for new admissions;
- making it difficult for providers to innovate and be creative by imposing an incoherent and inflexible regulatory system;
- promoting public use of survey results to make placement decisions based on a mistaken premise that these results can be used to objectively measure and compare quality across facilities, exclusive of other factors; and
- creating misleading messages about provider profitability, which undermine public support for adequate financing, when government reimbursement is already inadequate.

To further illustrate this point, a number of so-called "quality initiatives" for nursing homes were proposed earlier this year, which included: (1) mandating criminal background checks for nursing home and home care employees; (2) hiring additional nursing home surveyors; (3) increased fines for nursing home deficiencies and higher fines for repeat violations; (4) directing survey fines into a quality improvement account; (5) hiring new auditors for a Medicaid Fraud Strike Force Unit; and (6) establishing expedited procedures to secure involuntary receiverships (i.e., to replace facility operators who allegedly have not ensured safe resident environments).

As with many government initiated "solutions," these initiatives focus almost exclusively on punishments and sanctions rather than on proactive and productive ways of enhancing quality.

* * *

XV. Conclusion

Federal pressures have been responsible for the cataclysmic change over the last several months in the way New York state is administering the survey process. This is an apparent response to the federal government identifying New York as a state that cited relatively low numbers of deficiencies. At any point in time, one state will be citing the fewest deficiencies. Does this mean that this state has the worst nursing homes? If the process were effective in its application, it would mean that this state had the best facilities.

It is time to put an end to the flawed, egregious and ineffective surveillance process now in effect. The process compromises quality of care and quality of life for nursing home residents, picks on vulnerable, altruistic providers whose missions are to provide compassionate care, wastes taxpayer dollars, and is politically motivated and expedient.

Lawmakers, regulators, consumers and providers need to work collaboratively to advance the shared goal of protecting residents. Indeed, the National Nursing Home Reform Act of 1987, which was adopted as part of OBRA 87, specifically called for creating a survey that genuinely measures outcomes, but here we are, 14 years later, still evaluating the process of delivering care and the documentation of care delivery.

To this end, the major strategy should be to press the federal government to replace the flawed survey process with one that truly measures quality of care, quality of life and resident outcomes. It is time, in fact it is long overdue, for a total reexamination of the survey process at both the state and federal levels. Surveillance process reform must be a government imperative, one that involves a nationally focused effort representing all stakeholder constituencies. These stakeholders—consumers, government and providers—should be convened under CMS's leadership to systematically and objectively re-think and revise the current survey process, as well as to consider true measures of quality care.

It is also time for the media to report about nursing home care in a balanced and informed way in order to stem the misguided and overly negative messages to consumers who fear for their loved ones' lives. And, most importantly, it is time for nursing home residents and their families to be afforded an accurate assessment of quality of care and quality of life. NYAHSA and its members remain willing and ready to be part of these efforts.

Robert Abrams

Chair, Health Law Section

Bob is an executive partner of Abrams, Fensterman, Fensterman and Flowers, LLP, a 17-attorney law firm located in Lake Success, New York. The firm provides comprehensive legal services in several areas, including health law, guardianships, elder law, estate planning and administration, corporate, family/matrimonial and related litigation matters.

In furtherance of Bob's understanding and sensitivity to the needs of the elderly as well as disabled persons, he created and served as Editor-in-Chief of *Guardianship Practice in New York State,* a 1712-page book consisting of 27 chapters, over 100 forms and sample pleadings, a comprehensive list of guardianship cases and helpful practice tips. The book has been praised by many professionals, including a law school dean, who remarked that this book is "the most thoughtful and complete treatment of the subject to date. The authors, under the distinguished leadership of Bob Abrams, have not only done a great service to New York's bar and bench, but have also significantly contributed to the now decade-long change in the way the law treats the most vulnerable among us."

Bob is an active member of several professional organizations, including the National Academy of Elder Law Attorneys (NAELA); the American Health Lawyers Association (AHLA); the Nassau County Bar Association, where he serves on the Board of Directors; and the New York State Bar Association (NYSBA). He is the Chair of the NYSBA's Health Law Section and the former Chair of the Elder Law Section. He is the founder of Decision-Making Day, an annual volunteer program sponsored by the NYSBA and recognized by Governor George Pataki. This program was specifically designed to advise New Yorkers of the importance of advance directives, such as health care proxies and powers of attorney. Over the past few years, thousands of attorneys and tens of thousands of New Yorkers have participated in this program. Bob has also served former presidents of the NYSBA on various special committees dealing with pertinent issues, including continuing legal education (CLE), strategic planning and lawyer advertising. He is a sustaining member of the NYSBA and a Fellow of the New York Bar Foundation.

An informative and entertaining speaker, Bob has presented programs to a variety of legal, health care, professional and consumer organizations on both the state and national levels. He has served as a legal expert for Fox Cable Television in connection with the U.S. Supreme Court's ruling on assisted suicide, and has appeared on "Miller's Law," a national show, which is featured on Court TV.

Bob was selected by former Governor Mario Cuomo to serve as a New York State delegate to the White House Conference on Aging (WHCOA) in 1995. As a participant of the WHCOA, Bob was able to recommend national policy initiatives to his fellow conferees. The conference report was subsequently presented to President Bill Clinton and Congress.

Bob has and continues to serve several community, advocacy and public interest organizations in a variety of capacities. Along with the other attorneys in his firm, he has provided legal assistance to indigent individuals and nonprofit organizations.

In addition to his law degree, which he received as an evening division student at New York Law School, Bob earned a Master's Degree in Public Administration from New York University. He is also a New York State-licensed nursing home administrator.

Salvatore J. Russo

Chair-Elect, Health Law Section

Salvatore J. Russo is a health care lawyer with 19 years of experience. He is the Executive Senior Counsel for the Medical/Mental Health Division of the Office of Legal Affairs of the New York City Health & Hospitals Corporation. Mr. Russo is Counsel to the Metropolitan Health Administrators' Association. He has previously served as the In-house Counsel for Maimonides Medical Center of Brooklyn, and as the Director of Legal Affairs for the Greater New York Hospital Association. Mr. Russo is a Phi Beta Kappa graduate of New York University College of Arts and Science. He was awarded the degree of Juris Doctor from Hofstra University School of Law. Mr. Russo is an Adjunct Assistant Professor of Health Management and co-faculty advisor for the Health Care Certificate Program of the New York University School of Continuing and Professional Studies. He writes and lectures extensively in the area of medical/legal topics.

Mr. Russo is Chair-Elect of the Health Law Section of the New York State Bar Association. He previously served as Second Vice-Chair and Treasurer of the Health Law Section. He is also Co-Chair of the Health Rights Committee of the Section on Individual Rights and Responsibilities of the American Bar Association. Mr. Russo is Past Chair of the Public Health Committee of the New York State Bar Association. He is also Past Chair of both the American Bar Association's AIDS Coordinating Committee, and the Special Committee on AIDS and the Law of the New York State Bar Association. Mr. Russo is a member of the American Health Lawyers Association, the American Bar Association and the New York State Bar Association.

Mr. Russo's philanthropic activities include serving as a member of the New Leadership Group of the United Hospital Fund, as well as a member of the President's Roundtable of Xaverian High School in Brooklyn, New York. He has also served six years as a member of the Distributing Committee of the Board of Directors of the United Hospital Fund.

Mr. Russo is the recipient of the 1999 Metropolitan Health Administrators' Association Award of Distinction. He is also a recipient of the Distinguished Alumnus Award for 2000 from Xaverian High School in Brooklyn, New York.

* * *

James W. Lytle

Vice-Chair, Health Law Section
Chair, Biotechnology and the Law Committee

James W. Lytle is a partner in the New York City-based firm of Kalkines, Arky, Zall & Bernstein and is the partner responsible for the firm's Albany office. Prior to joining the firm, he was a partner in the firm of Whiteman, Osterman & Hanna in Albany, where he was a member of that firm's health care and government relations practices. Between 1983 and 1986, Mr. Lytle served as Assistant Counsel for Health and Human Services to Governor Mario M. Cuomo. He is a graduate of Princeton University, with a degree from the Woodrow Wilson School of Public and International Affairs, and he received his law degree from Harvard Law School. He has lectured on behalf of American Health Lawyers Association, the American Society of Law, Medicine and Ethics, the Hospital Education and Research Fund, and other groups. He is Chair of the State Communities Aid Association and a member of the Foundation of Empire State College Board.

Mr. Lytle's practice focuses primarily on the highly regulated area of health care law and regulation. He has represented a wide array of entities—including hospitals, nursing homes, home care agencies, managed care organizations, hospices, behavioral health providers, dialysis facilities and a broad array of other entities—in navigating through the legal, regulatory and political challenges of the modern health care environment.

Philip Rosenberg

Secretary, Health Law Section

Philip Rosenberg is a partner in the Albany office of Wilson, Elser, Moskowitz, Edelman & Dicker LLP. He has been representing health care providers and health care associations for more than 14 years. Mr. Rosenberg's practice encompasses a range of transactional, regulatory and litigation matters, with particular emphasis in reimbursement, fraud and abuse, licensure, tax-exemption, managed care and ERISA. Mr. Rosenberg has authored dozens of articles on health law, and is a frequent lecturer before national and state bar associations and health industry groups.

Mr. Rosenberg received his J.D., *magna cum laude*, from the Benjamin N. Cardozo School of Law at Yeshiva University and his B.S. from the School of Industrial and Labor Relations at Cornell University. Mr. Rosenberg serves as the Secretary of the Executive Committee of the New York State Bar Association. He is also a member of the American Health Lawyers Association and the Health Law Section of the American Bar Association.

* * *

L. Susan Scelzo Slavin

Treasurer, Health Law Section

L. Susan Scelzo Slavin is the litigation partner in the firm of Slavin, Angiulo & Horowitz, LLP in Jericho, New York. The firm practices a wide range of legal services including corporate transactions, commercial litigation, education law, employment discrimination, estate planing and administration, health law litigation, real estate transactions and trust and estate litigation. Ms. Slavin received her undergraduate degree from Boston University and her law degree, *cum laude*, from Touro College, Jacob D. Fuchsberg Law Center, where she was a member of *Law Review*. She is currently enrolled in a Master's of Theology program, having previously studied at Harvard University's Divinity School.

Ms. Slavin has been appointed to the American Cancer Society's Mission 2000, which is a planning effort to reorganize the organization nationally. She is a member of the Advisory Counsel of the American Cancer Society, Eastern Division, which comprises New York and New Jersey. She is a member of the Nassau County Breast and Cervical Cancer Advisory Committee, as well as Cancer Care's Public Policy Committee. She is a member of the American Bar Association, the New York State Bar Association, the Nassau County Bar Association and the Nassau County Women's Bar Association. She serves on the Executive Committee of the New York State Bar Association's Health Law Section as Treasurer and is former Co-Chair of the Section's Committee on Consumer/Patient Rights. Ms. Slavin also serves on the Board of Directors of various organizations, including the National Association of Women Business Owners, Long Island Chapter; Women on the Job; and the Nassau County Bar Association. She also serves as a liaison to the Nassau County Bar Association's Academy of Law, the academic arm of the Association.

Mark Barnes

Chair, Health Care Providers Committee

Mark Barnes, a partner at Ropes & Gray, has practiced and taught law, and administered governmental programs in the health care field for over 15 years. Educated at Yale Law School and Columbia University School of Law, Mark taught full time at Columbia for four years, and more recently has served as an Adjunct Professor of Law at a number of law schools, including Brooklyn Law School and New York University School of Law. He has taught courses in public health law, health care law and finance, managed care law and occupational health and safety.

Mark served as the Director of Policy for the New York State Department of Health AIDS Institute in the early 1990s. In 1993, he was a consultant to the White House National Health Care Reform Task Force, and he served from 1992 to 1994 as Associate Commissioner for Medical and Legal Policy for the New York City Department of Health. In the mid-1990s, Mark was the Executive Director of the AIDS Action Council, where he lobbied and advocated on AIDS funding and policy before Congress, federal agencies and the Office of the President.

Mark represents hospitals, health care associations, physicians, social services agencies and related organizations in regulatory, reimbursement, research, HIPAA compliance and litigation matters. Mark serves as a member of the National Human Research Protections Advisory Committee of the U.S. Office of Human Research Protections and a board member of Doctors of the World. His recent articles on HIPAA compliance and conflicts of interest in human research have appeared in *BNA Health Law Reporter*.

Mark is recognized as one of the top lawyers in the field of research compliance and HIPAA regulations.

* * *

Linda C. Fentiman

Chair, Health Care Internet Committee

Linda C. Fentiman is a Professor at Pace University Law School in White Plains, New York, where for five years she served as Director of the Health Law and Policy Program. She has practiced, taught and published in the areas of criminal law and health law, serving on the faculties of Columbia, Pace and Suffolk University law schools. Professor Fentiman also developed the innovative Health Law Distance Education Program at Pace, a totally asynchronous certificate program in health law, open to practicing lawyers and health care professionals. Linda's areas of expertise are public health law, bioethics (including organ transplantation and substitute medical decision-making for mentally incompetent individuals); health care access, particularly for children and people living with HIV/AIDS and other disabilities; telemedicine and Internet pharmacies; and mental disability law, with a focus on the insanity defense and competency to stand trial. Linda is Chair of the Subcommittee on Health Care and the Internet of the New York State Bar Association Health Law Section, a Fellow of the New York Academy of Medicine and a conference organizer and speaker at the annual ALI-ABA Program on Health Care Law and Litigation. Linda has also served as Chair of the Health Law Committee of The Association of the Bar of the City of New York, Chair of the Section on Mental Disability Law of the Association of American Law Schools, and a Consultant on Law and Ethics at the Massachusetts General Hospital in Boston.

Professor Fentiman holds a B.S. from Cornell University, a J.D. from the State University of New York at Buffalo and an LL.M. from Harvard University School of Law.

Patrick Formato

Chair, Membership Committee

Patrick Formato is a partner in the law firm of Abrams, Fensterman, Fensterman and Flowers, LLP in Lake Success, New York, and the Director of the firm's health law practice group. He received a B.A. from the State University of New York at Albany and a J.D. from Albany Law School. Mr. Formato is a member of the American Health Lawyers Association, the Health Care Compliance Association, the Nassau County Bar Association Hospital and Health Law Committee and the New York State Bar Association Health Law Section.

Mr. Formato has represented a variety of health care providers including but not limited to, skilled nursing facilities, diagnostic and treatment centers, home health care agencies, adult homes, and physicians and physician groups.

Mr. Formato counsels and represents clients in the development and implementation of corporate compliance programs for numerous health care providers. Furthermore, Mr. Formato has provided counsel and assisted health care providers in a variety of matters including but not limited to: fraud and abuse, survey, certification and enforcement, managed care agreements, employment, shareholder and partnership agreements, affiliation agreements, buy/sell agreements, licensure issues, the attainment of certificates of need, advance directives and treatment decision issues, real estate and general business/corporate matters.

Mr. Formato has presented programs to various health care and professional organizations on such topics as fraud and abuse, corporate compliance, reimbursement, and provider contracting. Mr. Formato has also been published in professional and industry journals and newsletters.

* * *

James F. Horan

Chair, Professional Discipline Committee

James F. Horan has served as an Administrative Law Judge for the New York State Department of Health since 1991. Previously, he worked as a Senior Attorney for the Health Department and as Law Assistant to Fulton County Judge Robert P. Best. Currently, he volunteers on Surrogate Decision Making Panels for the New York State Commission on the Quality of Care for the Mentally Disabled. He chairs the Professional Discipline Committee of the NYSBA Health Law Section and serves on the Section's Executive Committee. He also chairs the Administrative Law Judges Sub-Committee within the NYSBA Committee on Attorneys in Public Service. He received his A.B. from the University of Notre Dame and his J.D. from Albany Law School.

Ross P. Lanzafame

Chair, Securing Health Care for the Uninsured Committee

Ross Lanzafame is a partner at Harter, Secrest & Emery LLP in Rochester, New York. He counsels long-term and acute health care providers and health care professionals with regard to business, corporate and government regulatory matters. He advises clients on federal and state regulations governing facility operation, financing, medical records and data confidentiality, patient accounts management, and reimbursement programs such as Medicare and Medicaid. He prepares and appeals certificate of need applications for hospitals and nursing homes and handles special matters such as AIDS in the health care workplace. Ross develops corporate compliance plans and programs for facilities and professionals so as to assure compliance with regulatory and statutory mandates, in particular the fraud, anti-kickback and Stark provisions of federal and state law. In addition, Ross focuses on reimbursement issues affecting health care providers. He analyzes provider reimbursement rates, prepares and prosecutes rate appeals and hearings, and defends providers on rate audits. He provides the economic, methodological and technical analysis of reimbursement issues in support of provider rate litigation.

Prior to attending law school and earning his law degree, Ross managed the neonatal intensive care unit and all surgical units at a major area hospital for four years.

He is a member of the National Association of Chiropractic Attorneys, the National Health Lawyers Association and the American Bar Association Health Law Section. He is also a member of the New York State Bar Association's Health Law Section and Chair of the Section's Securing Health Care for the Uninsured Committee.

Ross is admitted to the bar in New York, Massachusetts and Pennsylvania. His community involvement includes membership on the Board of Directors of the Community Place of Greater Rochester, Inc.; American Lung Association of the Finger Lakes, Inc. (President); American Lung Association of New York State, Inc. (Nominating Committee); the Cornell Alumni Association of Greater Rochester (Past-President); the Rochester Chapter of the Cornell University Johnson Graduate School of Management Alumni Association (Secretary); and the St. Philip Neri-St. Andrew Church Parish Council (President). An avid photographer, he has won several local art awards. Other interests are travel, bicycling and hiking.

He is a graduate of Cornell University, where he also earned a Master's of Professional Studies, Hospital and Health Services Administration. He received his J.D., *cum laude*, from the State University of New York at Buffalo.

* * *

Vincent F. Maher

Chair, Ethical Issues in Provision of Health Care Committee

Vincent F. Maher is an associate in the firm of Gair, Gair, Conason, Steigman & Mackauf in New York City. With his unique background in medicine as a registered nurse and board certified nurse-anesthetist, it was only natural that when Vincent Maher came to the firm in 1985, he was assigned to work on one of the medical malpractice legal teams. Mr. Maher reviews the medical records of prospective cases, evaluates the theories of medical liability, considers the injuries, coordinates review of the cases by retained medical experts and serves as a resource to the firm.

He writes and lectures extensively in the United States and internationally on health issues in relation to law, policy and ethics. He is a tenured full Professor at Iona College, a Fellow of the New York Academy of Medicine, and also serves as Chair of the New York State Bar Association's Health Law Committee on Ethical Issues in the Provision of Health Care.

His other memberships include American College of Health Care Executives, American Health Lawyers Association, American Medical Writers Association and the Regis Bar Association.

Anne Maltz

Chair, Special Committee on Medical Information

Anne Maltz is a nurse-attorney in the Health Law Department of Herrick, Feinstein LLP of New York City. Over the past several years, she has developed a high degree of expertise in state and federal privacy regulations. She is currently Chair of the NYSBA's Special Committee on Medical Information and co-chaired and spoke at a NYSBA CLE-accredited full-day program on the federal electronic transmission, security and privacy regulations and was chair of a comparable program held in June 2001. She has lectured on privacy and confidentiality of medical records at New York Medical College Graduate School of Health Sciences, and on privacy and confidentiality in the context of the Internet for the NYSBA. She recently spoke on HIPAA at the National Labor & Management Conference in Miami, and to attorneys and staff of the New Jersey Department of Health and to attorneys of the New York Department of Health.

Previously, Anne served as general counsel for a major managed care organization in New York where she was in charge of overseeing and participating in provider contracting, licensing initiatives, corporate compliance, grievance and appeals matters, and provided legal support to human resources, provider relations, quality assurance, utilization management and other operational units.

Ms. Maltz holds a J.D. from Brooklyn Law School and a B.S.N. and M.A. in nursing administration from New York University. She is the author of numerous legal articles on health care issues which have appeared in the *New York Law Journal*, *Managed Care Interface* and *Managed Care Negotiator*. Her article on HIPAA appeared in the Summer/Fall 2000 issue of the NYSBA *Health Law Journal*.

* * *

Tracy E. Miller

Immediate Past Chair

Tracy Miller is Vice President for Quality and Regulatory Affairs at the Greater New York Hospital Association. In that capacity, she advances GNYHA's program initiatives related to health care quality, the health care Internet, health disparities, the protection of human subjects in research, genetics, and other issues. With a grant from the Robert Wood Johnson Foundation, Ms. Miller is leading a project to develop recommendations to address the legal, regulatory and policy issues posed by medical practice online.

Prior to joining GNYHA, Ms. Miller was a member of the Department of Health Policy at Mount Sinai Medical School where her work focused on health care quality and use of the Internet to improve patient self-care. In 1998-1999, Ms. Miller served as the Project Director of the Quality Forum Planning Committee, a national bi-partisan panel of health care, consumer and government leaders convened by Vice President Gore to build the National Forum for Quality Measurement and Reporting.

From 1995-1996, Ms. Miller served as the founding Executive Director of the New York State Task Force on Life and the Law established by Governor Cuomo. Under her leadership, the Task Force crafted policy and law for New York State on numerous issues, including the health care proxy, the determination of death, and the procurement and distribution of organs and tissues for transplantation.

Ms. Miller is Immediate Past Chair of the Health Law Section and former Chair of the Committee on Ethical Issues in the Provision of Health Care. She is a graduate of Brown University and Harvard Law School.

Peter J. Millock

Chair, Nominating Committee

Peter J. Millock is a partner at Nixon Peabody LLP and a member of its Health Services Practice Group. Mr. Millock's work is focused on affiliations and mergers of hospitals, physician practice issues, and regulatory and enforcement matters before state agencies. As part of his transactional work, he has counseled clients on federal antitrust laws, federal and state fraud laws and federal tax law.

Mr. Millock served as General Counsel, New York State Department of Health, between 1980 and 1995. He was chief legal advisor to the Commissioner of Health and provided advice to state policy-makers on all health-related matters.

Mr. Millock is a frequent speaker on health care issues before health and legal groups throughout the state. In 1993, he served on the President's Task Force on Health Care Reform as a member of the Legal Audit Team. Mr. Millock is an associate professor at the State University of New York at Albany, School of Public Health.

Mr. Millock received his B.A. in Economics from Harvard College, *magna cum laude*, Phi Beta Kappa; and his J.D. from the Harvard Law School, *cum laude*. He is admitted to practice in the state of New York and is a member of The Association of the Bar of the City of New York and the New York State Bar Association.

* * *

Lynn Stansel

Chair, In-house Counsel Committee

Lynn Stansel has been Associate General Counsel for Montefiore Medical Center in the Bronx, New York, for six years. Prior to coming to Montefiore, she was an attorney with Memorial Sloan-Kettering Cancer Center in New York City for four years. She spent the first seven years of her legal career as a commercial litigator with two Manhattan law firms.

Lynn earned a Master's in Hospital Administration and a J.D. from Duke University in Durham, North Carolina, in 1985. She holds a bachelor's degree in biology from Wittenberg University in Springfield, Ohio. In addition to the New York State Bar Association, Lynn is a member of the In-house Counsel Section of the American Health Lawyers Association.

She lives in Montclair, New Jersey, and has a 3-year-old daughter.

Robert N. Swidler

Acting Editor, *Health Law Journal*

Robert N. Swidler is General Counsel and Vice President for Legal Affairs of Northeast Health, a health care system in New York's Capital Region that includes Albany Memorial Hospital, Samaritan Hospital in Troy, several primary care centers, and "The Eddy"—a network of long-term care and residential facilities and services for seniors.

Previously, Mr. Swidler was director of the Health Law Practice Group of Hiscock & Barclay, (1995-1998) and Deputy Commissioner and Counsel to the New York State Office of Mental Health (1992-1995).

From 1990 to 1992, Mr. Swidler was Assistant Counsel to Governor Mario M. Cuomo, with responsibility for the areas of health, mental health and social services. He helped draft and negotiate numerous laws, including the Health Care Proxy Law (1990), the Medicaid Managed Care Act (1991), the Standby Guardian Law (1992), Early Intervention Services for Infants and Toddlers with Disabilities (1992) and the Mental Health Community Reinvestment Law (1992).

Before that, Mr. Swidler was Staff Counsel to the New York State Task Force on Life and the Law (1985-90), where he helped develop the Task Force's reports and recommendations on brain death, do-not-resuscitate orders, health care proxies, organ transplantation and surrogate parenting arrangements.

Mr. Swidler has written numerous articles on health law topics. From 1999-2000, he was Chair of the New York State Bar Association Health Law Section. He currently serves on the Section's Executive Committee and as Co-Editor of the NYSBA *Health Law Journal*.

Mr. Swidler is a graduate of Columbia Law School ('82), SUNY Binghamton (B.A. '77, M.A. '78) and Stuyvesant High School ('72). He lives in East Greenbush, New York, with his wife Mary and son Eric.

Section Committees and Chairs

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

Biotechnology and the Law
James W. Lytle (Chair)
Kalkines Arky, et al.
121 State Street, 3rd Floor
Albany, NY 12207
(518) 432-5990
Fax (518) 432-5996
e-mail: jlytle@kazb.com

Consumer/Patient Rights
Joseph R. Baker, III (Co-Chair)
Office of the Attorney General
120 Broadway, 25th Floor
New York, NY 10271
(212) 416-8521
Fax (212) 416-8034
e-mail: joseph.baker@oag.state.ny.us

L. Susan Slavin (Co-Chair)
Slavin Law Firm, PC
350 Jericho Turnpike, Suite 101
Jericho, NY 11753
(516) 942-9300
Fax (516) 942-4411
e-mail: ssesqs1@ix.netcom.com

Ethical Issues in the Provision of Health Care
Vincent F. Maher
Gair Gair & Conason
80 Pine Street, 34th Floor
New York, NY 10005
(212) 943-1090
Fax: (212) 425-7513
e-mail: vmaher@iona.edu

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

Health Care Internet
Linda C. Fentiman (Chair)
Pace University School of Law
78 North Broadway
White Plains, NY 10603
(914) 422-4422
Fax (914) 422-4229
e-mail:
lfentiman@law.pace.edu

Health Care Providers
Mark Barnes (Chair)
Ropes & Gray
885 Third Avenue, Suite 3200
New York, NY 10022
(646) 840-6800
Fax (646) 840-6850
e-mail: mbarnes@ropesgray.com

In-house Counsel
Lynn Ann Stansel (Chair)
Montefiore Medical Center
Legal Affairs
111 East 210th Street
Bronx, NY 10467
(718) 920-6624
Fax (718) 920-2637
e-mail: lstansel@montefiore.org

Managed Care
Frederick B. Cohen (Chair)
Independent Health
511 Farber Lakes Drive
Buffalo, NY 14221
(716) 635-3726
Fax (716) 635-3838
e-mail: fcohen@
independenthealth.com

Membership
Patrick Formato (Chair)
Abrams Fensterman et al.
5 Dakota Drive, Suite 206
Lake Success, NY 11042
(516) 328-2300
Fax (516) 328-6638
e-mail: pformato@abramslaw.com

Nominating
Peter J. Millock (Chair)
Nixon Peabody, LLP
1 Keycorp Plaza
Albany, NY 12207
(518) 427-2650
Fax (518) 427-2666
e-mail:
pmillock@nixonpeabody.com

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

Securing Health Care for the Uninsured
Ross P. Lanzafame (Chair)
Harter, Secrest & Emery
One Bausch & Lomb Pl.
Rochester, NY 14604
(716) 232-6500
Fax (716) 232-2152
e-mail: rlanzafame@hselaw.com

Special Committee on Medical Information
Anne Maltz (Chair)
Herrick Feinstein, LLP
2 Park Avenue
New York, NY 10016
(212) 592-1524
Fax (212) 592-1500
e-mail: amalt@herrick.com

Health Law Section

Committee Assignment Request

Please designate the Committee in which you are interested.

____ Biotechnology and the Law (HLS1100)

____ Consumer/Patient Rights (HLS1200)

____ Ethical Issues in the Provision of Health Care (HLS1300)

____ Fraud, Abuse and Compliance (HLS2400)

____ Health Care Internet (HLS2700)

____ Health Care Providers (HLS1400)

____ In-house Counsel (HLS2300)

____ Managed Care (HLS1800)

____ Membership (HLS1040)

____ Nominating

____ Professional Discipline (HLS2200)

____ Securing Health Care for the Uninsured (HLS2500)

____ Special Committee on Medical Information (HLS2600)

Name:_____

Firm:_____

Address:_____

City:_____ State:_____ Zip:_____

Phone:_____ Fax: _____

E-mail: _____

NYSBA 125 Years

Please return to:
Theresa Knickerbocker
New York State Bar Association
One Elk Street
Albany, New York 12207

Publication and Editorial Policy

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

Publication Policy: All articles should be submitted to either:

Dean Dale L. Moore
Albany Law School
80 New Scotland Avenue
Albany, NY 12208
e-mail: dmoor@mail.als.edu

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

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

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

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

ISSN 1530-3926

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

ADDRESS SERVICE REQUESTED

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