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Inside

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THE HEALTH LAW SECTION
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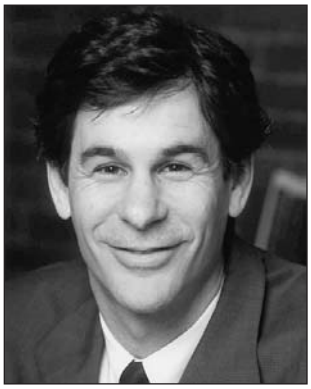
A Message from the Section Chair



There are certain signs of reaching middle age: humming to elevator music, wearing black socks with sandals and tracking monthly pension accruals. Another sure sign is when a year feels like weeks. In my case, then, youth must be long gone. It seems like yesterday when I was entrusted as Chair of the Section, and now it's time to pass on the baton.

Upon looking back at the past year, I am enormously grateful to the many individuals who have contributed their time and talent to the Section. As reported at our Annual Meeting, because of their contributions, the Section's activities and programs have continued to grow. Section membership is also at an all-time high of 1,242. A hearty thanks to the Section's CLE program chairs and speakers, the editors of and contributing authors to the *Health Law Journal,* disseminators of public service information, reviewers of legislative bills, drafters of position statements and those who have facilitated policy dialogues within and outside of the Bar Association. Also, a special thanks to the Committee Chairs (see last page of the *Journal*) who have not only participated in an array of Section programs, but dutifully served as liaisons to Section members.

I would also like to recognize Ed Kornreich and Ann Maltz, co-chairs of the Annual Program, as well as each of the presenters at the Program. While the Section's Annual Program was a one-day event for attendees, it was a multi-month process for those involved in planning the Program. By all accounts, their efforts paid off. The Annual Program, which addressed governance, ethics and compliance in the health care industry, received very favorable reviews, and was a capstone to the Section's CLE calendar.

Looking forward, there is no doubt that the Section will remain a vibrant meeting place for ideas, discussions and programs. Indeed, with the ongoing turbulence in the health care industry and the never-ending issues facing health lawyers, the Section's *raison d'etre* is greater than ever.

That does not mean, of course, that the Section can afford to lumber along, without reexamining its purpose and place. As is the case with any dynamic organization, to maximize its relevance in our shrinking world, the Section needs to periodically reassess itself to move in the right direction. Fortunately, the Section has a strong tradition of doing that.

Not too long ago, for example, a central activity of all NYSBA sections, including the Health Law Section, was to apprise their members of significant legal developments relevant to the section. Nowadays, however, there are several bar associations (e.g., AHLA, ABA) that competently perform that same function. Legal developments can also be readily accessed from countless professional and trade associations, government and even law firm websites. The myriad listserves, chat rooms and e-newsletters, moreover, offer commentaries on just about any significant federal or state legal development. In fact, to our benefit, information—along with a spin-doctor's two-cents—is often a click away.

Rather than expending its resources to race against what can be easily obtained on the Internet, the Section has chosen to report on legal developments less instantaneously, but more incisively. The Section, through various media including live discussions, course books and its preeminent *Health Law Journal* (which is also posted on the website), offers thoughtful and collaborative analyses that are beyond anything that can be gleaned from a chat room or e-newsletter. The Section, moreover, has enriched its own website to include materials that are not posted elsewhere on the Internet, including DOH opinion letters, and is currently exploring with DOH the feasibility of posting certain DOH administrative law judge decisions.

The Section has also sought to complement its CLEs with a mix of skill-based programs that emphasize how to do things, rather than what the law is. Due to the widespread availability of information, coupled with the proliferation of a CLE industry (thanks to the mandatory CLE requirements) that generally offers didactic programs, there are many available resources to acquire substantive knowledge. What is not readily available are programs that teach lawyers to *apply* that substantive knowledge effectively. Whether it is a program that would help lawyers hone their advocacy skills at professional disciplinary hearings or negotiating strategies in structuring a payor-provider agreement, there is an unquestionable need for "how to" programs.

Last Fall, the Section sponsored a successful skills-based program on health care provider transactions. The purpose of the program was not only to address the regulatory framework governing such transactions, but through hypothetical situations and break-out sessions,

to provide practical advice on how to navigate comfortably in certain transactional matters. The Section is currently planning another skills-based program for its annual retreat next year that will be interactive as well. Yes, it's a lot of work to develop a hands-on, skills-based CLE as it necessitates writing case studies, empanelling a seasoned faculty and designing a participatory approach, but, based on current and past feedback, such a CLE is an incredible learning experience for faculty and attendees alike.

The Section is also hoping to refocus its efforts to promote public service activities. One thought, which is in its planning stage, involves encouraging the Section's public service mission by using its website to coordinate *pro bono* activities with legal aid societies and similar advocacy groups. Whether it involves representing a patient at an external appeal or a struggling community-based mental health clinic in a reimbursement matter, the Section can serve as a clearinghouse to match a *pro bono* matter with a Section member willing to handle that matter.

Though the Section has not converted and cannot convert every idea and suggestion into an action plan, due to the contributions of scores of volunteer members, the Section has a record over its short history of evolving to stay on top of its game. So long as the Section remains in motion and welcomes change, that record will continue.

Finally, and speaking of being on top of her game, it is a true privilege to pass the Chair to Lynn Stansel. Lynn has been an indefatigable supporter of the Section for as long as I can remember. I can go on and on about Lynn and her contributions to the Section, but suffice it to say that Lynn is a thinker, a doer and a leader. Most important, Lynn has a clear vision. We will be well served in her capable and caring hands.

All the Best,
Philip Rosenberg

NOTE: Philip Rosenberg's term as Chair of the Health Law Section ended on June 1, 2005, and Lynn Stansel became Chair on that date. Her first message will appear in the Summer/Fall 2005 edition of the NYSBA Health Law Journal.

In the New York State Courts

By Leonard M. Rosenberg

Physician Entitled to Statutory Immunity from Liability for Filing of a Report of Suspected Child Abuse Based on Munchausen Syndrome by Proxy

Mercandetti v. County of Nassau and Gilbert Dick, M.D., Nassau County Supreme Court Index No. 9477/02 (http://decisions.courts.state.ny.us/10jd/nassau/decisions/index/index_new/oconnell/mar2005/009477-02.pdf). The Supreme Court, Nassau County, granted summary judgment dismissal of a suit filed by the parents of the infant plaintiff, Isabella Mercandetti, asserting a host of tort claims against defendants Gilbert Dick, M.D. and the Nassau County Department of Social Services, predicated upon defendants' actions in reporting Isabella's parents for suspected child abuse and the subsequent investigation of the charges. The suit was brought by the parents on behalf of themselves, Isabella and her twin siblings, as all three children were the subject of removal petitions filed with the Family Court by the Department of Social Services. The complaint sought millions of dollars in compensatory and punitive damages.

The Court dismissed the claims against Dr. Dick and Nassau County primarily on the basis of the statutory immunity afforded to mandated reporters of suspected child abuse by the New York Social Services Law ("SSL"). The SSL subjects certain individuals, including doctors, nurses, teachers, law enforcement personnel and others, to criminal and civil liability for their failure to report any suspected case of child abuse. Conversely, when one of these "mandated reporters" makes such a report in good faith they are immune from liability for the consequences of their report.

Dr. Dick, a pediatrician in private practice, provided primary pediatric care to Isabella for approximately one

year following her birth. During this time, Isabella suffered from an unexplained inability to gain weight, medically termed "failure to thrive." Dr. Dick recognized Isabella's failure to thrive within the first two or three weeks of her life, and saw her in his office over 40 times during the year he was her pediatrician in an effort to diagnose and treat any underlying medical cause for her unexplained inability to gain weight. During that year, Isabella was examined, tested, and evaluated by multiple medical specialists, underwent two inpatient hospital admissions, and had a nasogastric tube inserted to allow her care-givers to pump calories into her while she slept. Despite extensive testing and treatment, no medical cause could be found for Isabella's failure to thrive and her weight remained below the 5th percentile for children her age. On her first birthday she weighed only twelve pounds.

One of the myriad specialists to whom Isabella was referred for genetic testing, Dr. Harbison, ordered a "sweat test" to rule out Cystic Fibrosis ("CF") as a cause for Isabella's failure to thrive. Dr. Harbison ordered the sweat test even though Isabella had tested negative for CF at four months of age. CF is a genetic condition that is present at birth—it cannot be "caught" at a later date.

Contrary to Isabella's prior negative CF test, the sweat test results were extremely positive—so positive, in fact, that they were physically impossible. No living human could possibly have as much salt concentrated in their sweat as was indicated by Isabella's first positive sweat test. This "positive" sweat test result set off a chain of events that eventually led to Dr. Dick's report of Isabella's mother to Nassau County Child Protective Services for suspected abuse.

First, Dr. Harbison advised Isabella's parents that Isabella had CF and that Dr. Dick had "missed" this diagnosis. Dr. Harbison then called Dr. Dick to report that the results of the sweat test were "extremely" positive. Not having heard of such high results before, Dr. Dick consulted with several CF specialists and was advised that the results were impossible and that physiologically impossible sweat test results in the range of Isabella's test indicated likely tampering with the test sample. When Dr. Dick investigated the circumstances around the administration of the sweat test, he learned that Isabella's mother had been present during the testing and had taken Isabella to the ladies room, outside the sight of the technicians administering the test, during the testing process.

Because of the impossible results of the first positive CF test, Dr. Dick sent Isabella for a repeat test at a different facility, with instructions to that facility that the test be observed from start to finish. Again, the test result was so positive as to be physically impossible. Inquiry revealed that, once again, the child's mother had taken her to the ladies room while the sweat test was being administered. Under these circumstances—*i.e.*, Isabella's failure to thrive for one year despite extensive testing and excessive alleged caloric intake as reported by her mother; no credible underlying medical cause for Isabella's failure to thrive; and apparent tampering with the sweat tests by the child's mother, a Registered Nurse—Dr. Dick suspected that his patient Isabella was the victim of abuse/neglect *via* the deliberate withholding of food. Dr. Dick suspected that Isabella was a victim of

Munchausen Syndrome by Proxy ("MSP") at the hands of her mother.

The term MSP refers to a form of child abuse in which a child's caregiver, usually the mother who generally has some medical training, either fabricates or causes the symptoms of illness in her child and continually presents the child for medical care on the basis of the fabricated or induced symptoms. The abuse started by the mother may be continued by the child's physicians who proceed, in the most extreme cases, with invasive procedures and even surgery in an effort to find an underlying cause for the symptoms reported by the mother.

In an effort to get Isabella into an inpatient setting immediately, Dr. Dick advised the mother that the results of the second altered sweat test were positive, that Isabella had CF as Dr. Harbison had previously diagnosed, and that the test result was within physiologically possible ranges. He urged Mrs. Mercandetti to immediately admit Isabella to a hospital for further treatment for her CF.

Isabella's mother refused to admit her to a hospital for immediate treatment, even though over a year had passed without a diagnosis and despite the fact that Dr. Dick told her that Isabella needed to be hospitalized immediately. Instead, the mother stated that the family would be going on vacation the next morning and would consider admitting Isabella upon their return.

Pursuant to his mandated legal obligation to report to the state any suspected case of child abuse (SSL § 413), Dr. Dick made such a report. As a result of the report, Isabella was admitted to a hospital for five weeks of evaluation and testing, and Nassau County Department of Social Services ("DSS") commenced child abuse and neglect proceedings against Isabella's parents.

On the family's return from vacation, DSS sent a case worker to the child's home accompanied by two Nassau County police officers. The social worker advised the parents that Isabella needed immediate hospitalization and that they should agree to take Isabella to the hospital immediately or he would return with a court order for Isabella's removal. Isabella's parents complied and Isabella was admitted to a hospital for an inpatient evaluation.

After five weeks in the hospital, Isabella was discharged home to her parents. No medical diagnosis was found for her failure to thrive. However, a non-physician feeding therapist offered a "diagnosis" of "oral motor dysfunction," *i.e.*, difficulty in chewing/swallowing solid foods. The feeding therapist failed to explain how Isabella's "oral motor dysfunction" could have prevented her from getting adequate calories on her nearly all-formula diet, or how oral motor dysfunction could adversely affect the number of calories being pumped into the child via her nasogastric tube.

The Family Court dismissed the abuse/neglect charges against the parents, who then sued Dr. Dick and Nassau County for $10,000,000 in compensatory and punitive damages. The complaint asserted claims for negligence in removing Isabella from her home, assault, battery, false arrest/imprisonment, intentional infliction of emotional distress, *prima facie* tort, fraud, slander *per se,* negligent misrepresentation, violation of civil rights, invasion of privacy, abuse of process, medical malpractice, and loss of services.

Following extensive discovery, defendants filed motions for summary judgment dismissal of all claims. The centerpiece of the motions was the statutory immunity from liability for the good faith reporting of suspected child abuse conferred by Section 419 of the New York Social Services Law.

Plaintiffs opposed the motion, arguing (among other things) that Dr. Dick's abuse report was a pre-emptive effort to deflect a malpractice claim against him; that he "poisoned" the county social services staff against the plaintiffs; and that his "lie" to the mother about the results of the second (tampered) sweat test, all raised questions of fact as to his good faith in making the report, and therefore a trial was required. Plaintiffs did not submit an expert affidavit to support their claim for medical malpractice against Dr. Dick.

In rebuttal to Plaintiffs' opposition, Dr. Dick submitted an expert affidavit from a pediatrician and child abuse expert who has been qualified by the courts of New York in multiple cases as an expert in MSP. The expert's opinion was unequivocal that this was an MSP case, that Dr. Dick had an obligation to report it, and that Dr. Dick's care of Isabella did not constitute medical malpractice. Dr. Dick also submitted the ethical policies of the American Academy of Pediatrics and the American Medical Association with regard to his duty to protect Isabella from further abuse. Those policies state that Dr. Dick's duty was to Isabella as his patient, rather than to Isabella's parents, and that he is responsible, as her physician, to ensure her safety before confronting her parents regarding the suspected abuse. Accordingly, it was argued that Dr. Dick was justified in using Dr. Harbison's incorrect CF diagnosis as a means to attempt to persuade the child's family to admit her to a hospital immediately.

In a lengthy decision that focused on the background facts and medical records, the Court accepted defendants' arguments and dismissed the case in its entirety. The Court ruled that Dr. Dick, as a mandated reporter, was entitled to § 419 immunity from liability, noting the following:

> The Courts have recognized the strong public policy underlying Article 6 of the Social Services Law. "Because of the importance of these

> protections and immunities to the health and welfare of children, it is clear that only a persuasive showing of bad faith will permit [an action against a mandatory reporter] to proceed to trial." (*Satler v Larsen*, 131 AD2d 125, 126 [1st Dept, 1987]). Thus, while the qualified immunity afforded by Social Services Law § 419 may be overcome, the statutory presumption of "good faith" on the part of mandatory reporters can only be overcome with evidence of willfulness or gross negligence.

In dismissing the medical malpractice claim, the Court noted that it "reviewed the extensive deposition testimony, including that of many physicians, submitted on these applications. Nowhere is the opinion voiced by any witness that there was a departure from good and accepted practice by Dr. Dick."

The Court concluded its opinion by noting that "at the core of this controversy, . . . there seems to have been what Shakespeare described as 'the disease of not listening, the malady of not marking.'"

[Ed. Note: Garfunkel, Wild & Travis (Leonard M. Rosenberg and Colleen Tarpey) represented the defendant physician Dr. Dick in this case.]

In Scathing Decision, New York Federal Court Dismisses Charity Care Suit Premised on Tax Exempt Status of Non-Profit Hospitals

Kolari, et al. v. New York-Presbyterian Hospital, et al. (2005 WL 710452 (S.D.N.Y.)). This breach of contract action, one of dozens of similar actions filed in 23 district courts across the United States, was brought on behalf of uninsured and indigent patients who argued that private non-profit hospitals are required to provide free or reduced-rate services to uninsured persons.

Plaintiffs claimed that the defendant hospitals' tax exempt status created a contract between the hospitals and the United States government pursuant to 26 U.S.C. § 501(c)(3), which exempts from taxation any organization formed for charitable purposes. Plaintiffs argued that they were third party beneficiaries to this contract.

Disagreeing sharply, the Court labeled the plaintiffs' action "bootless" and chided them for raising the issue in the wrong forum.

"Plaintiffs here have lost their way; they need to consult a map or a compass or a Constitution because Plaintiffs have come to the judicial branch for relief that may only be granted by the legislature," the Court said. As a threshold matter, the Court noted, a plaintiff lacks standing to enforce rights allegedly created by another person's tax exemption. In this case, the Court held that the plaintiffs lacked standing to seek to enforce any "real or imagined" rights created by Section 501(c)(3).

In addition, the Court held that the federal courts are precluded by 26 U.S.C. § 7401 from enforcing any section of the Internal Revenue Code without authorization from the Secretary of the Treasury and the U.S. Attorney General. Thus, the Court held that the plaintiffs in this case did not establish subject matter jurisdiction and dismissed plaintiffs' claims pursuant to Federal Rules of Civil Procedure Rule 12(b)(1).

Further, the Court held that the IRS does not grant tax exempt status pursuant to 26 U.S.C. § 501(c)(3) by contract, but rather by administrative ruling. The Court noted that an IRS determination no more creates a contract than does any other judicial or administrative determination; thus the plaintiffs' claim that they were third party beneficiaries is untenable since no contract existed.

In a final attempt to substantiate their argument that Section 501(c)(3) creates a contract, the plaintiffs asserted that Section 501(c)(3) is analogous to the Hill-Burton Act, 42 U.S.C. § 291, a government program that awards funds to hospitals servicing uninsured or indigent patients. Plaintiffs argued that since courts recognize the Hill-Burton Act as an enforceable contract between hospitals and the government, Section 501(c)(3) should be as well.

The Court, however, pointed out that the Hill-Burton Act differs significantly from Section 501(c)(3) for the following reasons: (1) the Hill-Burton Act provided direct funds to hospitals, while Section 501(c)(3) provides tax exemptions; (2) the Hill-Burton Act required applicants to sign a "Memorandum of Agreement" containing express contractual language, but an exemption under Section 501(c)(3) is granted by an IRS determination with no such contractual agreement; (3) the Hill-Burton Act provided funds for organizations performing specific, pre-negotiated purposes, while Section 501(c)(3) provides tax exemptions to organizations for multiple permissible purposes; and (4) the Hill-Burton Act provided for a private cause of action to enforce the Act, while Section 501(c)(3) only permits the IRS or the organization seeking tax exemption to challenge a determination on Section 501(c)(3). Based on these reasons, the Court held that plaintiffs' analogy to the Hill-Burton Act was inaccurate.

Plaintiffs also argued that the defendants are debt collectors as defined by 15 U.S.C. § 1692 and as such they violated the Fair Debt Collection Practices Act ("FDCPA") by engaging in "aggressive, abusive, and humiliating collection practices." Plaintiffs' amended complaint also alleged that the outside collection agencies hired by the defendants acted as agents for the defendants in attempting to collect outstanding bills from uninsured patients.

However, the Court held that according to a plain reading of the FDCPA the defendants are not debt collectors subject to the provisions of the FDCPA, and that a creditor that is not itself a debt collector is not vicariously liable for the actions of a debt collector it has engaged to collect its debts. The Court held that plaintiffs failed to state a claim under the FDCPA upon which relief could be granted.

Plaintiffs further argued that the defendants conditioned emergency hospital treatment on plaintiffs' ability to pay in violation of the Emergency Medical Treatment and Active Labor Act ("EMTALA"). Under the EMTALA, a hospital participating in Medicare must provide a medical screening examination to anyone who comes into the emergency room to determine whether an emergency medical condition exists. If such a condition exists, a hospital is required under 42 U.S.C. § 1395dd(e)(1) to provide sufficient medical treatment to stabilize the condition.

To state a claim under the EMTALA, a plaintiff must allege that he or she went to the emergency room seeking treatment for a medical condition and that the hospital did not adequately screen him or her to determine if an emergency medical condition existed, or discharged or transferred him or her before such a condition had been stabilized.

Plaintiffs in this case, however, did not allege a refusal of services or screening, or that they suffered "personal harm as a direct result of a participating hospital's violation of a requirement section [of 42 U.S.C. § 1395(dd)(b)]." Moreover, the Court noted that the EMTALA authorizes recovery of damages for personal injury under the law of the state in which the hospital is located; the EMTALA does not allow for the injunctive or declaratory relief sought by plaintiffs.

Plaintiffs further alleged that the defendants violated 42 U.S.C. § 1983 and the Fifth and Fourteenth Amendments to the U.S. Constitution in that the defendants have assumed the role of providing the "essential public and government function of health care for uninsured and indigent patients" and that the defendants had overcharged such patients with the assistance of state procedures and laws. In addition, plaintiffs alleged that the defendants' billing and collection practices had a disparate impact on racial minorities and therefore the defendants had engaged in "invidious discrimination" against uninsured patients.

The Court noted that to state a claim under Section 1983, plaintiffs must establish that they were deprived of a right secured by the Constitution or laws of the United States and that the alleged deprivation was committed "under the color" of state law. The Court dismissed these claims, holding that there is no constitutional right to free health care and that the defendants were not "state actors."

In their final federal claim, plaintiffs alleged that by accepting federal tax exemptions, the defendants "created and entered into a public charitable trust to provide mutually affordable medical care to its uninsured patients." The Court, however, noted that charitable trusts are express trusts that arise and exist only pursuant to an expression by the settlor to create a trust. The defendants failed to demonstrate the existence of these basic requirements for the creation of a charitable trust, and the Court dismissed the claim.

Plaintiffs made several state law claims as well, that the Court held it was permitted to adjudicate pursuant to the supplemental jurisdiction conferred by 28 U.S.C. § 1367(a). These claims fared no better than plaintiffs' federal claims and were dismissed with prejudice. The Court stated, "Plaintiffs' state law claims, like their federal claims, are largely premised on Plaintiffs' baseless assertions that hospitals designated as charitable institutions are required to provide free health care to the uninsured and indigent. The state claims clearly raise the questions of federal health care policy, especially when viewed in the context of the dozens of nearly identical state law claims in the dozens of similar lawsuits filed in courts all over the United States."

In its decision, the Court noted that at oral argument, plaintiffs acknowledged that the "heart and soul" of their case was their belief that tax exempt hospitals are charging discriminatory rates that are much higher for their uninsured patients than they are for their patients who have either private medical insurance or are eligible for Medicaid or Medicare. The Court stated, "This orchestrated assault on scores of nonprofit hospitals, necessitating the expenditure of those hospitals' scarce resources to beat back merciless meritless legal claims, is undoubtedly part of the litigation explosion that has been so well-documented in the media."

Answering Certified Question from Second Circuit, Court of Appeals Rules that Insurance Carriers May Withhold Payment on Assigned No-Fault Claims for Services Provided by Fraudulently Incorporated Medical Enterprises

State Farm Mutual Auto. Ins. Co. v. Mallela, 2005 WL 705972, 2005 N.Y. Slip Op. 02416 (N.Y. March 29, 2005). Answering a certified question from the United States Court of Appeals for the Second Circuit, the New York Court of Appeals interpreted a regulation promulgated by the Superintendent of Insurance to conclude that insurance carriers may withhold payment for medical services provided by "fraudulently incorporated enterprises" to which patients assign their claims.

Plaintiff ("State Farm"), an insurance carrier, filed a complaint in the United States District Court for the Eastern District of New York seeking a declaratory judgment that it need not reimburse various medical service corporation ("MSC") defendants

for assigned no-fault claims. Patients covered by no-fault insurance regularly assign their claims to their health care providers in lieu of seeking reimbursement from insurance carriers. State Farm claimed that defendants, seeking to obtain reimbursement from insurance carriers, had structured MSCs in a manner that willfully evaded New York's prohibitions on non-physicians sharing ownership in such entities.

Specifically, State Farm's complaint alleged that unlicensed defendants paid physicians to use their names on paperwork filed with the state to incorporate the MSCs. Once established under the cover of the nominal physician-owners, the non-physicians actually operated the MSCs and hired management companies to bill management services provided to the MSCs at inflated rates. In this fashion, profits of the MSC went to the non-physicians who ran the management companies rather than the nominal physician owners.

Notably, State Farm did not dispute that the patients who assigned their claims had received appropriate health care from a qualified professional. This issue was central to the Eastern District's decision to dismiss State Farm's complaint. The trial court held that State Farm was obligated to pay the submitted no-fault claims so long as properly licensed medical providers acted within the scope of their licenses in rendering care. Defendants' non-compliance with state licensing and incorporation statutes did not negate State Farm's duty to reimburse the MSCs.

On appeal, the Second Circuit certified to the Court of Appeals the question of whether a medical corporation that is fraudulently incorporated under New York law is entitled to be reimbursed by no-fault insurers for medical services rendered by licensed medical practitioners. The Court of Appeals accepted the certification and held that such corporations are not entitled to reimbursement.

In reaching this conclusion, the Court of Appeals focused on a regulation promulgated by the Superintendent of Insurance interpreting a provision of the Insurance Law that requires no-fault carriers to reimburse patients (or their provider assignees) for "basic economic loss." In a 2002 regulation (the "Regulation"), the Superintendent declared that payments made to unlicensed providers were outside the definition of "basic economic loss," thus rendering such providers ineligible for reimbursement. The Superintendent, in an amicus brief, noted that he had promulgated the Regulation to combat a wave of fraud in the no-fault arena, highlighted by the corporate practice of medicine by non-physicians.

Assuming State Farm's allegations to be true for purposes of the motion to dismiss, the Court reasoned that the defendant MSCs violated applicable state licensing standards by allowing ownership or control by non-physicians. Further, the Court noted, a fraudulently incorporated MSC is a provider of health care services under the Regulation. The Court regarded the Regulation as within the scope of the Superintendent's authority, thus giving it the force of law, and concluded that "the Superintendent's regulation allowing carriers to withhold reimbursement from fraudulently licensed medical corporations governs this case." Based on the Regulations, carriers may "look beyond the face of licensing documents to identify willful and material failure to abide by state and local law."

The Court of Appeals analyzed and rejected two arguments raised by defendants. First, defendants argued the issue that was paramount to the Eastern District's dismissal of State Farm's complaint—that the actual care received by patients was within the scope of the licenses of the treating personnel. However, the Court focused on the fact that reimbursement for such care went to an MSC "that exists to receive payment only because of its willfully and materially false filings with state regulators."

Defendants also argued that the Regulation conflicted with the prompt-pay goals of the no-fault statutes, and argued that carriers would turn the investigatory powers related to the Regulation into "a vehicle for delay and recalcitrance." While acknowledging the tension between the dual state policies of prohibiting fraud in the ownership of MSCs and encouraging prompt payment of insurance claims, the Court stated that the Regulation "represents the policy choice of this State."

The Court further noted that the Regulation would not permit carriers to engage in widespread denial or delay of payment of no-fault claims, and sent a stern warning to the insurance industry. Noting that the Superintendent also had oversight of carriers' actions, the Court reasoned that carriers would only be able to invoke the Regulation to investigate an MSC's background where "behavior tantamount to fraud" was evident. Technical violations of licensing standards, such as the failure to hold an annual meeting or submit paperwork on time, would not subject an MSC to delayed payments. The Court warned, "We expect, and the Legislature surely intended, vigorous enforcement action by the Superintendent against any carrier that uses the licensing-requirement regulation to withhold or obstruct reimbursements to non-fraudulent healthcare providers."

The Second Circuit had also questioned whether, if the fraudulent MSCs were not entitled to reimbursement, State Farm could recover monies already paid to them, under theories of unjust enrichment or fraud. The Court of Appeals noted that no such claim would lie for payments made by carriers prior to the April 2002 implementation of the Regulation, and declined to answer this question as State Farm's pleadings did not make clear when it had paid the challenged monies to defendants.

Suspended Physician May Not Predicate Breach of Contract Claim Against Hospital Upon Medical Staff Bylaws

Mason v. Central Suffolk Hospital, 3 N.Y.3d 343, 819 N.E.2d 1029, 786 N.Y.S.2d 413 (2004). In this suit, the New York Court of Appeals addressed an issue that has produced inconsistent rulings from the Appellate Divisions: can the alleged violation of a hospital's medical staff bylaws support a breach of contract claim? In *Mason*, the Court ruled that a physician whose hospital privileges were suspended cannot state a cause of action for breach of contract against the hospital based upon the hospital's medical staff bylaws, absent express language in the bylaws that creates a right to that relief.

Plaintiff Roger Mason's medical staff privileges at Central Suffolk Hospital were curtailed in 1998 when the hospital suspended his privileges to perform advanced laparoscopic procedures, and required him to obtain a concurring second opinion before performing certain other kinds of surgery. In the suit that followed, Dr. Mason asserted a claim that the Hospital's medical staff bylaws were a contract between him and the Hospital, and that the Hospital had breached those bylaws by failing to follow the procedures therein by suspending his privileges without legitimate cause.

The Hospital's motion to dismiss Dr. Mason's complaint for failure to state a cause of action was denied by the Motion Court, but the Appellate Division for the Second Department reversed. In its affirmance of the Appellate Division's order, the Court of Appeals noted that the issue of whether a hospital's bylaws constitute a contract upon which a suspended physician may sue is an issue of first impression for the Court.

The Court ruled that no contract action could lie based upon the bylaws, in the absence of language in the bylaws clearly indicating a contractual limitation on the hospital. However, the Court noted that "a clearly written contract, granting privileges to a doctor for a fixed period of time, and agreeing not to withdraw those privileges except for a specified cause, will be enforced."

In this case, however, the Court noted that "not a word in the bylaws . . . says or implies that doctors have a vested right to hospital privileges. The most relevant provisions [Appointment and Reappointment, and Hearings and Appeals] . . . are procedural, not substantive. . . . It is most unlikely that these bylaw provisions were intended by anyone to create a monetary claim in favor of a doctor for wrongful termination or suspension of privileges."

The Court also rejected as "far-fetched" Dr. Mason's argument that a bylaw provision, conferring immunity from liability for actions taken in good faith, was intended to create a liability "where one would otherwise not exist."

In holding that the bylaws do not constitute a contract, the Court stated that, "[i]t is preferable for hospital administrators who decide whether to grant or deny staff privileges to make those decisions free from the threat of a damages action against the hospital. It is not just in the hospital's interest, but in the public interest, that no doctor whose skill and judgment are substandard be allowed to treat or operate on patients. A decision by those in charge of a hospital to terminate the privileges of, or deny privileges to, a doctor who may be their colleague will often be difficult. It should not be made more difficult by the fear of subjecting the hospital to monetary liability."

[Ed. Note—The full text of this Court of Appeals decision is set forth further below in this edition of the *Journal*.]

Medical Residents Are Required to Seek Public Health Council Review Prior to Litigating the Termination of Residency or Privileges

Indemini v. Beth Israel Medical Center, 4 N.Y.3d 63 (2005). Plaintiff, a second year medical resident at Beth Israel Medical Center, was terminated by the Hospital's Department of Emergency Medicine for several reasons, including poor judgment and poor performance while on probation. The Hospital's Staff Grievance Committee determined that the Department's decision to terminate Plaintiff was fully justified and that there was no evidence to conclude that its actions were pretextual. Shortly thereafter, the Hospital's Board of Trustees upheld the resident's termination.

Plaintiff challenged her termination by commencing this breach of contract action, based on allegations that her residency was terminated due to her union organizing activities, as well as her advocacy for the rights of other Hospital staff members. The Motion Court dismissed Plaintiff's action because she had failed to exhaust her administrative remedies. In particular, the Court found it was incumbent upon the resident to first seek review by the New York State Public Health Council ("PHC") under Article 28 of the New York State Public Health Law (the "PHL"). The Appellate Division, First Department, and the New York State Court of Appeals affirmed.

PHL § 2801-b provides that any physician claiming to be aggrieved by an improper practice of a hospital that curtails, terminates or diminishes the physician's professional privileges, may seek review by the PHC. Plaintiff argued that this statute does not apply to her because she is only a medical resident, not a member of the Hospital's medical staff. The Court of Appeals disagreed, finding that Section 2801-b applies to "physicians" and that a medical resident is undoubtedly a physician. Additionally, the Court of Appeals agreed with the Motion Court's finding that "the

statute gives no indication that the Legislature intended Residents, who perform medical duties under the direction of licensed physicians, to have greater access to the courts than physicians." To exclude residents from review by the PHC would not promote the statute's purpose of allowing an expert body to initially review a physician's complaint, and to promote pre-litigation resolution.

The Court of Appeals also rejected the resident's argument that PHC review would be redundant, since she had already exhausted the hospital's internal grievance procedure. The Court disagreed, noting that the PHC, as an impartial forum unconnected to the hospital, "not only affords a terminated physician an additional level of professional scrutiny, but also serves to protect the hospital by eliminating any hint of institutional bias." Thus, the Court ruled that neither a resident's grievance procedure, nor a physician's due process hearing under the medical staff bylaws, forecloses the requirement of PHC review prior to commencement of litigation. The Court expressly ruled that a medical resident's proper recourse for challenging termination from a hospital residency program is PHC review pursuant to PHL § 2801-b, "which cannot be avoided simply by asserting a breach of contract claim."

The Court declined to answer in this case the question of whether PHC review is required when a physician's (or medical resident's) privileges are "denied, curtailed or terminated solely because of alleged harassment or misconduct directed at a patient."

Obligation to Maintain Confidentiality of Physician Disciplinary Charges and Proceedings Continues Even After Final Determination if Physician Is Cleared of All Charges

Anonymous v. Bureau of Professional Medical Conduct, 2 N.Y.3d 663, 814 N.E.2d 440, 781 N.Y.S.2d 270 (2004). In this case, the Court of Appeals ruled that where disciplinary proceedings against a physician are determined in the physician's favor, the requirement of confidentiality under Public Health Law § 230 continues to exist. Accordingly, the Department of Health abused its discretion by posting on the Office of Professional Misconduct ("OPMC") website all charges filed against the physician, even though the physician had been exonerated after a hearing of all but one minor unrelated charge.

This case arose from a woman's complaint that the physician treated her late one evening with massage and acupuncture and that he kissed her. The physician claimed that the encounter was a date and not a medical appointment. OPMC charged the physician with "willfully harassing, abusing a patient physically," "failure to maintain records," "moral unfitness," "fraudulent practice" and "practicing beyond the scope."

After a hearing, the hearing committee rejected all charges except for one instance of failure to maintain a medical record, for calling in a prescription for this woman without documenting the prescription in a medical record. Despite the fact that the Committee found the charges to be without merit, OPMC nevertheless posted all charges on the Internet, and rejected the physician's objection that such posting breached the confidentiality provisions of the Public Health Law. The physician sued OPMC, seeking to force the Department to remove the unfounded charges from the internet.

Contrary to the Department's position that confidentiality ceases to exist after final determination regardless of the outcome, the Court of Appeals held that the obligation to maintain the confidentiality of disciplinary proceedings continues to exist even when the physician has been exonerated of the charges. The Court noted that confidentiality of disciplinary proceedings involving licensed professionals is intended to "protect professionals against the disastrous effect that public knowledge of unfounded charges can have on a professional career." The Court rejected as "unrealistic" the Department's position that dissemination of unfounded charges after they have been resolved will not injure a physician's reputation, because the public will also see that the charges have been dismissed. Therefore, the Court affirmed the Appellate Division order compelling the Department to withdraw the material from the Internet, and to keep the information confidential.

[Ed. Note: This summary is a follow-up to the Appellate Division decision noted in the *Journal*'s Summer/Fall 2003 issue, Vol. 8, No. 3.]

Department Chair's Widely Circulated E-mail Accusing Hospital Administration of Mismanaging the Institution Is Insubordinate and a Valid Basis for Employment Termination

Norman Trieger, D.M.D., M.D. v. Montefiore Medical Center, 15 A.D.3d 175, 789 N.Y.S.2d 42 (1st Dep't 2005). In this case, the Appellate Division, First Department, considered claims of age discrimination and breach of contract by Montefiore's former Chair of its Department of Dentistry, Dr. Norman Trieger.

Within weeks of signing a three year employment agreement, Dr. Trieger issued a memorandum accusing the Medical Center's Administration of mismanagement. Among other things, Dr. Trieger charged the Administration with exhibiting "autocratic, unilateral decision-making and administrative micro-management" and "impairing [the hospital's] efficiency of operation [causing it to] drift further down the spiral of deficit" towards its inevitable demise. Dr. Trieger distributed his memorandum, via e-mail, to 23 other clinical department chairpersons at the Medical Center, and urged them to rise up to "reclaim their prerogatives." After Dr. Trieger admitted writing the memo, which the Medical Center deemed insubordinate, its President promptly discharged Dr. Trieger and removed him from his

chairmanship. In response, Dr. Trieger sued Montefiore for age discrimination and breach of contract.

After discovery, the Medical Center moved for summary judgment dismissal of the contract and age discrimination claims. Turning first to the alleged breach of contract, the motion court noted that insubordination justifies termination of employment, "especially where high-level managers are concerned and where the efficient running of an enterprise demands a high degree of trust and cooperation among top personnel." Applying that principle, the motion court ruled that Dr. Trieger's memo was "clearly insubordinate on its face, and no rational jury could find that such a memo, written by a senior member of management and circulated to other department chairs, did not provide just cause for Dr. Trieger's termination." Likewise, the motion court dismissed Dr. Trieger's age discrimination claim, in part because "it defies logic that Dr. Spencer Foreman, the very same person with whom Dr. Trieger negotiated his three-year employment contract, would one month later terminate Dr. Trieger based on age." 3 Misc. 3d 1103(A); 787 N.Y.S.2d 681 (Sup. Ct., Bronx County, March 2004).

Dr. Trieger appealed the dismissal of both claims. Like the motion court, the Appellate Division noted that under New York law, an employer's determination of good cause justifying termination of an employment contract is entitled to deference, particularly where high-level management employees are involved. The Court then affirmed that Dr. Trieger's memorandum was insubordinate, and accordingly gave Montefiore just cause to terminate Dr. Trieger's employment contract.

Next, applying the burden shifting analysis set forth in *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 93 S. Ct. 1817 (1973), the Appellate Court held there was a "lack of evidence sufficient to raise an issue of fact as to whether the hospital's proffered reason for plaintiff's dismissal, circulation of the insubordinate memorandum, was a pretext for discrimination." Because Montefiore terminated Dr. Trieger immediately after he circulated the insubordinate memorandum, and there was no evidence in the record to show that the hospital's actions were pretextual, the Court also affirmed summary judgment dismissal of his age discrimination claim.

[Ed. Note: Garfunkel, Wild & Travis, P.C. (Leonard M. Rosenberg and Colleen McMahon) represented Montefiore Medical Center in this case.]

Ambulatory Surgery Center's Antitrust Suit Against Hospital Survives Summary Judgment

Rome Ambulatory Surgical Center, LLC v. Rome Memorial Hospital Center, Inc., 349 F. Supp.2d 389 (N.D.N.Y. 2004). This lawsuit was brought by plaintiff Rome Ambulatory Surgical Center, LLC ("RASC") against Rome Memorial Hospital, Inc. (the "Hospital") and its corporate parent. RASC, a freestanding ambulatory surgical facility located in Rome, New York, claimed that the Hospital participated in anticompetitive conduct aimed at harming RASC, by limiting patient referrals to RASC, including unlawful exclusive contracts with commercial third party payers. RASC claimed that such acts forced it to leave the market, taking with it the consumer benefits it provided: greater customer choice, higher quality service, and lower prices.

Per the Court's factual summary, there was a divide between physicians in Rome. One group was loyal to the Hospital, and one group was loyal to RASC. The Hospital's group included Rome Medical Group ("RMG"), the area's largest primary care practice. RMG referred most of its patients to the Hospital. In late 1996, RASC filed a Certificate of Need application with the Department of Health seeking approval for its proposed ambulatory surgical center. The Hospital and others opposed the application, and the physicians associated with the Hospital entered into a letter writing campaign for that purpose.

With respect to the third party payers, the largest two in the area were Blue Cross Blue Shield ("BCBS") and MVP Health Plan ("MVP"). RASC's entry into the market affected contract negotiations between the Hospital and the third party payers. The Hospital then negotiated exclusive contracts with BCBS and MVP, with the payers receiving reduced rates for ambulatory surgery with the Hospital. This affected RASC because third party payers effectively exercise patient choice by causing patients to pay out-of-pocket for uncovered procedures.

RASC alleged that it had lower than expected income due to low patient use of RASC as a result of the Hospital's alleged intimidation of its users, and conspiring with cooperating physicians to choke off referrals. Further, the month RASC opened, the Hospital amended its bylaws to allow the Board to consider whether a physician competes with the Hospital in evaluating medical staff appointments. Finally, RASC alleged that the Hospital harassed the physicians that supported RASC, including handing out unfavorable reviews, causing doctors to lose contracts with the Hospital, and reporting a doctor for an immigration violation. RASC brought suit under the Clayton Act, Sherman Act and under New York law, alleging antitrust and other violations. In this decision, the Northern District ruled on the parties' motions for summary judgment.

1. Standing

The Court found that RASC met the standing requirement for bringing suit under Section 4 of the Clayton Act, which provides standing to "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws." The Court found that RASC sufficiently pled causation in that the lower than expected use rates and the loss of the third party payor con-

tracts could be found to be material causes of RASC's injury, and RASC "set forth sufficient facts to allow an inference that defendants' conduct caused both circumstances."

Further, the Court found that RASC pled an antitrust injury as apposed to a competitive injury, by alleging that the Hospital "captured ambulatory surgery patients due to improperly influencing physicians' referral decisions as opposed to capture by providing better facilities or service." In addition, the Court found the injury standard satisfied because RASC claimed that BCBS terminated its contract with it as a result of an illegal exclusive contract as opposed to loss of the contract due to requested rate increases or financial insecurity. Thus, "instead of continuing to compete for patients by simply lowering its rates or offering a better facility, the Hospital [allegedly] acted to foreclose competition altogether through improper exclusive dealing."

2. Sherman Act Claims

RASC brought claims pursuant to Sections 1 and 2 of the Sherman Act. With respect to the Section 1 claims, the Court noted that a plaintiff "must produce evidence sufficient to show: (1) a combination or some form of concerted action between at least two legally distinct economic entities; and (2) such combination or conduct constituted an unreasonable restraint on trade either per se or under the rule of reason." The Court found that the restraints on trade alleged in this action were between the Hospital and its customers, referring physicians, and commercial payers, which are vertical restraints. Vertical restraints are generally subject to a "rule of reason" analysis.

Under the rule of reason, a plaintiff must initially show that the challenged action had an actual adverse effect on competition as a whole in the relevant market. This can be achieved by showing an actual adverse effect on competition, or by establishing the effect indirectly by establishing that defendants had sufficient market power to cause an adverse effect on competition. When using the market power alternative, plaintiff must also show that the defendants' conduct could harm competition.

RASC's first set of allegations are tying claims, i.e., a claim that there exists an arrangement "conditioning the sale or lease of one item (the "tying" product) on the purchase of another item (the "tied" product)." RASC claimed that defendants required the third party payers to contract for outpatient surgery services on an exclusive basis as a condition for contracting for general inpatient acute care hospital services on a discounted basis. However, the Court found that this claim failed as a matter of law because "plaintiff cannot demonstrate that defendants actually coerced the third party payers into entering into exclusive contracts for ambulatory services." On the contrary, the contracts were the product of negotiation.

However, the Court found that RASC's claim that the Hospital's contract with the commercial payers are illegal exclusive contracts which foreclose a significant degree of the Rome area third party payer submarket were sufficiently set forth to survive summary judgment under the rule of reason. Under this analysis a plaintiff must demonstrate, "(1) the anti-competitive market effects; (2) that the alleged conduct foreclosed a significant degree of trade; and (3) that the defendants' pro-competitive justification for the conduct is not valid." The Court found this standard met because RASC made a showing that (1) RASC's closure resulted in a loss of choice for Rome area patients, which constitutes a significant injury to competition; (2) that the exclusive contracts foreclosed 65% of the relevant submarket, which is a significant part of the relevant market; and (3) RASC raised issues of fact showing that the Hospital's pro-competitive justification, that the contracts allowed for efficiency gains, actually benefits competition.

RASC next alleged a conspiracy to restrain trade. To survive summary judgment on this claim, a plaintiff must show: "(1) a combination or some form of concerted effort between at least two legally distinct economic entities; and (2) the combination or conduct constituted an unreasonable restraint of trade . . ." The Court granted the Hospital's summary judgment motion on this claim because "plaintiff failed to demonstrate anticompetitive effects or an unreasonable restraint due to the alleged conspiracy between the Hospital and the cooperating physicians as required under a rule of reason analysis." RASC was unable to set forth facts sufficient to support an inference that any horizontal agreement existed between the Hospital's customers, the referring physicians and/or RMG, as is required for this claim.

RASC next alleged a *per se* illegal boycott, claiming that "the Hospital's inducement of BCBS and MVP into exclusive contracts, and the tacit conspiracy among defendants and the two payers to eliminate RASC from the market constitutes a *per se* illegal boycott." The Court granted the Hospital's summary judgment motion with respect to this claim because RASC was unable to raise a question of fact to support an inference that there was an agreement or understanding between MVP and BCBS concerning RASC, and RASC must show a horizontal agreement to be successful.

Finally, the Court determined RASC's Section 2 Sherman Act claims. The first of these claims alleged a monopoly leveraging and monopoly of the outpatient surgery market. Plaintiff needed to show that defendant: "(1) possessed monopoly power in one market; (2) used that power to gain a competitive advantage . . . in another distinct market; (3) caused injury by such anticompetitive conduct; and (4) demonstrate that there is a dangerous probability of success in monopolizing a second market." The Hospital's summary

judgment motion was granted with respect to this claim because it was based on the exercise of monopoly power in the inpatient services market, and plaintiff failed to define that market in order to show market share or, alternatively, to offer direct evidence of defendant's power to "control prices or exclude competition within it."

With respect to RASC's claim that the Hospital's alleged conduct was part of an attempt to monopolize the outpatient surgery market, the Court found that RASC put forth sufficient questions of fact to survive summary judgment. The Court held that the conduct alleged in its Section 1 Sherman Act claims, which included a conspiracy and physician intimidation to restrict referrals to RASC, were sufficient to sustain this Section 2 Sherman Act Claim.

The Court further held that RASC put forth sufficient questions of fact as to whether the Hospital participated in a conspiracy with the referring physicians to monopolize the outpatient surgery market. Thus, this claim also survived summary judgment.

Disappointed Organ Donee Has Insufficient Property Right and No Standing to Sue

Colavito v. New York Organ Donor Network, 2005 WL 375611 (E.D.N.Y. 2005). Plaintiff Colavito, who suffers from end-stage renal disease, was a long-time friend of Mr. Lucia. Mr. Lucia's wife designated both of Mr. Lucia's kidneys to Mr. Colavito after Mr. Lucia was declared brain dead. She signed a consent form from the New York Organ Donor Network (the "NYODN") for a directed donation, specifying "kidney" as the organ to be directed to Colavito. The form contained a clause regarding redirection of the organ, at NYODN's discretion, should logistical or medical issues preclude transplantation to the directed donee. She testified that she understood, however, that both kidneys were sufficiently matched to Mr. Colavito, and one kidney could be redirected only if transplant of the first kidney was a success.

Mr. Colavito went to the hospital for the transplantation, but the surgeons discovered that of Mr. Lucia's two kidneys, one was unfit to transplant, and the other already had been transplanted into someone else. Mr. Colavita sued NYODN, alleging fraud, conversion and violation of New York's anatomical gifts law.

NYODN first asserted that Mr. Colavito had not met the $75,000 amount in controversy requirement. The Public Health Law prohibits the sale of human organs, they argued, therefore the kidneys cannot be given an economic value. The Court did not address this issue in the context of "amount in controversy," because it found the compensatory and punitive damages sought under the fraud claim sufficient to satisfy the amount in controversy.

The Court, however, granted NYODN summary judgment on plaintiff's fraud claim based on lack of causation. Because Mr. Colavito's claimed injuries (remaining on dialysis instead of with a functioning kidney) did not result from an action or inaction he made in reliance on a misrepresentation, the Court concluded that he could not sustain a claim for fraud. The Court noted "the sole actions that plaintiff claims to have taken . . . are going to the hospital and preparing for surgery. But the actions which Mr. Colavito took are not what left him without a kidney, which is the harm he alleges."

The issue of whether a specified donee of an anatomical gift may sustain a claim for conversion is an issue of first impression for the courts. While the U.S. District Court reviewed cases regarding the narrow parameters of property rights attaching to dead bodies, it went on to explain that "[d]eath is unique," and applying the general concepts of property law in such a situation is not completely appropriate. Courts generally recognize a "quasi-property" right or a "property interest," but use of the word "property" is for convenience rather than for assignment of blood rights. The Court quotes Prosser's *The Law of Torts* 58-59 (4th Ed. 1971) as follows: "The courts have talked of a somewhat dubious 'property right to [a] body, usually in the next of kin . . . [which] cannot be conveyed, can be used only for the one purpose of burial, and . . . has no pecuniary value.'"

The Court granted summary judgment dismissal of the conversion claim, based on its unwillingness to either expand the limited right in a dead body that next of kin has for burial purposes, or to violate public policy by placing value on a human organ.

Mr. Colavita also alleged violation of N.Y. Public Health Law Article 43, that allows for an anatomical gift to be given to a specified donee. Whether a donee has standing to sue under this law is another question of first impression for the court in this case. In reviewing the law, Section 4301(5) gave the Court pause, where it said, "The rights of the donee created by the gift are paramount to the rights of others. . . ." Section 4301 also provides that the donee shall not accept an anatomical gift if there is "actual notice of contrary indication by the decedent" or if it is "contrary to the decedent's religious or moral beliefs" or if the donation was not properly authorized. The Court concluded that the statute itself provides no instruction as to standing, nor specific or detailed rights to donees, but rather that the statute's main emphasis is on the donee's role in accepting a gift in accordance with the donor's intention. Thus the Court turned to the legislative history of the statute for guidance, but found no standing or other rights afforded to donees, and thus the Court refused to recognize a private right of action for donees.

Appellate Division Rejects Non-Patient's Medical Malpractice Claim for Hepatitis C Infection

Candelario v. Teperman, 15 A.D.3d 204, 789 N.Y.S.2d 133 (1st Dep't

2005). In this case, the Appellate Division followed a 2003 Court of Appeals holding that a physician does not owe a duty of care to a non-patient, and ordered the dismissal of a complaint brought by a woman who allegedly contracted hepatitis C through the care of her mother, a former patient of defendant.

Plaintiff's mother was treated for hepatitis C by a physician at New York University Medical Center (the "Hospital") from 1992 until her death in 1994. At various times during her treatment, plaintiff's mother was released from the Hospital and cared for by plaintiff at home. In 1997, plaintiff was diagnosed with hepatitis C. She alleged that, while caring for her mother, she came into contact with her mother's bodily fluids, which were capable of transmitting the hepatitis C virus.

Plaintiff sued the treating physician and the Hospital, alleging that defendants, although aware of plaintiff's care for her mother, neither warned plaintiff of the contagious nature of hepatitis C, nor instructed her to take precautions against infection. After discovery, defendants moved for summary judgment dismissing plaintiff's complaint. The trial court denied defendants' motion, and defendants appealed.

Reversing the trial court, the Appellate Division for the First Department relied on the Court of Appeals case *McNulty v. City of New York*, 100 N.Y.2d 227 (2003), holding that a physician does not owe a duty of care to a non-patient even if the physician knows that the non-patient is caring for the physician's patient, unless the physician's treatment of that patient is the cause of the non-patient's injury. The Appellate Court noted that there was no allegation that defendants' treatment of plaintiff's mother caused plaintiff to become infected with hepatitis C. The Court also rejected plaintiff's effort to distinguish *McNulty* by arguing that a different rule should apply for a patient's "close relative," or by characterizing her claim as one for ordinary negligence instead of medical malpractice.

The Appellate Division also held that sections of the State Sanitary Code, even if applicable to plaintiff's claims, did not create a private cause of action in plaintiff's favor. Similarly, no cause of action arose from Public Health Law § 225 (powers of the Public Health Council) or Public Health Law § 2222 (requirements for physicians treating tuberculosis).

OPMC Lacks Authority to Subpoena Information Not Related to Complaint Against Physician

N. (Anonymous) v. Novello, 13 A.D.3d 631, 787 N.Y.S.2d 379 (2d Dep't 2004). The Appellate Division ruled that the State Board for Professional Medical Conduct had no authority to issue a subpoena to compel production of materials unrelated to the complaints made against the physician. The Court noted that although the issuing agency need only establish that the material sought bears a reasonable relation to the matter under investigation, the agency has no right to subpoena any information it chooses in the hopes of finding violations.

Accordingly, the Court affirmed the grant of the physician's motion to quash portions of the OPMC's subpoena, since 10 of the listed categories of information sought "were not related to the complaints contained in the confidential report submitted to the . . . court . . . but instead sought general information regarding any possible other wrongdoing by the petitioner."

Hearsay Admissible in Medical Resident's Grievance Hearing; Deference Given to "Subjective Professional Judgments"

Ono, M.D. v. The Long Island College Hospital, 785 N.Y.S.2d 76 (1st Dep't 2004). The Long Island College Hospital (the "Hospital"), which relied on documents provided to it by the District Attorney's office in dismissing a medical resident based on misconduct, rejected the resident's challenge to the Hospital's consideration of the information. The criminal charges against the resident were subsequently dropped, but were pending at the time the Hospital considered them, thus the D.A.'s file had not yet been sealed.

The Appellate Division also did not find the reliance on hearsay a weakness, "because an administrative determination may be based on hearsay and, accordingly, the relevant inquiry in assessing the adequacy of the evidence underlying an administrative determination is not whether the evidence is hearsay, but whether it is sufficiently relevant and probative to lend rational support to the determination."

In the record of the administrative proceeding, the Appellate Division found a rational basis for a finding of misconduct based on evidence that the participant possessed a controlled substance and engaged in sexual misconduct. Thus, the termination of the participant did not "shock [its] sense of fairness." Lastly, the Appellate Division noted that in administrative proceedings such as determinations of the fitness of a medical resident, subjective professional judgments are involved, to which the courts are ordinarily bound to defer.

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

In the New York State Legislature

By James W. Lytle

The lesson of 2005: Even a budget that was not officially completed until April 12th is still on time.

After the Legislature strived mightily to enact the 2005-06 budget on time and actually passed the vast majority of appropriation and budget policy legislation via a publicly visible conference committee process prior to the April 1st deadline, a few issues remained unresolved that required an additional week to two to resolve. Even though there were reports well into the second week of April that any chance for agreement with the Governor appeared dim, negotiators ultimately were able to reach agreement with the Governor the old-fashioned way—in closed-door negotiations between Governor Pataki and the legislative leaders. While the return to "three men in a room" appeared necessary to close the deal, the 2005 budget process will still properly be regarded as one of the more transparent and timely in recent memory.

As is almost always the case, the budgetary negotiations resulted in more than just fiscal changes: this budget enacted important changes relating to the future of the Medicaid program, the restructuring of the fiscal relationship between state and local governments relating to the financing of the program and the enactment of new cost containment initiatives and cost savings, through provider taxes, benefit reductions, increased copays and a new preferred drug list.

Rather than reciting the full litany of changes enacted by the budget and its aftermath, I thought it might be more useful and more timely to focus on just two of the more significant policy changes that might have more long-term ramifications.

Selective Medicaid Rate Setting for Specialty Inpatient Services

The final budget agreement included an authorization, for the first time, of selective contracting for inpatient services. The final agreement authorized negotiated Medicaid fee-for-service payment rates for specialty inpatient hospital services provided by selected hospitals for the period April 1, 2005 though March 31, 2010. The bill limits the number of sites for the program to no more than five "geographically defined" inpatient hospital sites, to be determined by the Commissioner, at which five specialty inpatient services may be selected for these negotiated rates.

The five inpatient services will be chosen by the Commissioner based on the following criteria:

- Opportunity to provide the services more efficiently and economically;
- Existence of a correlation between volume of services or procedures and improved patient outcomes that is recognized by medical experts;
- Relationship to other quality and patient programs undertaken by the DOH, including Centers of Excellence;
- Impact on geographic accessibility of services;
- Low utilization of the services or delivery of services in units with low occupancy;
- Any other criteria determined by the Commissioner.

In determining which hospitals will have specialty rates, the Commissioner is directed to consider:

- Consultations with hospitals, associations, consumers;
- Patient access to the select services;
- Historical volume of services provided by the hospital;
- Consistency with other quality initiatives of the Department, including Centers of Excellence;
- The "order and timeline" by which the services shall be provided; and
- Other criteria that the Commissioner deems appropriate.

The rates for the selected services at the designated hospitals must be agreed upon by the Commissioner and the hospital. Rates may be established through two approaches: (1) without a competitive bid, pursuant to a negotiation and administrative rate appeal process; and/or (2) through a competitive bidding process. Rates established without a competitive bid must be "reasonable and adequate to reimburse the costs of an economically and efficiently operated provider of services." The bill prohibits a Medicaid fee for service reimbursement to non-selected hospitals within the geographically defined site for the specified services, unless the services were previously approved by the Commissioner, or if the services were the result of an emergency admission.

This section is contingent on approval of a federal waiver application to ensure federal financial participation. The Commissioner is required to provide a copy of the application to the Legislature prior to submission, although she may take steps to implement this section prior to Centers for Medicare and Medicaid Services approval. The Commissioner must report to the Governor and legislature regarding the implementation of this section

within 18 months after the issuance of specialty rates.

The Commission on Health Care Facilities in the 21st Century

The 2005-06 budget also provided for the establishment of a Commission on Health Care Facilities in the Twenty-First Century ("the Commission") to make recommendations for reconfiguring hospital and nursing home bed supply to conform to regional needs. The so-called "base-closing commission" is charged with the obligation to recommend closing, resizing, consolidating, converting, or restructuring health care facilities.

The Commission will have eighteen "statewide" members and an additional six regional members in each of six state regions. The eighteen statewide members are appointed as follows: two to be appointed by the Senate leader, one by the Senate minority leader; two by the Speaker of the Assembly; one by the Minority Leader of the Assembly and twelve by the Governor. The Commissioner of Health is directed to appoint a liaison from the department, a liaison from the Public Health Council, and a liaison from the State Hospital Review and Planning Council. The Dormitory Authority director is to appoint one or more liaisons to the Commission.

Regional members will be drawn from the following six regions: Long Island, New York City, Hudson Valley (Delaware, Dutchess, Orange, Putnam, Rockland, Sullivan, Ulster and Westchester), Northern New York, Central New York and Western New York. The regional members for each region are designated as follows: two appointed by the Governor; two by the Senate majority leader and two by the Assembly speaker. These regional members may vote only on recommendations relating solely to the regional member's respective region.

Each region will also have an advisory committee, with an undetermined number of members, to be appointed equally by the Governor, speaker and majority leader. The regional advisory committees must develop recommendations for reconfiguration in their region, and may conduct formal public hearings with input from local stakeholders. The recommendations shall include recommended dates by which such actions should occur, necessary investments to carry out the recommendations, and the justification for the recommendations. If the regional advisory committee fails to make recommendations, the Commission must still perform its duties.

The Health Commissioner and the Director of the Dormitory Authority are required to provide to the Commission a list of factors to be considered by the Commission in fulfilling its mission, including:

- Need for capacity in that region;
- Capacity currently existing in the hospital and nursing home systems in that region;
- Economic impact of "right sizing actions on the state, regional and local economies, including the impact on health care workers";
- Amount of capital debt the institutions carry and their financial status;
- Availability of other sources of funding for capital expense and a plan for paying or retiring debt;
- Existence of other health care services, including the availability of services for the uninsured and underinsured and Medicaid beneficiaries, including non-hospital service providers;
- Potential conversion of facilities to other uses;
- Extent to which the facility services the health care needs of the region, including Medicaid recipients, the uninsured and underserved communities; and
- Potential for improved quality of care and redirection of resources toward reinvestment, and the extent to which any restructuring will result in greater stability and efficiency in the delivery of health care services.

Additional factors may be added by the Commissioner and the Director, and the Commission itself may consider additional factors.

Regional advisory reports must be submitted not later than November 15, 2006. The Commission must make its recommendations no later than December 1, 2006. Its recommendations must be made in collaboration with the regional advisory committees to the extent practicable. In addition the Commission can make recommendations on a streamlined regulatory process and changes to the hospital and nursing home reimbursement system.

The Governor must transmit the Commission's report with his written approval on or before December 5, 2006 to the Legislature. Unless a majority of the members of each house vote to adopt a concurrent resolution rejecting the recommendation in their entirety by December 31, 2006, the Commissioner will implement the recommendations of the Commission. However, implementation may not begin prior to December 31, 2006. The Commissioner is authorized to take any action related to the establishment, construction, approval, suspension or revocation of the operating certificates, closure, consolidation, conversion or restructuring of hospitals as recommended in a "reasonable, cost efficient manner" to carry out the recommendations. The Commissioner's authority under the law expires June 30, 2008.

Mr. Lytle is a partner in the Albany office of Manatt, Phelps & Phillips, LLP. **Mr. Lytle would like to acknowledge the assistance of his colleague from that office, Karen Lipson, with the preparation of this article.**

In the New York State Agencies

By Frank Serbaroli

HEALTH DEPARTMENT

Approval of Laboratories Performing Environmental Analysis

Notice of adoption. The Department of Health amended Subpart 55-2 of Title 10 N.Y.C.R.R. to lessen the regulatory burden on environmental laboratories that conduct businesses in more than one state, codify criteria for method approval, clarify criteria for compliance and enforcement activities and address new technology and practices in such labs. Filing date: October 28, 2004. Effective date: November 17, 2004. *See* N.Y. Register, November 17, 2004.

Animals in Health Care Facilities

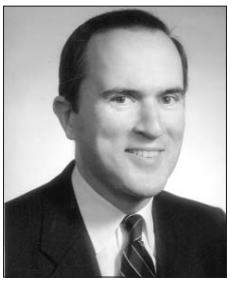
Notice of adoption. The Department of Health amended §§ 405.24 and 415.29 of Title 10 N.Y.C.R.R. to make the current standards for accessing service animals that provide assistance to the disabled consistent with the Americans with Disabilities Act and to update additional standards for animal-assisted therapy programs in nursing homes. *See* N.Y. Register, November 17, 2004.

Medicaid Enteral Nutrition Reimbursement Methodology

Notice of adoption. The Department of Health amended § 505.5 of Title 18 N.Y.C.R.R. to decrease Medicaid reimbursement for enteral nutrition. Filing date: November 16, 2004. Effective date: January 1, 2005. *See* N.Y. Register, November 17, 2004.

Medicaid Utilization Thresholds

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend §§ 511.10–511.13 of Title 18 N.Y.C.R.R.



to more properly reflect the maximum number of physician, pharmacy, mental health and laboratory services that the Department will pay for Medicaid recipients in a benefit year. *See* N.Y. Register, December 1, 2004.

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

Notice of adoption. The Department of Health added a new § 400.23 to Title 10 N.Y.C.R.R. and amended §§ 763.13 and 766.11 of Title 10 N.Y.C.R.R and § 505.14 of Title 18 N.Y.C.R.R. to protect nursing home residents and home care clients by requiring non-licensed nursing home and home care staff who provide direct care or supervision to undergo criminal history checks. Filing date: December 21, 2004. Effective date: April 1, 2005. *See* N.Y. Register, January 5, 2005.

Nursing Home Pharmacy Regulations

Notice of emergency rulemaking. The Department of Health amended § 415.18(g) and (i) of Title 10 N.Y.C.R.R. to make a wider variety of medications available in nursing home emergency medication kits and to allow verbal orders from a legally authorized practitioner in order to respond quickly to the needs of residents. Filing date: January 14, 2005. Effective date: January 14, 2005. *See* N.Y. Register, February 2, 2005.

Controlled Substances in Emergency Kits

Notice of emergency rulemaking. The Department of Health amended §§ 80.11, 80.47, 80.49 and 80.50 of Title 10 N.Y.C.R.R. to allow Class 3a facilities (nursing homes, adult homes and other long term care facilities) to maintain controlled substances in emergency kits and administer them to a patient in an emergency situation. Filing date: January 14, 2005. Effective date: January 14, 2005. *See* N.Y. Register, February 2, 2005.

Health Provider Network Access and Reporting Requirements

Notice of emergency rulemaking. The Department of Health amended §§ 487.12, 488.12 and 490.12 of Title 18 N.Y.C.R.R. and §§ 400.10, 763.11, 766.9 and 793.1 of Title 10 N.Y.C.R.R. to require adult homes, enriched housing programs, residences for adults, Article 28 facilities (Hospitals), Article 36 facilities (Home Care Services) and Article 40 facilities (Hospice) to establish and maintain Health Provider Network accounts with the Department of Health for the purpose of exchanging information with the Department in a rapid, efficient manner in times of emergencies or urgent matters. Filing date: January 14, 2005. Effective date: January 14, 2005. *See* N.Y. Register, February 2, 2005.

Rate of Payment for Limited Home Care Services Agencies

Notice of adoption. The Department of Health added a new Subpart 86-8 to Title 10 N.Y.C.R.R. to reduce Medicaid expenditures for certain personal care services furnished to eligible residents of an adult home or enriched housing program by providing reimbursement directly to the

limited home care services agency rather than an outside personal care provider or certified home health agency. Filing date: January 14, 2005. Effective date: February 2, 2005. *See* N.Y. Register, February 2, 2005.

Serialized Official New York State Prescription Form

Notice of emergency rulemaking. The Department of Health added a new Part 910 to Title 10 N.Y.C.R.R. and amended §§ 85.21, 85.22, 85.23 and 85.25 of Title 10 N.Y.C.R.R. and §§ 505.3, 528.1 and 528.2 of Title 18 N.Y.C.R.R. to prevent prescription fraud by enacting the official New York State prescription form to be used for all prescribing done in New York State. Filing date: January 21, 2005. Effective date: January 21, 2005. *See* N.Y. Register, February 9, 2005.

Expansion of the New York State Newborn Screening Panel

Notice of emergency rulemaking. The Department of Health amended §§ 69-1.2 and 69-1.3 of Title 10 N.Y.C.R.R. to add twenty inherited metabolic disorders to the current New York State newborn screening panel. Filing date: January 25, 2005. Effective date: January 25, 2005. *See* N.Y. Register, February 9, 2005.

Standard Autopsy Protocols for Unanticipated Infant Deaths

Notice of adoption. The Department of Health added a new § 69-9 to Title 10 N.Y.C.R.R. to establish standard autopsy protocols consistent with the International Standardized Autopsy Protocol for Sudden Unexpected Infant Death for any person under the age of one year whose death is unanticipated by medical history or when the cause of death is unknown. Filing date: February 1, 2005. Effective date: February 16, 2005. *See* N.Y. Register, February 16, 2005.

Communicable Diseases List

Notice of emergency rulemaking. The Department of Health amended § 2.1 of Title 10 N.Y.C.R.R. to add laboratory-confirmed influenza to the list of communicable diseases to be reported to the Department to enable the Department of Health to have more comprehensive and complete information on influenza cases and permit the state and local health departments to channel limited vaccines, anti-viral agents and public health resources to those in greatest need during an influenza outbreak. Filing date: February 4, 2005. Effective date: February 4, 2005. *See* N.Y. Register, February 23, 2005.

Part-Time Clinics

Notice of emergency rulemaking. The Department of Health amended §§ 703.6 and 710.1 of Title 10 N.Y.C.R.R. in order to clarify and enhance the regulatory requirements that apply to part-time clinics and to require prior limited review of all part-time clinic sites. Filing date: February 15, 2005. Effective date: February 15, 2005. *See* N.Y. Register, March 2, 2005.

Adult Care Facility Inspection Reports

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend §§ 486.2 and 486.5 of Title 18 N.Y.C.R.R. to require the Department's inspection reports to determine whether an adult care facility's operation is in compliance with adult care facility regulations pursuant to a recent State Supreme Court decision (*Bayview Manor Home for Adults v. Novello*, Index No. 7662-20, Supreme Court, Albany Co., decision of August 20, 2003). *See* N.Y. Register, March 2, 2005.

Self-Attestation of Resources for Medicaid Applicants and Recipients

Notice of emergency rulemaking. The Department of Health amended § 360-2.3(c)(3) of Title 18 N.Y.C.R.R. to allow a Medicaid applicant or recipient to attest to the amount of his or her resources unless the applicant or recipient is seeking Medicaid payment for long-term care services. Filing date: February 25, 2005. Effective date: February 25, 2005. *See* N.Y. Register, March 16, 2005.

Review Criteria for Therapeutic Radiology

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend §§ 708.2, 708.5 and 709.16 of Title 10 N.Y.C.R.R. to revise certificate of need criteria for therapeutic radiology. *See* N.Y. Register, March 23, 2005.

INSURANCE DEPARTMENT

New York State Partnership for Long-Term Care Program

Notice of adoption. The Department of Insurance amended Part 39 (Regulation 144) of Title 11 N.Y.C.R.R. to add three new plan designs to the New York State Partnership for Long-Term Care Program, change the existing plan design to incorporate Evolution Board resolutions and recommendations of the Governor's Working Group on Healthcare Reform and reflect the adoption of the demonstration project as a program. The new plan designs offer either more affordable long-term care coverage or greater coverage for residential facility and home care and greater choice of optional additional benefits. Filing date: January 5, 2005. Effective date: January 26, 2005. *See* N.Y. Register, January 26, 2005.

Claim Submission Guidelines for Medical Service and Hospital Claims

Notice of adoption. The Department of Insurance added Part 217 to Title 11 N.Y.C.R.R. to create claim payment guidelines setting forth what is needed to determine when a health care insurance claim is considered complete and ready for payment in order to resolve conflicting views between the health care providers and the insurance industry as to compliance with New York's prompt payment statute. Filing date: January 12, 2005. Effective date: February 2, 2005. *See* N.Y. Register, February 2, 2005.

Healthy New York Program

Notice of emergency rulemaking. The Department of Insurance added § 362-2.7 and amended §§ 362-2.5, 362-3.2, 362-4.1, 362-4.2, 362-4.3, 362-5.1, 362-5.2, 362-5.3, and 362-5.5 of Title 11 N.Y.C.R.R. to reduce the cost of, lessen the complexity of and add a second benefit package to the Healthy New York program. Filing date: March 8, 2005. Effective date: March 8, 2005. *See* N.Y. Register, March 23, 2005.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a partner in Cadwalader, Wickersham & Taft LLP's 18-attorney health law department. He is the Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and serves on the Executive Committee of the New York State Bar Association's Health Law Section. He is the author of "The Corporate Practice of Medicine Prohibition in the Modern Era of Health Care" published by BNA as part of its Business and Health Portfolio Series. The assistance of Ms. Stephanie Marcantonio and Ms. Vimala Devassy, associates at Cadwalader, Wickersham & Taft LLP, in compiling this summary is gratefully acknowledged.

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In the Journals

By Dale L. Moore

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- Forrest Lee Andrews, *Comment: Small Bites: Obesity Lawsuits Prepare to Take on the Fast Food Industry*, 15 Albany Law Journal of Science & Technology 153 (2004).
- Beverly Cohen, *An Examination of the Right of Hospitals to Engage in Economic Credentialing*, 77 Temple Law Review 705 (2004).
- Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 New York University Annual Survey of American Law 241 (2004).
- Andrew J. McClurg, *Dead Sorrow: A Story about Loss and a New Theory of Wrongful Death Damages*, 85 Boston University Law Review 1 (2005).
- Ashley R. Melson, *Bioterrorism, Biodefense, and Biotechnology in the Military: A Comparative Analysis of Legal and Ethical Issues in the Research, Development, and Use of Biotechnological Products on American and British Soldiers*, 14 Albany Law Journal of Science & Technology 497 (2004).
- Richard S. Saver, *Medical Research Oversight from the Corporate Governance Perspective: Comparing Institutional Review Boards and Corporate Boards*, 46 William and Mary Law Review 619 (2004).
- Alissa Schecter, *Choosing Balance: Congressional Powers and the Partial-birth Abortion Ban Act of 2003*, 73 Fordham Law Review 1987 (2005).
- Daniel Sperling, *Maternal Brain Death*, 30 American Journal of Law and Medicine 453 (2004).

For Your Information

By Claudia O. Torrey

On January 31, 2005, the Office of Inspector General ("OIG") of the Department of Health and Human Services issued a new supplemental guidance for hospitals.[1] The new guidance supplements the OIG's 1998 Compliance Program Guidance ("CPG") for hospitals, which concerned the fundamentals of establishing an effective compliance program.[2] Thus, the two documents are to be utilized together by hospitals in order to operate effective compliance programs that decrease errors, fraud, and abuse.[3]

Section two of the supplemental CPG is entitled *Fraud and Abuse Risk Areas.* According to the supplemental CPG, hospitals should pay particular attention to the following areas for potential fraud and abuse issues: submission of accurate claims and information; the referral statutes; payments to reduce or limit services; the Emergency Medical Treatment and Active Labor Act; substandard care; relationships with federal health care beneficiaries; Health Information Portability and Accountability Act privacy and security rules; and, billing Medicare or Medicaid substantially in excess of usual charges.[4] The supplemental CPG also addresses potential fraud and abuse risks in: compensation packages between hospitals and hospital-based physicians (hospitalists, pathologists, etc.); hospital discounts to uninsured patients; and hospital-oriented professional courtesies for physicians.

COMMENTARY

The theme for this issue of the *Health Law Journal* is fraud, abuse and compliance; however, this columnist would feel remiss as a health law attorney in not acknowledging the health law issues that have taken center stage in the media over the last two weeks.

As this column was going to press (March 31, 2005), Mrs. Terri Schiavo, of Pinellas Park, Florida, died. For those for whom the name does not "ring a bell," Mrs. Schiavo was a forty-one-year-old brain damaged woman whose parents and husband have been battling over her care within the legal system. Ironically, at this same writing, Pope John Paul II has become gravely ill, and the health of Prince Rainier III, royal ruler of the tiny European principality of Monaco, has taken a turn for the worse. While the circumstances surrounding Mrs. Schiavo will probably put her in the annals of health law, these three courageous people have caused an entire nation to look closely at issues concerning the right to die (and to live).

One can certainly predict that over the next year, if not the next decade, Congress, states, and individuals will be looking at: the importance of a living will and/or a durable health care power of attorney (New York State has a health care proxy law);[5] whether or not there should be a national definition for "persistent vegetative state;" whether or not it is ever appropriate to slowly withdraw or completely withhold food and hydration, or is this state-sanctioned euthanasia; does the same reasoning apply to someone who is brain damaged, and/or of diminished mental capacity?

It can be safely stated that increased costs in, and demands on, our health care system will cause society to look closely at these issues. One would not want to see one of the wealthiest countries in the world exacerbate a slippery slope divide between the perception of health care as a right, and the perception of health care as a privilege. Irrespective of where one stands on these issues, most people will probably agree that what they expect from their health care system is to be treated competently, fairly, and humanely.

Endnotes

1. 70 Fed. Reg. 4858–4876 (January 21, 2005), *OIG Supplemental Compliance Guidance for Hospitals*.
2. *See* 63 Fed. Reg. 8987 (February 23, 1998), *OIG Compliance Program Guidance for Hospitals*.
3. 70 Fed. Reg. at 4876.
4. *Id.* at 4859.
5. Public Health Law Art. 29-C (McKinney 2005).

Claudia O. Torrey, Esq. is a member of the American Bar Association, the American Health Lawyers Association, and a sustaining member of the New York State Bar Association. She is also the author of "Emerging Ethical Issues in the Provision of Health Care," chapter thirty-five in the *Legal Manual for New York Physicians*, published by the Continuing Legal Education Department of the New York State Bar Association (2003). The second edition is slated to be published during 2005.

ER Call Coverage: A Growing Crisis

By Marcia B. Smith

The delivery of inpatient care, the maintenance of a 24/7 emergency department, and the requirement to accept all patients regardless of ability to pay are the distinguishing features of a hospital. They are also the most costly. It is often the difficulty in maintaining these services that is at the root of a hospital's financial problems.[1]

Introduction

One of the most important missions of a hospital is to provide essential emergency services to its community. We all take comfort in knowing that we can seek treatment in an emergency room, at any time of the day or night, if we are injured or become sick. Emergency rooms have also become the providers of last resort for the vulnerable uninsured population, who do not have access to preventive care and often wait until their condition is at an advanced stage to seek care.

Our access to emergency care is protected by state licensing requirements and the Emergency Medical Treatment and Active Labor Act ("EMTALA"). Hospitals participating in Medicare must provide a medical screening exam to any individual who comes to its emergency room and requests examination and treatment for a medical condition, regardless of the individual's ability to pay for these services.[2] About one-fourth of emergency room patients must be seen by a physician specialist, such as a neurosurgeon or cardiologist. Therefore, EMTALA also requires hospitals to maintain an on-call list of physician specialists who are available for consultation and can come to the emergency room. The number and type of specialists who are required to be on-call must be sufficient to meet the needs of the hospital's patients, taking into account its resources and the availability of physicians.[3]

EMTALA does not require specialists to accept call. For personal and financial reasons, many physicians are looking for ways to avoid the obligation. An on-call physician must be ready, willing and able to drop whatever she is doing and come to the emergency room immediately. It doesn't matter that she told her daughter that she would read her a bedtime story or is tired and needs to be well-rested for the elective surgery procedure scheduled for early the next morning. Increasingly, the physician will receive little or no reimbursement for the valuable services that she provides.

Hospitals often mandate that physicians agree to take call as a condition of membership on their medical staff. This approach allows hospitals to meet their legal obligations, without any additional cost. It does nothing, however, to address physician concerns about increased call obligations, inadequate reimbursement and additional legal liability. New approaches are needed that address the concerns of all stakeholders.

Hospitals may offer physicians financial incentives to take call, as long as any compensation paid meets fraud and abuse requirements. Compensation arrangements can be tailored to meet the specific needs of a hospital. Typical arrangements include payments based on on-call time or "beeper weight," tier-based compensation, reimbursement guaranties, and exclusive group contracts. Because compensating the specialists to accept call will tax New York hospitals' already scarce resources, hospitals should also consider expanding the number of individuals who are available to take call through the use of physician extenders, leveraging available staff through the use of hospitalists and dual-coverage arrangements, and contracting with a management service organization to administer call coverage schedules.

Hospitals' Obligation to Maintain On-Call List

General hospitals in New York are required to provide emergency services, and to evaluate, treat and stabilize a patient with an emergency condition.[4] Emergency rooms ("ERs") should be staffed by physicians who are board-certified in emergency medicine and certified in advance trauma life support. The ER physicians are trained to handle a variety of conditions and injuries. Emergency practitioners must consult with specialists, however, regarding treatment, admission to the hospital, and follow-up care. It is estimated that one-quarter of all emergency room visits will require the involvement of a consulting medical or surgical specialist.[5] In New York, that means more than 1.8 million specialist consultations per year.

A number of these patients are "unassigned" patients, meaning they do not have a designated physician on the hospital's medical staff. Unassigned patients may include uninsured/self-pay patients, those in fee-for-service Medicare or Medicaid, and tourists or non-residents. They also include managed care enrollees who do not have a relationship with a particular specialist in the required area. Uninsured adults are less likely to have a personal doctor or health care provider and more likely to put off seeing a doctor when

needed.[6] Not surprisingly, they are also much more likely to report being in poor or fair health than are adults who are insured.[7]

Hospitals have the burden to ensure specialists are available both for consultation and to come to the emergency room, if necessary. New York State Department of Health ("DOH") regulations require hospitals to schedule round-the-clock coverage of the emergency room for every medical-surgical specialty that is organized as a department or clinical service of the hospital's medical staff and which has sufficient physician staffing.[8] To participate in Medicare, hospitals must maintain an on-call list that "best meets the needs of the hospital's patients who are receiving services required under [EMTALA] in accordance with the resources available to the hospital, including the availability of on-call physicians."[9]

Under EMTALA, hospitals must provide a medical screening exam to any individual who comes to the ER and requests examination and treatment for a medical condition.[10] If the hospital determines that the individual has an emergency medical condition, it must then stabilize the condition or provide for an appropriate transfer. Screening and stabilization services must be provided without regard to the individual's ability to pay.

Which specialists must be available and for what period of time will depend on the number of physicians on staff and the frequency with which the hospital's patients require the services in a particular specialty. When it issued the latest EMTALA regulations, the Centers for Medicare and Medicaid Services ("CMS") made it clear that it will not apply the "Rule of Three" in deciding whether a hospital is meeting the EMTALA requirements.[11] The "Rule of Three" states that whenever there are at least three physicians in a specialty, a hospital must provide 24/7 coverage in that specialty. CMS's repudiation of the Rule of Three is helpful as it may relieve some of the burden on hospitals and physicians, but CMS left open the question of what rule of thumb should be applied. Hospitals that guess wrong are subject to penalties of up to $50,000 per violation and exclusion from Medicare.[12]

If there were no constraints, hospitals would provide 24/7 coverage for every specialty offered to inpatients. This level of coverage would ensure a specialist was available for consultation and a trip to the emergency room whenever he was needed. A physician who agrees to be placed on the on-call list and is on duty is subject to penalty if he refuses to appear when called or negligently fails to provide the necessary stabilizing services.[13] The maximum penalty is $50,000 for each such violation. If the violation is gross and flagrant or is repeated, the physician may be excluded from participation in Medicare and Medicaid.

Physicians' Reluctance to Accept On-Call Obligations

EMTALA does not impose an obligation on physicians to accept call. The burden is on the hospitals to find ways to staff their on-call coverage schedules. Fewer physicians are agreeing to take call. In a 2001 telephone survey of ER directors and personnel, the Department of Health and Human Services, Office of Inspector General ("OIG") found that 54 percent of doctors and nurses believed staffing was a problem for some specialties. Table 1 shows the most commonly mentioned areas of concern.[14]

Table 1

Areas for which specialist coverage is a concern

1. Neurosurgery
2. Cardiovascular surgery and cardiology
3. Pediatrics and subspecialties
4. Orthopedic surgery
5. OB/GYN and neonatal services
6. Neurology
7. Plastic surgery
8. Psychiatry and subspecialties

Physicians with significant on-call obligations are, in general, less satisfied with their jobs.[15] Even if the specialist is never called to the emergency room, he must be ready to go if necessary. Taking call interferes with office visits, family time and personal interests. A physician who is called into the ER in the middle of the night will not be well-rested for office visits the next day.

EMTALA is an unfunded mandate. Hospitals and physicians are required to provide evaluations and stabilizing care to patients who come to the emergency room, regardless of their ability to pay. Tax exempt hospitals typically view (or should view) the provision of providing free care as part of their charitable purposes. Physicians in private practice are not obligated to provide free care and, for understandable reasons, many are unwilling to do so.

Specialists who treat unassigned patients in the ER stand a good chance of not being reimbursed for their services. In one study, nearly eight in ten physicians reported having trouble obtaining payment for on-call services.[16] The problem is not limited to self-pay

patients, an estimated one-third of whom actually pay their ER bills. Fifty-four percent of call specialists surveyed by the California Medical Association reported receiving no payment from health plans.[17] Health plans may deny coverage based on a determination that the "prudent layperson" standard was not met or may refuse to pay the standard charges of physicians who do not have a contract with the plan.

A bill has been introduced in the New York State Senate that would require nonparticipating providers, including physicians and hospitals, to accept the "usual and customary" fees of managed care plans as payment in full for emergency services provided to the plans' enrollees.[18] In the case of Medicaid, Family Health Plus and Child Health Plus enrollees, reimbursement to nonparticipating providers would be set at the Medicaid rate, which is significantly lower than the rates paid by private plans.

If passed, the bill would allow managed care plans to effectively set the prices paid for emergency services provided by specialists who agree to accept call. It is unlikely that hospitals or physicians would be satisfied with the level of reimbursement offered by the plans. The plans have no incentive to set compensation at a reasonable rate as the hospitals are obligated to provide the emergency services to their enrollees regardless of reimbursement rates. ER physicians agree that passage of such a bill would further exacerbate the problem of securing specialist coverage in the ER.[19]

Although the Senate bill is sponsored by the Chair of the Senate's Health Committee, no companion bill has been introduced in the Assembly and the bill has not advanced as of this writing. A similar bill introduced in the Assembly in a prior session did not advance. It is therefore unlikely that any legislative developments in this area are imminent.

Physicians are also legitimately concerned that agreeing to take call can subject them to fines under EMTALA and will lead to more lawsuits, which means additional increases in their malpractice premiums. Unassigned ER patients do not have an established relationship with the specialist and are reported as being more willing to bring suit against the physician.[20] Many of the ER patients are in a chronic condition, due to a traumatic injury or lack of adequate primary care, which results in more complications and greater liability exposure. Further, specialists who take call may also be asked to practice outside their usual area of expertise. For example, a neurologist who treats primarily adult patients may be required to treat a child or infant, even if the physician has little or no experience treating such patients.

Mandatory Call Obligations

The shortage of on-call physician specialists is well-documented and of growing concern. Studies and surveys by the General Accounting Office,[21] OIG,[22] and the American Hospital Association[23] and anecdotal tales of hospitals closing their ERs due to lack of specialty coverage have highlighted the need for hospitals to take action to secure adequate coverage.

One way hospitals can meet their state licensing and EMTALA obligations is to mandate that specialists accept call as a condition of medical staff membership. Call obligations have long been viewed as the ethical and moral duty of physicians and the medical staff bylaws of most hospitals in New York include such a requirement. Mandating call ensures the availability of those specialists who are on the medical staff. It does not ensure that there will be adequate coverage for a particular specialty that is underrepresented on the medical staff.

Mandatory on-call obligations work well when the physicians are employees of the hospital and are paid to accept call. Hospitals that employ physicians absorb the risk of non-payment for services and can ensure sufficient staff coverage to avoid over-burdening the physicians.

The problem with this approach for independent members of the medical staff is that it does not address any of the reasons why they are reluctant to accept call. If pushed too far, some specialists will avoid on-call obligations by resigning their medical staff privileges. In a nationwide survey, the Clinical Advisory Board found that 48 percent of specialists and 36 percent of surgeons would move some or all of their business if forced to accept call.[24] These physicians could move their practice to an alternative setting, such as an ambulatory surgery center ("ASC"), that has no call obligations. ASCs, which are often owned by physicians, compete with the hospitals to provide certain diagnostic and surgical procedures. Hospital administrators facing a group of specialists who are threatening to resign their medical staff privileges to avoid call obligations must address the group's concerns or risk a significant loss of business.

In recognition of the inability of New York hospitals to face this dilemma on their own without additional leverage, the Health Care Reform Working Group is recommending that the Governor consider mandating coverage commitments as a condition of participation in the physician excess malpractice insurance program and as a requirement for certification to perform designated surgical procedures in private offices.[25] Such

requirements could work if they provided something of value to the physicians for which they would be willing to trade their services. Before DOH can link call coverage commitments to certification of private office surgeries, however, it must first be given authority to regulate such surgeries.[26]

Offering Incentives to Take Call

Hospitals can secure the specialists' voluntary acceptance of call by offering them compensation. Paying specialists to accept call addresses their most significant concern: no or inadequate reimbursement for their services. This compensation can take the form of payments to accept call for a set amount of time (e.g., per diem, per month or per annum), a promise to ensure an agreed-upon level of reimbursement if the physician is required to come to the hospital, or both. Hospitals can also enter into an exclusive arrangement with a group to provide on-call services in a particular specialty.

Hospitals should not have to compensate every physician the same amount. The amount of the payment should vary based on the hospital's demand for the services and the supply of available physicians. Specialists who are in high-demand, such as neurologists, would be compensated at the highest level. The number of tiers or levels will depend on the hospital's patient mix, ER usage and physician supply.

Tier-based compensation arrangements cannot be imposed on the medical staff. Specialists in all but the highest paid group will be quick to take offense when told that their services are worth less than those of another group. Before establishing such an arrangement, the hospital must engage in a negotiation process with the medical staff that involves a wide spectrum of disciplines.

Compensation guarantees will work well at those hospitals in which the primary concern is ensuring adequate reimbursement for the services provided by the specialists who come to the ER and provide emergency services. The hospital may guarantee payments for uninsured patients only or for all patients based on a set rate, usually a percentage of Medicare for the relevant CPT code. If the patient is uninsured, the hospital will pay the physician directly at the agreed-upon rate. The physician assigns his or her right to payment to the hospital, which can then bill the patient directly. If the patient has insurance, the physician bills for the services and must substantiate any request made to the hospital for a stipend by submitting documentation that the claim was denied or was reimbursed at less than the agreed-upon rate.

Hospitals may also enter into an exclusive arrangement with a group of specialists for call coverage. The agreement would give the specialists an exclusive right to provide call coverage and pay them fair market value for their services. The need for an exclusive arrangement must be justified as improving the quality of care in the emergency room and meeting other needs of the hospital, such as providing needed services to charity care patients.

Compensation Arrangements Must Meet Stark Exception

If the hospital pays a stipend for on-call coverage, it will create a financial relationship between itself and the physician specialists, who refer Medicare and Medicaid patients to the hospital for designated health services. Under the Stark law, a hospital may not accept referrals for inpatient or outpatient services that will be reimbursed by Medicare from a physician with which it has a financial relationship, unless an exception applies.[27] Therefore, any payments to the specialists to accept call must meet a Stark exception.

Payments for on-call coverage can be structured to meet either the personal services exception or the fair market value Stark exceptions. To meet an exception, the following requirements must be met:

- The agreement must be set out in writing, be signed by the parties and specify the services covered by the arrangement;
- The arrangement must cover all the services to be furnished by the physician to the entity;
- The aggregate services contracted for cannot exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
- The term of the agreement is for a specified timeframe and the parties can only enter into one arrangement for the same items or services during the course of a year; and
- The arrangement cannot violate any other state or federal law.[28]

Meeting a Stark exception can reduce the risk that the payments will violate the federal and state anti-kickback statutes. These statutes make it a crime to knowingly and willfully offer, pay, solicit or receive remuneration in order to induce referrals of patients for the furnishing of items or services under any federal healthcare program, including Medicare or Medicaid.[29] Unlike the Stark law, which can be violated regardless of the parties' intent, the anti-kickback statutes are not violated unless the parties to an arrangement acted

with knowledge of the statute and the intent to violate it. Meeting a Stark exception is good evidence that the hospital is intending to offer remuneration to the physicians to accept call and not to refer patients to the hospital.

Fair market value is the key to meeting a Stark exception and reducing the risk of an anti-kickback violation. Hospitals should insist that the amount of an hourly stipend be established using one of the methodologies provided in the fair market value safe harbor. The safe harbor provides two methodologies for establishing that an hourly rate is fair market value: (1) the hourly payment is less than or equal to the average hourly rate for emergency room physicians in the relevant physician market; or (2) the hourly payment is less than or equal to the rate determined by averaging the 50th percentile national compensation levels for physicians with the same specialty in at least four national salary surveys.[30] Hospitals can choose from six national surveys in calculating this average. If the relevant specialty does not appear in the survey, the safe harbor looks to the salary for general practitioners.

Under Stark, if the payments are made to a group rather than directly to a referring physician, the payment may not create a financial relationship between the hospital and the referring physicians in the group. An indirect compensation arrangement between a hospital and a referring physician arises when the hospital makes payments to a group and has knowledge that the referring physicians in the group receive compensation that varies with or otherwise takes into account the volume or value of referrals to or other business generated for the hospital.[31] When the physician is an employee of the group, the relevant compensation arrangement is the one between the group and the physician. When the physician is an owner of the group, the relevant compensation arrangement is the one between the hospital and the group.

Any arrangement for payment of call should be approved by the hospital's governing body or authorized committee, particularly as one or more of the physicians may be considered a "disqualified person" under the intermediate sanctions law.[32] The board must be given appropriate data, both as to the need to pay the physicians and the amount of the payments. The minutes should adequately document the board or committee's decision.

Compensation schemes can quickly grow beyond a hospital's ability to finance the payments. One hospital was confronted with a demand from its three general surgeons to receive payment for on-call coverage. It agreed to make payments to the three physicians based on their increased call burden. Eighteen months later, the hospital is proposing to pay stipends to 155 physicians covering 17 specialties at a cost of over $1 million per year, without any additional increase in revenues. According to the Healthcare Association of New York State, not-for-profit hospitals have lost over $2 billion in the last five years. Most cannot afford to compensate specialists for on-call services.

Because of their escalating cost and financial burden, there is growing public concern that paying specialists to accept call is not economically sustainable. Providers are calling for legislative and regulatory action that would make managed care plans legally responsible for the cost of medically necessary emergency services, establish regional emergency medical services plans, and provide funding for EMTALA-mandated services to hospitals, and through the Medicare resource-based relative value scale, to physicians.[33]

Other Approaches

Other approaches include augmenting the medical staff by using physician extenders, leveraging available staff by employing hospitalists and allowing physicians to be on-call at more than one hospital or to schedule elective surgery while on-call, and contracting with a management services organization to administer call coverage schedules.

EMTALA permits an on-call physician to send a non-physician practitioner to meet her obligations.[34] Whether a non-physician practitioner may respond on behalf of the on-call physician depends on the patient's medical need and the scope of the non-physician practitioner's privileges at the hospital. The hospital must ensure, however, that the on-call physician is ultimately responsible for the individual regardless of who responds to the call.

Hospitals may also try staffing the ER using hospitalists. Hospitalists are internists that specialize in treating inpatients. Hospitalists can reduce the number of calls to specialists for medical ER patients by assessing unassigned patients to determine whether a specialist must be called in immediately or can be deferred until the next day.

Hospitals can also work with physicians to reduce their on-call responsibilities by allowing a physician to be on-call simultaneously at one or more hospitals or to schedule elective surgery while on-call. Hospitals must establish written policies and procedures to follow when the on-call physician is not available to respond because he or she has been called to the other hospital to evaluate an individual or is in surgery.[35] Such policies may include procedures for back-up on-call physi-

cians or an appropriate transfer that meets EMTALA guidelines. Unfortunately, because of anti-trust concerns, unaffiliated hospitals cannot jointly contract with physicians for on-call services. Although EMTALA allows each hospital to contract separately for the same coverage, the contracts must be negotiated independently, which will mean paying twice for the same coverage.

If available, hospitals can also contract with a management service organization ("MSO") to recruit, schedule and pay specialists to provide on-call services. The MSO could also bill for the services and ensure appropriate coding to legally maximize reimbursement. Payments to an MSO would create a buffer between the hospital and the referring physicians and further reduce the risk of a Stark or anti-kickback violation. Under this arrangement, the hospital is the provider of the service and would own the accounts receivable. It would compensate the MSO for the difference between the amount it collected on behalf of the hospital less the amount paid to the physicians, plus a management and billing fee. Specialists are paid at a fixed rate per relative value unit or a percentage of Medicare.

Conclusion

Emergency services are a public good and more must be done to ensure that hospitals and physicians have the resources they need to provide these services. Because of EMTALA's unfunded mandate, hospitals are often required to give patients and payers a "free ride." It would be callous to suggest that patients with an emergency medical condition should be turned away if they cannot afford to pay. General hospitals in New York cannot continue to provide these services, however, unless they receive adequate reimbursement or sufficient subsidies to do so.

Endnotes

1. Health Care Reform Working Group, Initial Recommendations for Reform, at p. 13 (Nov. 17, 2004) (*Working Group Report*).
2. 42 U.S.C. § 1395dd(a).
3. 42 C.F.R. § 489.24(j).
4. 10 N.Y.C.R.R. § 405.19(a)(2).
5. California Healthcare Foundation, *On-Call Physicians at California Emergency Departments: Problems and Potential Solutions* p. 2 (January 2005) (*CHF Study*).
6. State Health Access Data Assistance Center, *Characteristics of the Uninsured: A View From the States* (May 2005).
7. *Id.* New York has more than 3 million persons under the age of 65 without health insurance coverage, almost half of whom are working adults.
8. 10 N.Y.C.R.R. § 405.19(d)(1)(iv).
9. 42 C.F.R. § 489.24(j).
10. 42 U.S.C. § 1395dd(a).
11. 68 Fed. Reg. 53222, 53252 (Sept. 9, 2003).
12. 42 U.S.C. § 1395dd(d)(1)(A).
13. *Id*. § 1395dd(d)(1)(B).
14. U.S. Department of Health and Human Services, Office of Inspector General, *The Emergency Medical Treatment and Active Labor Act: Survey of Hospital Emergency Departments*, OEI-09-98-00220 (January 2001).
15. *CHF Study*, at p. 5.
16. *Id.* at p. 3.
17. *Id.* at p. 4.
18. S.2556 (Feb. 18, 2005).
19. New York State Chapter of the American College of Emergency Physicians, *Memorandum in Opposition: S.2556 Hannon, Prohibition on Balance Billing of Emergency Service* (2005).
20. *CHF Study*, at p. 5.
21. GAO, *Hospital Emergency Departments: Crowded Conditions Vary Among Hospitals and Communities* (March 2003). The GAO found that lack of on-call specialty coverage was a contributing factor to hospitals being on diversion status and boarding patients in the ER.
22. *See supra* note 11.
23. The Lewin Group, *Emergency Department Overload: A Growing Crisis; The Results of the AHA Survey of Emergency Department and Hospital Capacity* (April 2002).
24. *CHF Study*, at p. 8 (citing the Clinical Advisory Board, *Call Coverage Strategies: Securing Physician On-Call Compensation* (2003)).
25. *Working Group Report*, at p. 21.
26. *Id.* at p. 9. As the Group notes, "[in the private setting], there is no certificate of need (CON) process or accreditation process and, therefore, no way of monitoring quality, incidents reporting or services provided."
27. 42 U.S.C. § 1395nn.
28. 42 C.F.R. § 411.357(d)(l).
29. 42 U.S.C. § 1320a-7b(b); N.Y. Soc. Serv. Law § 366d.
30. 42 C.F.R. § 411.351.
31. *Id*. § 411.354(c)(2).
32. A "disqualified person" is (i) any person who on the date of a transaction with a tax-exempt organization is, or at any time during the five-year period ending on the date of the transaction was, in a position to exercise substantial influence over the affairs of the organization, (ii) a member of the family of such a person and (iii) an entity that is more than 35% owned or controlled by a disqualified person, directly or indirectly. 26 U.S.C § 4958(f).
33. *CHF Study*, at p. 8.
34. 68 Fed. Reg. 53222, 53256 (Sept. 9, 2003).
35. 42 C.F.R. §489.24(j)(2).

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Fraud and Abuse in the Medical Transportation Industry

By Melissa M. Zambri

Introduction

When fraud and abuse in health care is discussed, the first industry examples provided are often regarding hospitals and physicians. However, for attorneys who work with medical transportation providers frequently, the last few years have likely produced an increasing number of audits and investigations of these clients, with such medical transportation companies often being the subject or target of an investigation or an important witness in another provider investigation. This article will outline the fraud and abuse issues that often come into play in the medical transportation industry and suggest compliance measures, with an emphasis on the ambulette industry, which is seldom discussed in such articles.

Medical Transportation Providers and Reimbursement Requirements

Generally, medical transportation is provided by an ambulance or ambulette service.[1] Ambulance providers are licensed to provide emergency medical services and the transportation of the sick, disabled or injured persons to or from facilities providing hospital services.[2] The ambulance, which can be a motor vehicle, aircraft, boat or other form of transportation, is designed and equipped to provide emergency medical services during the transit of the patient.[3] An ambulette service transports the invalid, infirm or disabled to and from providers of medical care.[4] An ambulette service is prepared to provide personal assistance[5] and vehicles are designed and equipped to provide non-emergency care, either through wheelchair-carrying capacity, stretcher-carrying capacity, or the ability to transport disabled individuals.[6] Medicaid recipients are expected to use available resources for travel similar to those used for other activities. Thus, if a recipient has access to transportation (a private vehicle or funds for mass transit) to attend other activities of daily living, he or she is expected to use those resources for medical services.[7]

Focusing on Medicaid coverage,[8] reimbursement for ambulance services is limited to passenger occupied transportation.[9] Under Medicaid, an ambulance is generally only used for non-emergency transportation when the patient's medical condition requires transportation in a recumbent position, on a stretcher and/or while receiving life support, such as oxygen, by trained medical personnel.[10] In non-emergency situations, a determination must be made by the local department of social services or state agency of fiscal responsibility whether the use of an ambulance, rather than another mode such as ambulette service, taxi service, livery service or public transportation, is medically necessary.[11] Non-emergency ambulance services must be ordered by the recipient's physician, physician's assistant, or nurse practitioner.[12] A diagnostic and treatment center, hospital, nursing home, intermediate care facility, long term home health care program, home and community based services waiver program, or managed care program may order non-emergency ambulance transportation services on behalf of the ordering practitioner.[13] The ordering practitioner must note in the recipient's patient record the recipient's condition which qualifies the use of non-emergency ambulance services.[14] Medicaid provides prior authorization for non-emergency transportation services to ensure that the recipient uses the means of transportation most appropriate to the patient's needs and that an adequate but less costly transportation plan cannot be arranged.[15]

Medicaid is a large payor of ambulette services.[16] Ambulette services must be ordered by a physician or other appropriate practitioner,[17] who initially determines when such transportation is medically necessary.[18] Reimbursement for ambulette services is limited to passenger occupied transportation to or from a covered service.[19] Prior approval[20] is required in that a determination must be made by the local department of social services or state agency of fiscal responsibility whether the use of an ambulette, rather than a non-specialized mode such as taxi service, livery service or public transportation, is medically necessary.[21] Ambulette providers are bound by the operating authority granted to them by the New York State Department of Transportation (NYSDOT).[22] In accordance with NYSDOT procedures, each service is given the authority to operate within a certain geographic area.[23] Within the prescribed geographic area, transportation is to be "open to the public."[24] Service is not to be withheld between any points within the boundaries of the provider's operating authority when the ambulette service is open for business.[25] Thus, an ambulette service participating in Medicaid may not refuse Medicaid transportation within the ambulette service's area of operation.[26] Ambulette providers whose operating authority has been revoked by the NYSDOT are removed from the New York State Department of Health's Medicaid participating provider list.[27] Ambulette drivers must also be qualified under Article

19-A of the New York State Vehicle and Traffic Law.[28] In addition, ambulettes operating in New York City must be licensed by the New York City Taxi and Limousine Commission.[29]

All ambulette or van providers who transport more than one Medicaid recipient at the same time and who are reimbursed for vehicular mileage must claim only for the actual number of miles from the first pick-up of a Medicaid recipient to the final destination and drop-off of all recipients.[30] Payment to a provider of ambulette services will only be made for services documented in contemporaneous records, typically referred to as "trip tickets."[31] Documentation must include the following:

- recipient's name and Medicaid identification number;
- origination of the trip;
- destination of the trip;
- date and time of service; and
- name of the driver transporting the recipient.[32]

Stretcher transportation of a Medicaid recipient by an ambulette service is allowed under Medicaid when the recipient is not in need of any medical care or service enroute to his or her destination, and the recipient must be transported in a recumbent position.[33] The ambulette service is not allowed to provide any medical service to the recipient.[34] The ambulette vehicle must be configured to be able to hold a stretcher securely during transport.[35]

Ambulette transportation may be ordered if any of the following conditions is present:

- The recipient needs to be transported in a recumbent position and the ambulette service is able to transport a stretcher;
- The recipient is wheelchair bound and is unable to use a taxi, livery service, bus or private vehicle;
- The recipient has a disabling physical condition which requires the use of a walker or crutches and is unable to use a taxi, livery service, bus or private vehicle; or
- An otherwise ambulatory recipient requires radiation therapy, chemotherapy, or dialysis treatments, which results in a disabling physical condition after treatment, making the recipient unable to access transportation without the personal assistance provided by an ambulette service.[36]

Ambulette transportation may also be ordered if:

- The recipient has a disabling physical condition other than one described above or a disabling mental condition requiring the personal assistance provided by an ambulette service; and
- The ordering practitioner certifies in a manner designated by and submitted to the department that the recipient cannot be transported by a taxi, livery service, bus or private vehicle and there is a need for ambulette service.[37]

The ordering practitioner must note in the recipient's patient record the recipient's condition which qualifies him or her to use ambulette services.[38]

Reimbursement is not provided for any mode/type of transportation when any of the following situations exist:

- the transportation service is available to others in the community without charge;
- the service is provided by a medical institution or program and the cost is included in that institution's or program's Medicaid rate; or
- transportation services are not actually provided to a Medicaid recipient.[39]

The social services districts may establish payment rates from the following options:

- a flat-rate for all transportation services provided;
- a base rate for all transportation services provided, plus a mileage charge;
- a flat-rate for transportation services within a specified area; or
- a mileage rate based on distance.[40]

New York City, for example, has established a fixed payment amount to reimburse trips within the five boroughs. Mileage is not given for trips within the boroughs. For long distance trips that occur outside of the five boroughs, New York City does allow for mileage reimbursement in addition to the fixed payment amount. New York City Medicaid recipients are generally expected to obtain their medical care and services within five miles of their residence. This five-mile geographic area is considered to be the common medical marketing area (CMMA). Transportation can be ordered for trips greater than five miles from the recipient's residence, when the medical care or service is unavailable within the CMMA.[41]

When a recipient resides in a borough contiguous with Westchester or Nassau County, and the recipient is traveling into the other county for medical care or service, mileage can be ordered when the transport is over five miles from the recipient's residence. If the one-way trip is greater than five miles, the mileage begins at the NYC/other county border (not the recipient's residence). For example, if a recipient travels ten miles from Queens to Nassau County, and two miles are traveled in Queens and eight additional miles are traveled in Nassau County, then the one-way mileage is eight miles. Transports to medical care or service within five miles of the recipient's residence should never receive a mileage add-on.[42]

The local social services district may establish a reduced rate for transportation of additional persons, day treatment transportation, and transportation for purposes of obtaining regularly recurring medical care.[43] As such, special rules may apply for transportation to and from day programs.[44]

An additional rate may be established for attendant costs and bridge and road tolls.[45] A toll may be claimed when the toll is incurred while a passenger is in the vehicle and for only one toll per crossing, not multiple tolls based on a toll per passenger.[46]

Fraud and Abuse Issues

The medical transportation industry has experienced a number of instances of provider and supplier fraud and abuse. Examples have included:

- improper transport of individuals with other acceptable means of transportation;
- medically unnecessary trips;
- trips claimed but not rendered;
- misrepresentation of the transport destination to make it appear as if the transport was covered;
- false documentation;
- billing for each patient transported in a group as if he/she was transported separately;
- upcoding; and
- payment of kickbacks.[47]

The following is a discussion of certain specific instances of provider violations and related guidances.

False Claims and Statements

As is the case in all segments of the health care industry, medical transportation providers are often investigated for false claims and statements. For example, the New York State Attorney General and State Insurance Superintendent announced guilty pleas in two separate indictments of owners of several ambulette companies for submitting fraudulent transportation bills to insurance carriers. The companies billed no-fault claims for round-trip ambulette transports when none were provided or over-billed insurance companies for ambulette transportation when service was provided by private cars. The defendants reportedly submitted documentation of the trips containing forged patient signatures to support the fraudulent billings.[48]

In another case, a New York ambulance company operator was sentenced to 78 months in prison, was ordered to pay restitution of more than $57 million, and was subject to an $8 million forfeiture order for health care fraud arising from his fraudulent operation of several ambulance and ambulette services. In March 1990, the individual had been excluded from participation in the Medicare and Medicaid programs for a period of 25 years. In order to try to improperly circumvent the program exclusion, he established secret ownership of five ambulance and ambulette companies in Brooklyn, which continued to bill Medicare and Medicaid. He had also offered and paid bribes and kickbacks to employees of various hospitals to induce them to order ambulance and ambulette services from the companies.[49]

Two owners of a medical transportation company were sentenced to eight years' imprisonment, seven years' probation and ordered to pay $1.3 million in restitution for submitting false claims to Medicaid, including billing for stretcher services that were not provided and excessive mileage.[50] Another provider transported patients on one-way trips of 17 miles but billed between $420 and $588 for the services.[51] A third company billed Medicaid for extra attendants on patient transports when in actuality there were no attendants present.[52]

A Maryland ambulance was fined $100,000 and its owner was sentenced to five years' imprisonment, five years' probation and ordered to pay restitution in the amount of $245,000 for billing ambulance services that were not necessary and/or provided for persons who did not qualify for ambulance transportation.[53] Further, an executive director of a medical transportation company pled guilty to mail fraud for inflated charges, mileage and wait time on trips.[54] Another owner and operator pled guilty to Medicaid fraud for billing for multiple riders, excessive mileage and services not rendered.[55]

Note that in one case, an attorney pled guilty to a federal charge of conspiracy to defraud the United States by making false statements on applications to Medicare and Medicaid, which falsely listed the owner of an ambulance company for which the attorney acted as president.[56] The applications did not list the true owner, director and controller of the company, who was a convicted felon officially excluded from participation in the Medicare and Medicaid programs.[57]

Inappropriate Recordkeeping

Both the medical transportation provider and the ordering practitioner can be sanctioned for failing to maintain required documentation. For example, a physician who routinely ordered ambulette services without documenting medical necessity, among other recordkeeping violations, was excluded from the Medicaid program for five years.[58]

Anti-Kickback Violations

One of the most discussed issues in medical transportation kickback violations is the provision of free transportation. The United States Department of Health and Human Services Office of Inspector General (the OIG) provided advice on this issue to a hospital that proposed to offer certain patients who had been referred to it for extended courses of treatment free transportation services.[59] The hospital wished to provide services in the city in which it was located and a ten-county rural area covering over 8,000 square miles. The entity was to provide services to many medically underserved patients and was the only provider, or one of a very few providers, of certain services. Public transportation in the area was limited. Free transportation was only provided to patients in the entity's primary service area or for whom the entity was the nearest provider of the prescribed services. Transportation was not of the ambulance variety. To receive the free transportation, a patient needed to have 1) been referred for certain services; 2) been unable to provide his or her own transportation and had no other regular and reliable means of transportation (either public or private); and (3) been at significant medical risk if treatment was not provided. The free services were not marketed or advertised. On average, 6 percent of patients received the free service, the average age of the patients was 66, and the average distance of the transportation provided was 28 miles. The costs of the transportation were not claimed directly or indirectly on any federal health care program cost report or claim.

The OIG stated that health care providers that offer free goods or services, such as free transportation services, to Medicare or Medicaid patients may be subject to civil monetary penalties. Additionally, free transportation services, said the OIG, may implicate the criminal anti-kickback statute which prohibits the offering of anything of value to any person to reward or induce referrals (including self-referrals) for items and services reimbursable under Medicare or Medicaid. However, the OIG recognized that many arrangements involving free transportation have beneficial effects on patient care. However, given the potential for abuse, the OIG stated that it would evaluate arrangements involving free transportation on a case-by-case basis and consider:

- the population to whom free transportation services are offered;
- the nature or type of free transportation services offered;
- the geographic area in which free transportation services are offered;
- the availability and affordability of alternate means of transportation;
- whether free transportation services are marketed or advertised and, if so, how;
- the type of provider offering the free transportation services; and
- whether the costs of the free transportation services will be claimed directly or indirectly on any federal health care program cost report or claimed or otherwise shifted to any federal health care program.

The above factors are weighed to assess the level of risk presented by an arrangement. The OIG stated that, in the specific case reviewed, it would not seek to sanction the entity.[60]

In a later guidance, the OIG addressed a hospital's existing program to provide free transportation for the hospital's patients and their families to the hospital and to hospital-owned ambulatory surgical centers. The OIG stated that free local transportation valued at no more than $10 per trip and $50 per patient in the aggregate on an annual basis is permissible. However, complimentary transportation that exceeded those limits implicated the anti-kickback statute. The OIG went on to state that it was considering developing a regulatory exception for some complimentary local transportation of a higher value for some beneficiaries residing in a provider's primary service area. However, while no such exception existed, the OIG expressed that until it promulgated an exception or stated that it will no longer pursue such exception, the OIG will not sanction certain hospital-based complimentary transportation programs that:

- existed prior to August 30, 2002;
- offer transportation uniformly to all patients;
- offer transportation only to and from the hospital or hospital-owned surgical centers for services at those facilities (or for family members accompanying or visiting facility patients);
- offer transportation only in the facility's primary service area;
- do not claim costs on any federal health care program cost report or claim and are not otherwise shifted to any federal health care program; and
- offer transportation that does not include ambulance transportation.[61]

Licensing and Regulatory Violations

As stated, medical transportation providers and their drivers are required to maintain required licensures to be eligible for reimbursement. Thus, when Medicaid audited an ambulette company and found that one-half of its drivers were unlicensed and that many of its records for services rendered failed to identify the driver of the ambulette, the provider was excluded from Medicaid for two years and directed to make restitution.[62]

The New York State Department of Health has issued special guidance for the medical transportation industry in areas where providers have had compliance issues. For example, medical transportation providers may in the course of business have to lease vehicles or subcontract with other providers where a vehicle shortage must be addressed. In these cases, the provider of service must place its own sign on the vehicle and ensure that the vehicles are appropriately inspected, that the drivers of the vehicles are in compliance with licensing requirements and that adequate records are maintained. Often, providers have been unaware of their responsibilities when subcontracting for these services.[63]

Suggestions for Items to Address in a Compliance Program for Medical Transportation

Perhaps more than any other health care segment, due to their size[64] and fiscal constraints, medical transportation companies are reluctant to invest the time and resources needed to create an effective compliance program. However, given the fraud and abuse issues and increased oversight, it is important for these providers to formulate and maintain an effective program taking into account the size, structure and resources of the organization. Among the issues that should be addressed are:

- Medicare, Medicaid and other insurance coverage criteria for emergency and non-emergency transports;[65]
- The importance of complete and accurate documentation to determine and verify the medical necessity of transports;[66]
- Billing for appropriate levels of services based on the services provided;[67]
- Processes for obtaining signed certification statements or prior approval, as required;[68]
- Processes for obtaining advanced beneficiary notices, as required;[69]
- Processes for ensuring that interfacility transports are billed appropriately;[70]
- Processes for ensuring the medical necessity of all transports and services;[71]
- The anti-kickback statute, fair market value and the discount safe harbor;[72]
- Gifts and inducements;[73]
- Restocking arrangements;[74] and
- Waiver of co-payments.[75]

Conclusion

The medical transportation industry in New York consists of a variety of different size providers, some with sophisticated procedures in place to control recordkeeping and billing and some with virtually no knowledge of the importance of compliance in today's health care industry. As such, it is important to counsel these clients as to fraud and abuse issues. When an investigation or audit occurs, it is very often helpful to retain the skills of a consultant or independent auditor knowledgeable about the industry to review the records and procedures of the client for use in strategy decisions and with negotiations. In addition, medical transportation clientele should be encouraged to retain health care counsel when audited or investigated or when seeking to structure transactions with other health care providers or for the purchase and sale of a medical transportation business. Above all, medical transportation companies should consider the adoption of a compliance program, with training and internal auditing mechanisms, to seek to resolve issues prior to an audit or investigation.

Endnotes

1. Note that Medicaid reimbursement is available in limited circumstances for upstate taxi services and New York City livery services. Computer Sciences Corporation, MMIS Provider Manual: Transportation §§ 2.5, 2.7. New York City livery may be ordered when: the recipient is able to travel independently but, due to a debilitating physical or mental condition, cannot use the mass transit system; the recipient is traveling to and from a location which is inaccessible by mass transit; or the recipient cannot access the mass transit system due to temporary severe weather, which prohibits the use of the normal mode of transportation. New York State Department of Health Office of Medicaid Management, *Ordering Transportation Services in New York City*, Medicaid Update (February 2005).
2. 18 N.Y.C.R.R. § 505.10(b)(2); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.2. Transportation by ambulance is required if the patient requires medical care or medical monitoring as directed by a physician during the transport. Examples include, but are not limited to, administering oxygen to a patient who does not normally use it, assessment, maintaining IVs, cardiac monitoring, or the periodic monitoring of pulse, respiration, blood pressure or other vital signs and documenting changes in a patient's condition. New York State Department of Health Bureau of Emergency Medical Services, Policy Statement No. 99-08 (October 10, 1999).
3. 18 N.Y.C.R.R. § 505.10(b)(1-2); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.2. Emergency medical services means the provision of urgent initial medical care including, but not limited to, the treatment of trauma, burns, and respiratory, circulatory and obstetrical emergencies. 18 N.Y.C.R.R. § 505.10(b)(11).
4. 18 N.Y.C.R.R. § 505.10(b)(4); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.2.
5. 18 N.Y.C.R.R. § 505.10(b)(4). Personal assistance is the provision of physical assistance by the ambulette provider or its employee to a Medicaid recipient for the purpose of assuring safe access to and from the recipient's place of residence, ambulette vehicle and the Medicaid covered heath service provider's place of business and can include assistance to the recipient in walking, climbing or descending stairs, ramps, curbs or other obstacles, opening or closing doors, accessing an ambulette vehicle, the moving of wheelchairs or other items of medical equipment and the removal of obstacles as necessary to assure the safe movement of the recipient. In providing personal assistance, the provider or the provider's employee will physically assist the recipient which shall include touching, or, if the recipient prefers not to be touched, guiding the recipient in such close proximity that the provider of services will be able to prevent any potential injury due to a sudden loss of steadiness or balance. A recipient who can walk to and from a vehicle, his or her home, and a place of medical services without such assistance is deemed not to require personal assistance. 18 N.Y.C.R.R. § 505.10(b)(16); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.2. The Medicaid program does not limit the number of stairs or floors in a building that a provider must climb in order to provide personal assistance. Personal assistance has been described as a door-to-door service, requiring staff to transport the recipient from his or her front door (apartment door, room in a nursing home, etc.) to the door of the medical practitioner. New York State Department of Health Office of Medicaid Management, *Ambulette Transportation Staff*, Medicaid Update (September 2002).
6. 18 N.Y.C.R.R. § 505.10(b)(3); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.2.
7. New York State Department of Health Office of Medicaid Management, *New York City Rules for Ordering Transportation for Medicaid Recipients*, Medicaid Update (December 2002).
8. Medicaid covers transportation services when essential and appropriate to obtain medical services and supplies covered by Medicaid, upon prior authorization. Prior authorization is not required to obtain transportation for emergency care. NYS Soc. Serv. Law § 365-a(2)(j). Note that Governor Pataki's 2005-2006 New York State Budget proposed to repeal this section of the Social Services Law. The memorandum in support sets forth, "Section 50 reclassifies transportation as an administrative service, thereby providing counties and DOH with greater flexibility to contract with lower cost providers and encourage greater use of existing public transportation."
9. 18 N.Y.C.R.R. § 505.10(e)(5); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.3.1.
10. 18 N.Y.C.R.R. § 505.10(c)(3); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.2; New York State Department of Health Office of Medicaid Management, *Ordering Transportation Services in New York City*, Medicaid Update (February 2005). Medicare authorizes non-emergency ambulance transport, with an appropriate practitioner's statement, where the beneficiary is bed-confined (unable to get up without assistance, unable to ambulate, and unable to sit in a chair or wheelchair) and his or her medical condition is such that other methods of transportation are contraindicated, or the beneficiary's medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. 42 C.F.R. § 410.40(d); U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14250 (March 24, 2003). *See also* U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Review of Ambulance Charges Claimed by Caritas Norwood Hospital Fiscal Years 2002 and 2003 (December 2004). Note that an ambulette may transport a person who requires oxygen, as long as the passenger self-administers the oxygen. Ambulette service personnel may not administer oxygen. Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.2; New York State Department of Health Bureau of Emergency Medical Services, Policy Statement No. 99-08 (October 10, 1999).

    Medicare Part B in many instances also covers ambulance services, where the patient is suffering from an illness or injury which contraindicates transportation by any other means. 42 C.F.R. § 410.40(d). The requirement is presumed to be met where the patient:

    - was transported in an emergency situation, such as a result of accident, injury, or acute illness;
    - needed to be restrained;
    - was unconscious or in shock;
    - required oxygen or other emergency treatment on the way to the destination;
    - had to remain immobile because of a fracture that had not been set or the possibility of a fracture;
    - sustained an acute stroke or myocardial infarction;
    - was experiencing severe hemorrhage;
    - was bed confined before and after the ambulance trip; or
    - could be moved only by stretcher.

    Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.3.4. Ambulance services are covered under Medicare Part A when a hospital inpatient is transported to and from another hospital or freestanding facility to receive special-

ized treatment not available at the first hospital. The ambulance service is included in the hospital's Medicare Part A payment. In such situations, when an ambulance service transports a hospital inpatient covered under Medicare to medical care not available at the hospital, the ambulance service seeks reimbursement from the hospital. In general, when an original admitting hospital sends a Medicaid inpatient to another hospital for purposes of obtaining a diagnostic or therapeutic service not available in the admitting hospital, the original hospital is responsible for the costs of transportation and neither hospital may bill the Medicaid program separately for the transportation services. The hospital reimburses the ambulance or other transportation service for the transport of the patient, as the Medicaid inpatient rate is generally inclusive of all services provided to the Medicaid patient. Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.3.4; New York State Department of Health Office of Medicaid Management, *Hospital Reimbursement for Outside Care Reimbursement Policy*, Medicaid Update (August 2004). Note that for Medicare purposes, transport in a vehicle other than an ambulance is generally not covered. *See* U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14251 (March 23, 2003); U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Non-Emergency Transportation for Dialysis Patients (August 1994).

11. 18 N.Y.C.R.R. § 505.10(e)(3); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.3.1; New York State Department of Health Office of Medicaid Management, *New York City Rules for Ordering Transportation for Medicaid Recipients*, Medicaid Update (December 2002).

12. 18 N.Y.C.R.R. § 505.10(d)(4); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.3.1.

13. 18 N.Y.C.R.R. § 505.10(d)(4); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.3.1.

14. 18 N.Y.C.R.R. § 505.10(c)(4); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.3.1; New York State Department of Health Office of Medicaid Management, *New York City Rules for Ordering Transportation for Medicaid Recipients*, Medicaid Update (December 2002).

15. New York State Department of Health Office of Medicaid Management, *New York City Rules for Ordering Transportation for Medicaid Recipients,* Medicaid Update (December 2002). Prior authorization usually must be obtained before each trip (or round trip) taken by the recipient. However, if a recipient requires regular transportation due to extended treatment and the recipient's medical appointment is at the same location, and if the same provider is to transport the recipient, prior authorization may be granted for an extended period as determined by the Prior Authorization Official. Whenever such prior authorization for non-emergency transportation is not obtained, reimbursement will be denied. However, prior authorization does not guarantee payment. For example, provider eligibility and recipient eligibility requirements that are not met may result in the denial of a claim payment. Computer Sciences Corporation, MMIS Provider Manual: Transportation §§ 2.2, 2.2.3, 2.3.3. When a recipient requires an appointment for a medical service on a weekend or holiday, and the appointment is made on that same weekend or holiday, authorization may not be obtained until the next business day. In such cases, the transportation provider receives the transportation request directly from the ordering practitioner's office or medical facility at which the recipient has the medical appointment. The transportation provider shall contact the ordering provider on the next business day in order to obtain authorization for services rendered. All authorization guidelines must be followed before authorization is granted to the transportation provider. Computer Sciences Corporation, MMIS Provider Manual: Transportation §§ 2.2.1, 2.3.3, 2.4.3.

16. *See* New York State Department of Health Office of Medicaid Management, *Transportation News,* Medicaid Update (June 2003).

17. Also physician's assistants, nurse practitioners, dentists, podiatrists or optometrists may order ambulette services. 18 N.Y.C.R.R. § 505.10(d)(4); Computer Sciences Corporation, MMIS Provider Manual: Transportation §§ 2.2.3, 2.4.1. A diagnostic and treatment center, hospital, nursing home, intermediate care facility, long term home health care program, home and community based services waiver program, or managed care program may order ambulette transportation services on behalf of the ordering practitioner. 18 N.Y.C.R.R. § 505.10(d)(4); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1.

18. 18 N.Y.C.R.R. § 505.10(b)(15); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.2.

19. 18 N.Y.C.R.R. §§ 505.10(a), (e)(5); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1.

20. For more information regarding prior approval, *see In re New York State Med. Transporters Ass'n, Inc. v. Perales*, 77 N.Y.2d 126 (1990); New York State Department of Health Office of Medicaid Management, *New City Rules for Ordering Transportation for Medicaid Recipients,* Medicaid Update (December 2002).

21. 18 N.Y.C.R.R. § 505.10(e)(3); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1. Under 18 N.Y.C.R.R. § 505.10(d)(7), the prior authorization official uses the following criteria in determining whether to authorize payment of transportation expenses: (i) when the Medicaid recipient can be transported to necessary medical care or services by use of private vehicle or by means of mass transportation which are used by the Medicaid recipient for the usual activities of daily living, prior authorization for payment for such transportation expenses may be denied; (ii) when the Medicaid recipient needs multiple visits or treatments within a short period of time and the Medicaid recipient would suffer undue financial hardship if required to make payment for the transportation to such visits or treatments, prior authorization for payment for such transportation expenses may be granted for a means of transportation ordinarily used by the Medicaid recipient for the usual activities of daily living; (iii) when the nature and severity of the Medicaid recipient's illness necessitates a mode of transportation other than that ordinarily used by the Medicaid recipient, prior authorization for such a mode of transportation may be granted; (iv) when the geographic locations of the Medicaid recipient and the provider of medical care and services are such that the usual mode of transportation is inappropriate, prior authorization for another mode of transportation may be granted; (v) when the distance to be traveled necessitates a large transportation expense and undue financial hardship to the Medicaid recipient, prior authorization for payment for the Medicaid recipient's usual mode of transportation may be granted; (vi) when the medical care and services needed are available within the common medical marketing area of the Medicaid recipient's community, prior authorization for payment of transportation expenses to such medical care and services outside the common medical marketing area may be denied; (vii) when the need to continue a regimen of medical care or service with a specific provider necessitates travel which is outside the Medicaid recipient's common medical marketing area, notwithstanding the fact that the medical care or service is available within the common medical marketing area, prior authorization for payment of transportation expenses to such medical care and services outside the common medical marketing area may be granted; and (viii) when there are any other cir-

cumstances which are unique to the Medicaid recipient and which the prior authorization official determines have an effect on the need for payment of transportation expenses, prior authorization for payment for such transportation expenses may be granted.

22. 18 N.Y.C.R.R. § 505.10(e)(6)(ii); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.2.
23. Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1.
24. *Id*.
25. *Id*.
26. *Id*.
27. *Id*.
28. 18 N.Y.C.R.R. § 505.10(e)(6)(ii); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.2.
29. 18 N.Y.C.R.R. § 505.10(e)(6)(ii).
30. For example, Ace Company's reimbursement has been established at $20 per one way pickup plus $1.00 per loaded mile. On Monday, Ace is authorized to transport Mrs. Jones to her Friday morning clinic appointment, a one way mileage of 13 miles. On Tuesday, Ace is authorized to transport Mr. Frank to the same clinic at the same time, a one way mileage of 7 miles. Since the recipients live on the same route, Ace will pick up both recipients in the same vehicle. Ace must claim the base rate and the mileage rate of 13 miles for Mrs. Jones, who is the first one picked up. Ace must only claim the base rate for Mr. Frank. Even though Ace has been authorized 7 miles for Mr. Frank, since these 7 miles are concurrent miles already paid for under Mrs. Jones' claim, Ace may not claim for these 7 miles. Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1.
31. 18 N.Y.C.R.R. § 505.10(e)(8); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1; New York State Department of Health Office of Medicaid Management, *Transportation*, Medicaid Update (June 2003).
32. 18 N.Y.C.R.R. § 505.10(e)(8); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1.
33. Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1.
34. *Id*.
35. *Id*.
36. 18 N.Y.C.R.R. § 505.10(c)(2); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1.
37. 18 N.Y.C.R.R. § 505.10(c)(2); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1. Note that the February 2005 Medicaid Update, a publication of the New York State Department of Health Office of Medicaid Management, lists the following guidelines for ordering ambulette transportation: the recipient requires the personal assistance of the driver in entering and exiting the recipient's residence, the ambulette, and the medical facility; the recipient is wheelchair-bound (non-collapsible or requires a specially configured vehicle); the recipient has a mental impairment and requires the personal assistance of the ambulette driver; the recipient has a severe, debilitating weakness or is mentally disoriented as a result of medical treatment and requires the personal assistance of the ambulette driver; or the recipient has a disabling physical condition which requires the use of a walker, cane, crutch or brace and is unable to use a livery service or mass transit. New York State Department of Health Office of Medicaid Management, *Ordering Transportation Services in New York City*, Medicaid Update (February 2005).
38. 18 N.Y.C.R.R. § 505.10(c)(4); Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.4.1.
39. 18 N.Y.C.R.R. § 505.10(e)(9). Note that the MMIS Provider Manual for Transportation adds when there is a rate listed but no effort is made to collect the fee from non-Medicaid community members or when the provider is out of compliance with licensure requirements. Computer Sciences Corporation, MMIS Provider Manual: Transportation §§ 2.2.2, 2.3.4, 2.4.4.
40. 18 N.Y.C.R.R. § 505.10(f)(5)(i).
41. New York State Department of Health Office of Medicaid Management, *Transportation News,* Medicaid Update (June 2003); New York State Department of Health Office of Medicaid Management, *Ordering of New York City Ambulette Services,* Medicaid Update (January 2002).
42. New York State Department of Health Office of Medicaid Management, *Transportation News,* Medicaid Update (June 2003).
43. 18 N.Y.C.R.R. § 505.10(f)(5)(ii).
44. Computer Sciences Corporation, MMIS Provider Manual: Transportation § 2.6.
45. 18 N.Y.C.R.R. § 505.10(f)(5)(iii).
46. New York State Department of Health Office of Medicaid Management, *New York City Transportation News*, Medicaid Update (September 2003).
47. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14246 (March 24, 2003).
48. Press Release of the Office of New York State Attorney General Eliot Spitzer, *Ambulette Companies and Four Principals Indicted in No-Fault Billing Scam* (December 8, 2003).
49. U.S. Dep't of Health and Human Serv. Office of Inspector Gen. and the U.S. Dep't of Justice, Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2003 (December 2004).
50. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Annual Report State Medicaid Fraud Control Units for Fiscal Years 1997, 1998 AND 1999 (June 2000), at 15.
51. *Id*.
52. *Id*.
53. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Annual Report State Medicaid Fraud Control Units for Fiscal Year 2000 (December 2001), at 11.
54. *Id.* at 20.
55. *Id. See also* State of Ohio Office of the Auditor, Review of Medicaid Provider Reimbursements Made to Crest Transportation Service (June 2000), where provider was found to have billed for services not documented, failed to maintain or receive physician certifications, transported ambulatory recipients, billed multiple transports as individual transports, and billed for persons transported for reasons other than to receive covered services.
56. *In re John T. Hug, Jr.*, 10 A.D.3d 126 (1st Dep't 2004).
57. *Id.*
58. *Pekarsky v. Comm'r of the N.Y. Dep't of Social Serv.*, 257 A.D.2d 905 (3d Dep't 1999). Note that Medicaid reimbursement can be claimed by school health providers when certain criteria are met. In such a case, an audit of the Department of Health and Human Services Office of Inspector General found that documentation for many of these claims was deficient (such as not

including the date transportation was provided), that transportation was frequently claimed on days when a Medicaid-reimbursable school health service was not claimed, that claims were made where transportation services were not included in the child's individualized education plan or individualized family service plan, that claims were made when the recipient was not transported and that insufficient services were sometimes provided. The OIG recommended a $17,238,611 refund to the federal government. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Review of Medicaid Transportation Claims Made by School Health Providers in New York State (August 2004).

59. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Advisory Opinion No. 00-7 (November 17, 2000).

60. *Id*. Note that the OIG listed the following abusive arrangements involving free transportation services:

- Psychiatric facilities offering out-of-state patients free round-trip airline tickets to Florida in order to receive services at their facilities;
- Van drivers soliciting, and offering free transportation services to, Medicaid patients for health care providers who compensate the drivers on a per patient or per service basis;
- Unscrupulous health care providers offering residents of nursing facilities and other congregate care facilities free transportation services to and from their offices for services that are frequently of questionable necessity;
- Hospitals offering patients free limousine services; and
- Hospitals offering patients free ambulance services without making individual determinations of financial need.

Id.

61. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Letter Regarding Complimentary Local Transportation Program (December 9, 2002).

62. *In re Joackim Charles et al. v. Comm'r of the N.Y. Dep't of Social Serv.*, 240 A.D.2d 490 (2d Dep't 1997).

63. New York State Department of Health Office of Medicaid Management, *Transportation Providers and Subcontracting Transports*, Medicaid Update (August 2004).

64. For example, the OIG commented as follows on the ambulance industry, "The . . . industry is comprised of entities of enormous variation: some . . . companies are large, many are small; some are for-profit, many are not-for-profit; some are affiliated with hospitals, many are independent; and some are operated by municipalities or counties, while others are commercially owned." U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14246 (March 24, 2003).

65. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Corporate Integrity Agreement with TransCare New York, Inc. (May 8, 2003); U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14250 (March 24, 2003).

66. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Corporate Integrity Agreement with TransCare New York, Inc. (May 8, 2003); U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14250-51 (March 24, 2003). Ambulance suppliers should maintain, at a minimum: dispatch instructions, if any; reasons why transportation by other means was contraindicated; reasons for selecting the level of service; information on the status of the individual; who ordered the trip; time spent on the trip; dispatch, arrival at scene, and destination times; mileage traveled; pickup and destination codes; appropriate zip codes; and services provided, including drugs and supplies. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14251 (March 24, 2003).

67. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Corporate Integrity Agreement with TransCare New York, Inc. (May 8, 2003); U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14250-51 (March 24, 2003). Additional attention should be paid by ambulance suppliers for billings produced where the patient died before the transport and where multiple ambulances responded to the same call. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14254 (March 24, 2003).

68. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Corporate Integrity Agreement with TransCare New York, Inc. (May 8, 2003); U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14250 (March 24, 2003).

69. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Corporate Integrity Agreement with TransCare New York, Inc. (May 8, 2003).

70. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Corporate Integrity Agreement with TransCare New York, Inc. (May 8, 2003); U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14250-51 (March 24, 2003).

71. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., Corporate Integrity Agreement with TransCare New York, Inc. (May 8, 2003); U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14250 (March 24, 2003).

72. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14251-52 (March 24, 2003).

73. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14252-53 (March 24, 2003).

74. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14253 (March 24, 2003).

75. U.S. Dep't of Health and Human Serv. Office of Inspector Gen., OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14245, 14253 (March 24, 2003).

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"Caveat Confirmator": Legally False Claims And the Federal False Claims Act

By John M. O'Connor

False claims recoveries in the health care field are a growth area. In the 2003 fiscal year, the government collected $1.48 *billion* in suits initiated by whistleblowers under the federal False Claims Act. Most of that was obtained in the health care industry.

The Federal False Claims Act provides for penalties against those who file false claims with the government and gives a portion of the government's recovery to qualifying individuals who have provided the information on which the government's recovery is based. (These whistleblower suits are also called "*qui tam*" actions, a Latin shorthand for "one who brings the action for himself as well as the king.")

Large amounts of money are involved and health care entities are especially vulnerable. Health care entities, such as hospitals, laboratories, nursing homes, and physician practice groups submit a high volume of claims to the government. A false claim is punishable by a penalty of $5,000 to $10,000 *per claim*. Even more formidable is the prospect of facing damages for claims that may have spanned several years—and then having those damages multiplied by three, as provided in the False Claims Act.

Range of Damages

For example, $641 million was recovered from HCA Inc. (formerly Columbia/HCA) to settle claims of overbilling and kickbacks. The whistleblowers' combined take was $154 million. A California hospital system paid $51 million to settle allegations that unnecessary cardiac procedures were performed. SmithKline Beecham Clinical Laboratories paid $325 million based on allegations that lab tests were either not needed or not performed.

A health care provider's first reaction to the prospect of mega-damages under the False Claims Act might easily be, "That can't happen here." Assuming that most health care entities view themselves as law abiding, there may be a tendency to believe that the False Claims Act will only ensnare those who specifically set out to defraud the government and "We don't do that here." This reaction is understandable—but very dangerous.[1]

First, although the statute exacts penalties only where the false claim is submitted "knowingly," the definition of "knowing" includes "reckless disregard of truth or falsity" and "acts in deliberate ignorance of truth or falsity." In other words, even if a health care entity did not intentionally sit down and decide to defraud the government, a court or jury might later decide that it had been reckless or culpably ignorant.

Second, claims can be considered "false" in ways that are not obvious. For example, courts have recognized a "certification theory" of liability under the False Claims Act. If payment is conditioned upon a certification or representation by a health care provider that it has complied with certain federal statutes or regulations, or with certain contractual terms, and it is later proven that these provisions were not complied with, then the prior representation may be held false, subjecting the entity to the treble damages and penalties provided in the False Claims Act. Since such false certifications may have occurred over a period of several years involving numerous claims, the potential exposure can be daunting.

The Second Circuit's Decision in *Mikes*

In the Second Circuit, the leading case on this "false certification" liability is *Mikes v. Straus*, 274 F. 3d 687 (2d Cir. 2001) ("*Mikes*"). In *Mikes*, the Second Circuit held that a false certification that applicable laws and regulations had been complied with could be a violation of the False Claims Act ("FCA"), but not every law or regulation would lead to FCA liability.[2]

The Second Circuit noted that a claim could be "factually false" or "legally false." As one might expect, a factually false claim "involves an incorrect description of goods or services provided or a request for goods and services never provided."[3] The legally false claim involves a "false representation of compliance with a federal statute or regulation or a prescribed contractual term."[4]

"Legally False" Claims

The legally false claim may be based upon an express false certification or an implied false certification. "An express false certification is, as the term sug-

gests, a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment."[5] An implied false certification is based upon the act of submitting a claim for payment from the United States where compliance with certain governing federal rules is a precondition for payment.

The Second Circuit held that a claim under the FCA is legally false only if a party certifies compliance with a statute or regulation that is a condition to governmental payment.[6] In other words, it is not every false certification or representation of compliance with a statute or regulation that will be a false claim within the meaning of the FCA. The United States must have conditioned compliance with the statute or regulation as a requirement for payment.

The facts in the *Mikes* case, and the Court's analysis of those facts, illustrate the application of this distinction. The plaintiff in *Mikes* was an individual whistleblower, not the government. The plaintiff, a pulmonologist, sued her former employer, a partnership of physicians. She alleged that spirometers had not been properly calibrated, that spirometry procedures were performed by medical assistants who had not been properly trained by the employer, and that these practices violated government regulations.[7]

The plaintiff claimed that there was an express false certification and an implied false certification. The defendants submitted their claims on the forms designated by the Health Care Finance Administration ("HCFA"). The form, HCFA-1500, stated:

> I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate supervision.[8]

The Court agreed that in signing and submitting this form, the defendants expressly certified that they would comply with the terms on the form and that such compliance was a precondition of government payment.[9]

The plaintiff Mikes argued that guidelines published by the American Thoracic Society ("ATS"), a division of the American Lung Association, set out the generally accepted standards for spirometry and that the defendants had violated those standards, including the recommendation that the spirometers be calibrated daily. The Second Circuit held that non-compliance with the ATS standards did not implicate the defendants' statements in the certification, *i.e.*, that the services were "medically indicated and necessary." The Court held that the plaintiff Mikes challenged only the "quality of defendants' spirometry tests and not the decisions to order this procedure for patients."[10] The Court pointed out that the medical necessity for a procedure and the quality of that procedure "are distinct considerations."[11]

So, even if adherence to the ATS guidelines were required, and even if the defendants violated those guidelines, it still could not be said that the express certification in the HCFA-1500 form was false.

Mikes also claimed that the defendants had made implied false certifications. While the Second Circuit approved the theory of implied false certification as a basis for a false claim under the FCA under certain circumstances, it held that Mikes' allegations were insufficient to state such a claim. The Court held that by submitting a claim for payment, the defendants had impliedly certified that they had complied with the following section of the Medicare Act:

> [N]o payment may be made under [the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.[12]

Since this section "*expressly* prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision."[13]

Again, however, there was no false certification within the meaning of the FCA because Mikes' claims went to the *quality* of the spirometry tests and not to whether they were reasonable and necessary.

The Court acknowledged that Mikes had cited a statute that mandated a qualitative standard of care.[14] However, the Court held that the statute Mikes cited was not an explicit condition of receiving *payment* on a claim; it was a condition of the health care practitioner's *participation* in the Medicare program. The remedy for violation was not refusal to pay a claim but sanctions for the practitioner.

Worthless Services

Although the government has not conditioned payment on the quality of the services performed, the Second Circuit recognized that a claim for payment for

services that are so deficient as to be worthless would be a violation of the FCA that was independent of any certification made by the claimant, whether express or implied.[15] The Court viewed a claim for worthless services as akin to seeking reimbursement for a service not provided and therefore derivative of a factually false claim. "In a worthless service claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all."[16]

However, in *Mikes*, the Court held that plaintiff's allegations could not succeed on a "worthless services" basis because there was no showing that the defendants "knowingly," as that term is defined in the FCA, submitted a claim for worthless services.[17]

District Court Decisions

Three District Court decisions within the Second Circuit have further delineated the elements of a "legally false" claim under the FCA.

The District of Connecticut tackled false certification issues in the medical device context in *In re Cardiac Devices Qui Tam Litigation*, 221 F.R.D. 318 (D. Conn. 2004). The action was initiated by a whistleblower and the government eventually intervened. The complaint alleged that the defendant hospitals had submitted false claims in that they sought and received payment from the government for services performed using medical devices that had not been approved for marketing by the FDA. The complaint alleged that the manufacturers of the cardiac devices in question provided the devices to the hospital defendants pursuant to an "Investigational Device Exception," which restricted their use to "carefully monitored clinical trials, the purpose of which was to gather evidence of the safety and effectiveness of the devices."[18] None of the devices had been approved for marketing by the FDA and the Medicare manual stated that: "Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not considered reasonable and necessary."[19]

The defendants argued that the government was, in effect, alleging a *per se* fraud theory, *i.e.*, "equating fraud with an alleged violation in a 1000-page manual."[20] However, citing *Mikes*, the District Court held that the Medicare statute expressly conditions payment by the government on procedures being "reasonable and necessary," and that the complaint stated a cause of action for legally false certification of compliance with the "reasonable and necessary" statutory pre-requisite to payment.

What Is "Knowingly"?

The hospital defendants' "*per* se" argument resurfaced in another context in connection with the FCA's requirement that a false claim must be made "knowingly" to incur FCA liability. As the Court pointed out, the FCA defines "knowingly" in three ways: (1) actual knowledge that the claim is false; (2) acting in deliberate ignorance as to whether the claim is true or false; or (3) acting in reckless disregard as to whether the claim is true or false.[21] No proof of specific intent to defraud is required. At the other end of the spectrum, negligence or innocent mistake does not constitute a false claim.

Although rejecting the defendants' contention that the government was equating a failure to adhere to a Medicare Manual provision with fraud, the Court held the defendant hospitals to a standard that, as a practical matter, can be viewed as approaching a *per se* rule.

Government's "Catch 22"

The District Court first held that, "'Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment.'"[22] The government then parlayed an allegation that the defendant hospitals did not follow a requirement in the Medicare Manual, into an allegation that the defendants acted "knowingly" within the meaning of the FCA by constructing what might be viewed as a "Catch 22" argument. The government first pointed out that each of the defendant hospitals had been provided with a copy of the Medicare Manual and that there was a duty on the part of hospitals to familiarize themselves with the provisions. According to the government, if the hospitals actually reviewed the Medicare Manual, they had actual knowledge of the provisions in question and so the claims were knowingly false. On the other hand, if the hospitals did not actively and regularly review the Medicare Manual, then they acted with "reckless disregard" of their compliance with Medicare rules and instructions. Under this theory, it would seem that once the hospitals have the Medicare Manual in hand, at least at the pleading stage, it will be very difficult to avoid the conclusion that they acted knowingly within the meaning of the FCA.[23]

Anti-Kickback and the FCA

In *United States ex rel. Barmak v. Sutter Corp.*, No. 95 Civ. 7637 KTD RLE, 2002 WL 987109 (S.D.N.Y. May 14, 2002), the operative allegation for present purposes was that the defendants had fraudulently obtained Medicare overpayments by paying kickbacks to hospitals and doctors for patient referrals.[24]

With respect to the kickback allegations, the Court held that those violations of the federal anti-kickback statute could not form the basis for a claim under the FCA. The District Court reasoned that the anti-kickback statute was a federal criminal statute, that no private cause of action was created, and that the Court had no reason to believe that Congress intended to "subvert the Department of Justice's exclusive jurisdiction over the anti-kickback statute by grafting the FCA's *qui tam* provisions onto it."[25] The District Court recognized that the Fifth Circuit had come to the opposite conclusion and had ruled that violation of the anti-kickback provisions could form the basis for an FCA claim. The Second Circuit had not yet addressed this issue and the District Court noted that the question was a "hotly disputed and controversial area of the law."[26] The Court also stated that a violation of the anti-kickback statute would not, in any event, be an *ipso facto* violation of the FCA.

Bidding

In *United States ex rel. Taylor v. Gabelli*, 03 Civ. 8762 (SAS), 2004 WL 1719357 (S.D.N.Y. July 29, 2004), the District Court addressed allegations that bidders for licenses issued by the Federal Communication Commission violated the FCA by falsely certifying that they met the government's definitions of "small" or "very small" business for purposes of obtaining a discount in connection with the auction of licenses for the use of a spectrum, or range, of radio frequencies.

With respect to the unsuccessful bidders, the Court held that the allegedly false certifications were not false claims within the meaning of the FCA. The Court applied the principle set forth in *Mikes*, that to constitute a legally false certification under the FCA, the statute or regulation not complied with must be a prerequisite to a payment by the government. Where the defendant's non-compliance with a statute or regulation "'would not have influenced the Government's decision to pay,' the failure to comport with the regulations cannot serve as a basis for an FCA claim."[27] In *Gabelli*, the Court held that, "A bid, by its very nature, does not request or demand monetary compensation."[28] Accordingly, even if unsuccessful bidders had falsely certified compliance with regulations on their bids, there was not a false claim under the FCA.

With respect to successful bidders, the Court's conclusion was different. A potential bidder was required to file an application "certifying, among other items, the applicant's eligibility for a federal discount and status as a qualified entry."[29] There were a series of auctions and qualifying "small" and "very small" business were entitled to discounts of percentages that varied by the auction; for example, in one auction, very small businesses were entitled to a 25 percent discount and small businesses were entitled to a 15 percent discount. The plaintiff whistleblower, an attorney specializing in federal administrative and telecommunications law, alleged, among other things, that the defendants that were successful bidders had falsely certified that they met the government definitions of "small" and "very small" businesses, and as a result received discounts to which they were not entitled.[30]

The defendants argued that plaintiff's allegations amounted to a disagreement with the defendants' "legal determination" as to whether they qualified for "small" or "very small" bidding status and that there were no "false or fraudulent statements.[31]

The *Gabelli* court held that the complaint stated a cause of action under the FCA against the successful bidders. The complaint alleged that the successful bidders had deliberately and falsely certified that they were small or very small businesses, entitled to federal discounts ("bidding credits"), and that such false certifications, if proven and knowingly made, sought "payment from the federal treasury (bidding credits)."[32]

"Reverse False Claim"

The plaintiff whistleblower in *Gabelli* also invoked the concept of "reverse false claims." In most false claims cases, the false claim seeks to have the government pay out money to which the claimant is not entitled. In a "reverse false claim," the defendant seeks to avoid paying money owed the government.[33] The whistleblower argued that once a bid was successful, the obligation to pay the full non-discounted amount of the bid attached. Since the successful bidders were required to file a more complete application following the bid, the whistleblower argued that a false certification in the post-bid application (stating that the defendants were entitled to a discount as small or very small businesses) was an attempt to avoid or decrease a pre-existing obligation to pay money to the government—a "reverse false claim." The Court did not rule as to whether the complaint stated a cause of action under this theory. Instead, it held that the plaintiff, in effect, was alleging two theories of false certification, *i.e.,* that the defendants sought to: "(1) receive federal monies and (2) decrease their contractual obligations."[34] The Court held that these two theories were "two ways of describing the same transaction." The "reverse false claims" theory was dismissed, the Court stating it was "redundant."[35]

For health care providers, the *Gabelli* decision again illustrates the application of the *Mikes* holding that a claim can be "legally false" if it falsely certifies that statutory or regulatory requirements have been complied with and the statute or regulation in question is a condition for payment from the government. Although the District Court viewed the "reverse false claim" presented in *Gabelli* as "redundant" in light of the circumstances in that case, the discussion of this theory is a reminder that the false certification theory will also be applicable if the effect is not to obtain payment from the government, but rather to reduce or avoid an obligation to pay the government.

Conclusion

Since claims submitted for payment of federal monies can be "legally false," express or implied certifications must be taken seriously, including representations contained in standard forms, statutes, and regulations. For example, the standard form in *Mikes* required the physicians requesting payment for the medical procedures to certify that the services were: (1) medically indicated and necessary for the health of the patient; (2) furnished either (a) personally by the signing physician or (b) by an employee of the signing physician under the signing physician's "immediate supervision" and "incident to my professional service." (The person certifying should break down the language in this fashion because that is what government counsel will do to determine whether there has been a violation.) If any of the statements certified are incorrect, and are later held to have been "knowingly" made, heavy liability under the False Claims Act awaits.

A "legally false" certification can also be triggered by the mere submission of a claim even if there are no express representations made. The very presentation of the claim is an implied certification that there has been compliance with certain statutory and regulatory requirements. The requirements that have been impliedly certified are those on which the government has conditioned eligibility for payment; not all false certifications create liability under the False Claims Act. As demonstrated by the *Mikes* decision, where Medicare payment is sought, one such implied certification is that all services and items for which payment is sought are: (a) "reasonable and necessary"; and (b) for the purpose of either the diagnosis and treatment of illness of injury, or to improve the functioning of a malformed body member.

The *Cardiac Devices* case demonstrates that the government can define the meaning of "reasonable and necessary" in its manuals and that the very presentation of a claim is an implied certification that the procedures are "reasonable and necessary" as defined in the manual. Accordingly, in order to know exactly what is being certified by presenting a claim, the person presenting must know what provisions in the regulations or applicable manual affect the meaning of "reasonable and necessary." The implied certification will be that these provisions, as well as any other provisions on which the government has conditioned payment, have been complied with. If there has been no such compliance, the presentation of the claim may be held "legally false."

For False Claims Act liability, the false claim must be made "knowingly" and innocent mistakes or negligence do not create liability. However, the statutory definition of "knowingly" includes reckless disregard of the requirements on which federal payment is conditioned, and courts have held that participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment. The result is that, even if the claim was presented without any conscious knowledge that it was legally false, there may nevertheless be liability under the False Claims Act if it is later held that the circumstances evidence a reckless disregard of the requirements for proper payment. Since the government has argued that failure to actively and regularly review the applicable Medicare manual constitutes reckless disregard, and since the False Claims Act provides for treble damages and penalties per claim, those persons who are certifiers, including those causing certifications to be made by others, must proceed with caution: caveat confirmator.

Endnotes

1. According to press releases from the United States Attorney's Office for the Southern District of New York, in 2004 alone two prestigious New York hospitals, two insurance companies, and a billing company settled False Claims Act cases for an aggregate total of over $36 million. Press releases, United States Attorney, Southern District of New York (March 11, 2004; August 12, 2004; August 13, 2004; September 23, 2004) (on file with the author).

   The complaints against one hospital involved allegations that claims were submitted under the names of doctors when in fact the services (newborn deliveries) were performed by midwives and other doctors, including residents, who were not eligible for Medicaid reimbursement. The complaint against the other hospital involved allegations that it had improperly retained payments received from Medicare for graduate medical education expenses.

   The two insurance companies settled allegations that the cost reports they submitted to the government misrepresented their compliance with previously approved budgets in order to obtain performance incentive payments and greater reimbursement. The billing company was alleged to have submitted claims for reimbursement to Medicare and Medicaid on behalf

of health care providers and to have used "default" diagnosis codes that were false and bore no relationship to the actual diagnosis given to patients or the actual procedure performed. The government also alleged that this caused it to pay for abortion services that were not covered by federal law.

Medicaid is provided by states with the United States paying a portion of state Medicaid costs.

2. The elements of liability under the FCA are submitting: (1) a claim; (2) to the United States government; (3) that is false or fraudulent; (4) knowing of its falsity; and (5) seeking payment from the federal treasury. *Mikes*, 274 F.3d at 695.
3. *Id.* at 697.
4. *Id*. at 696.
5. *Id.* at 697-98.
6. The Court noted that in so holding it was joining the Fourth, Fifth, Ninth, and District of Columbia Circuits. *Id.* at 697.
7. Spirometry is a diagnostic pulmonary function test. With the type of spirometers used by the defendants, the patient blows into a mouthpiece to measure volume and speed of exhale. *Id*. at 694.
8. *Id.* at 698. The form also stated "No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations." *Id.* at 699. The Court noted that the Medicare regulations stated that certification is a prerequisite to Medicare payment.
9. *Id*.
10. *Id*.
11. *Id.* at 699.
12. 42 U.S.C. § 1395y(a)(1)(A) (2005); *Id.* at 701.
13. *Id*. (emphasis in original).
14. Section 1320c-5(a) of 42 U.S.C. (2005) provides that health care practitioners must assure, to the extent of their authority, that "services or items ordered or provided by such practitioner . . . will be of a quality which meets professionally recognized standards of health care . . . ."
15. The *Mikes* court cited with approval *SmithKline Beecham, Inc.*, 245 F.3d 1048 (9th Cir. 2001) (allegation that falsification of laboratory test data, when test results fell outside of acceptable standard of error, states worthless services claim).
16. *Id*. at 703.
17. The Court stated that the defendants had produced "overwhelming" evidence of their genuine belief that the spirometry procedures they performed had medical value. The defendants stated they relied on the instruction manual for the machines and their former chief medical assistant, a non-party, gave testimony that the Court concluded supported their claim that they had held a good faith belief in the medical value of the procedures they performed. *Id*.
18. 221 F.R.D. at 329.
19. *Id.* at 335.
20. *Id.* at 334.
21. 31 U.S.C. § 3729(b).
22. *Id*. at *339. The District Court in *Cardiac Devices* quoted *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001) (quoting *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 63 (1984)).
23. With respect to some, but not all, of the hospital defendants, the government alleged additional facts regarding actual knowledge. As to these defendants, the government made an additional claim of common law fraud. *Id*. at *340-41, *331.
24. 2002 WL 987109 at *1. The whistleblower plaintiff had brought a prior FCA complaint and the government had intervened in part. That earlier complaint, which alleged, among other things, that the defendants had violated the FCA by waiving co-payments for sales of medical equipment, had been settled. Promptly after the settlement, the plaintiff whistleblower brought a second action. The Court dismissed the other claims in the second complaint on grounds of *res judicata* and failure to properly plead fraud.
25. *Id. at* *6.
26. *Id.* at *5.
27. *Id.* at *12, quoting *Mikes*.
28. *Id.*
29. *Id*. at *2.
30. *Id*. at *5.
31. *Id*. at *13.
32. *Id*.
33. *Id*. at *10. There is liability under the FCA if a person "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7)(2005).
34. *Id.* at *14.
35. The Court did not address the rationale for dismissing a claim because it was an alternative theory of liability. Litigants frequently proceed on alternative legal theories, which, of course, can become very significant if one theory is later found deficient for some reason on appeal. Also, the "reverse false claim" theory was arguably the theory that was better suited to the allegations of the complaint, since the alleged false certification apparently reduced the amount that the successful bidders would otherwise have had to pay the government.

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Economic Credentialing: An Old Debate Renewed

By Paul Gillan

> Doctors who develop group practices to capture ancillary profits represent an economic threat to hospitals. . . . On the other hand, hospitals are developing satellite clinics and other outpatient facilities to assure themselves of a steady flow of referrals. As a result, doctors and hospitals may be on a "collision course" as doctors invade institutional services and hospitals invade ambulatory care.[1]

This quote, taken from a text more than 20 years old, could as easily have been plucked from today's debate over "economic credentialing"—the use of financial and other non-clinical criteria to determine a physician's hospital staff privileges. In the early nineties, as managed care made significant inroads into health care markets across the United States, hospitals turned to economic credentialing in an effort to protect themselves. The move drew sharp criticism from physician advocacy groups[2] and spurred a great deal of academic and professional commentary.[3]

More recently, as hospitals face the continuing decline of reimbursement, fierce competition from standalone ambulatory surgery centers and specialty hospitals, and the migration of other traditionally facility-based services to large group practices,[4] "economic credentialing" is once again the topic of the day. The HHS Office of Inspector General ("OIG") re-fueled the public debate in 2002 by soliciting comments on "certain credentialing practices" which clearly describe economic credentialing.[5] In New York, physicians have recently unlimbered the principles of antitrust law in an effort to prevent hospitals from engaging in economic credentialing, with some success.[6] Hospitals and physicians alike are carefully monitoring the developments in this field.

While Paul Starr's vision of doctors and hospitals on a "collision course" was accurate to a degree, the collision does not appear to have been the kind one might have expected. Rather than a "direct violent striking together,"[7] the conflict has looked more like the meeting of tectonic plates: a constant underlying tension caused by the inexorable movement of two forces against each other, with occasional and significant manifestations on the surface. It is doubtful that any OIG guidance could settle the matter entirely; nor will significant developments in the antitrust arena solve the underlying tension. The underlying conflict is, after all, fundamental to the hospital/medical staff structure and will be with us as long as that structure endures.

New York law, for the nonce, is relatively friendly to economic credentialing. It permits hospitals to make credentialing determinations based on, among other things, the "objectives of the institution."[8] There is no sign from the legislature that any revisions to the law are imminent. Physicians reacting to economic credentialing practices at New York hospitals may thus find the going to be difficult for the time being. Nevertheless, hospitals considering the economic implications of their credentialing decisions must stay within certain parameters or risk repercussions under the anti-kickback and antitrust laws.

What Is Economic Credentialing?

Commentators in this area typically begin by saying there is no established definition of economic credentialing.[9] They then cite either the American Medical Association ("AMA") definition, which is:

> the use of economic criteria unrelated to quality of care or professional competence in determining a physician's qualifications for initial or continuing hospital medical staff membership or privileges.[10]

or the American College of Medical Quality ("ACMQ") definition, which is

> [defining] a healthcare professional's qualifications based solely on economic factors that are unrelated to the individual's ability to make standard of care medical review or direct clinical care decisions.[11]

ACMQ's definition is narrower in that it focuses on economic factors as the "sole" basis for a credentialing decision, rather than economics being "one" basis. This also makes ACMQ's definition more realistic. AMA's definition, however, seems to be the most prevalent.

In any event, for purposes of this discussion, "economic credentialing" encompasses the various forms of economic credentialing including "pure" economic credentialing, "conflict credentialing," "competitive credentialing," and other names by which the practice goes.

A quick pass over AMA's language is enough to spot the problems. First of all, what are "economic criteria?" My simple dictionary permits me to interpret "eco-

nomic" as referring to (1) the management of a business enterprise; (2) the science of production and distribution of goods and services; (3) matters of finance; or (4) a substitute for "utilitarian."[12] Unabridged dictionaries may offer more options.

This is not simply an exercise in academics, and in fact illustrates the fundamental split between hospitals and physicians. Hospitals view economic credentialing as essential to the management of a business enterprise (definition one in my example). To borrow the language from New York's statute,[13] economic credentialing advances the "objectives of the institution." From the hospital's perspective, it is impossible to separate the objectives of the institution from financial considerations. Physicians, on the other hand, tend to see economic credentialing as a matter of finance (definition three in my example). That is to say, they decry economic credentialing practices as focusing purely on financial considerations. From that perspective, arguments of quality and other facets of the "objectives of the institution" are pretextual arguments obscuring the "real" purpose of protecting hospital revenues and stymying competition.

What Are the Anti-Kickback issues?

Economic credentialing has been around for quite some time. Yet only relatively recently has the issue been interjected into the realm of the anti-kickback law. The American Medical Association again takes credit for this development.

In December 1999 the AMA asked the OIG to issue a special fraud alert regarding the practice of economic credentialing.[14] OIG declined. AMA persisted[15] and in December 2002 OIG published a solicitation for comments on the topic.[16]

In its solicitation, OIG posed five questions for discussion, among which a few are particularly relevant: Are hospital privileges remuneration? Should the exercise of discretion by the privilege-granting hospital affect the analysis under the anti-kickback statute? Can privileges ever be conditioned on referrals, other than minimums necessary for clinical proficiency?

OIG has given little indication of where it is inclined to fall on these questions. One might infer reluctance from the long period of time the AMA lobbied just to get a solicitation for comment—a result far short of the special fraud alert AMA initially sought. Also, although AMA specifically sought a special fraud alert, OIG's request for comments indicated that AMA asked for "guidance."[17] On the other hand, one might as easily view the solicitation itself as signaling a policy concession for which OIG now seeks statistical and anecdotal support.

There are few clues. In its solicitation for comments, OIG fleshes out one question with the following remarks:

> Several credentialing practices have been brought to our attention that give the privilege-granting hospital discretion to evaluate the "financial conflict" created by a physician's outside business interests and permit the physician to retain privileges subject to periodic review. Such discretionary decision-making appears to raise substantial risks under the anti-kickback statute (i.e. privileges are conditioned on a sufficient flow of referral business).[18]

This remark contrasts sharply with commentary following the question of whether a denial of clinical privileges to physicians with competing economic interests would also be a violation:

> A credentialing policy that *categorically* refuses privileges to physicians with significant conflicts of interest *would not appear to implicate the anti-kickback statute in most situations.*[19]

OIG does not seem hesitant to say what it regards as the likely outcome of the analysis. Thus, the following remark causes the most concern:

> Some hospitals have apparently attempted to condition privileges on a physician's referral of a predetermined level of his or her hospital business to the hospital. *Assuming the privileges have monetary value, such conditions would appear to be suspect under the anti-kickback statute.*[20]

"Suspect" does not, of course, mean "prohibited." There is no indication whether OIG supports the underlying assumption that privileges have monetary value, and the outcome of the analysis after considering the relevant justifications for economic credentialing is far from clear. OIG's ambivalence, however, warrants caution.

The anti-kickback statute itself provides that

> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging 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 . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.[21]

If clinical privileges are "remuneration" and the granting of privileges is given to induce the referral of patients to the hospital for the furnishing of health care services, a *prima facie* case of an anti-kickback violation is met. There are no statutory exceptions or regulatory safe harbors that address economic credentialing.[22]

Are Clinical Privileges "Remuneration"?

Whether clinical privileges are remuneration is at the core of the debate. The AMA feels strongly that clinical privileges are within the traditional notion of remuneration.[23] Other commentators feel equally as strongly that they are not.[24] The question has not been addressed by any court.

The AMA posits that, particularly in these days of managed care and giant health systems, clinical privileges are a necessity to physician practice.[25] Surgery, for one example, or invasive cardiology, for another, are not office-based; they require some kind of affiliation with a medical facility. Without such an affiliation, physicians practicing invasive cardiology would be unable to practice, at least in that capacity.[26] Viewed in this light, the "value" of clinical privileges to the physician is obvious. (AMA's position is increasingly difficult to defend, however, given the proliferation of facilities where such procedures may be performed.)

Other commentators respond that "value" does not refer to the subjective value of a thing or act, but rather to value as determined objectively, such as by measuring an amount or percentage of cash, or the particular dollar value of a tangible gift.[27] Clinical privileges themselves have no value until the physician takes the further step of admitting a patient and performing services. Furthermore, the prospect of referrals exists in every privileging circumstance. If clinical privileges are to be categorically considered remuneration, then every credentialing decision undertaken by a hospital must undergo anti-kickback analysis. Such a result, it is argued, is unworkable.[28]

Two seminal cases interpreting the term "remuneration" serve only to underscore the breadth and sweep of the statute's reach. In *U.S. v. Greber*,[29] the U.S. Court of Appeals for the Third Circuit noted that kickbacks can take many forms, including cash but also including "long-term credit arrangements, gifts, supplies and equipment, and the furnishing of business machines."[30] The Court favored an "expansive reading" of the statute in light of the important public function it serves. Incidentally, the "expansive reading" approach is inconsistent with the "rule of lenity," a familiar tenet in criminal law practice which requires ambiguities in a statute to be construed in favor of the defendant. Proponents of economic credentialing have argued that the rule of lenity must apply to anti-kickback statute interpretations.[31]

In a second case, *U.S. v. Bay State Ambulance*,[32] the Court of Appeals for the First Circuit reviewed a series of transactions and found "remuneration" both in cash payments as well as in gifts of automobiles. Interestingly, the payments and gifts were provided under the guise of "consultant fees." The defense took the position that the consultant arrangement was legitimate, and that the prosecution would have to prove that the fees were excessive or above fair market value in order to prove a kickback. The Court disagreed with this position and in its discussion noted that "[t]he gravamen of Medicare Fraud is inducement. *Giving a person an opportunity to earn money may well be an inducement* to that person to channel potential Medicare payments towards a particular recipient."[33]

The language in *Bay State* does not fit well into the arguments in favor of economic credentialing. If the mere opportunity to earn money is indeed an "inducement" to referrals, then the argument that clinical privileges are valueless is simply not viable.[34]

The Need for a Safe Harbor

At least one purpose of all credentialing determinations is the expectation of referrals. After all, the principal means by which patients come to a hospital are through referrals from physicians holding privileges there. It would be a silly result indeed if the only hospitals physicians could refer to were those where they did not hold privileges. (Though, in truth, stranger results under the anti-kickback statute could be imagined.)

AMA argues that "*[e]xclusive* credentialing policies, under any name or label, therefore, have the same effect as other forms of kickbacks that have been the subject of various OIG advisory opinions."[35] The anti-kickback statute may not accommodate such a fine cut. If exclusive credentialing practices are a kickback, ordinary credentialing practices are a kickback too.

Opponents of economic credentialing portray the practice as one entirely divorced from quality issues. The name itself suggests a purely monetary focus.

AMA's definition specifies that the basis of the decision is "economic criteria unrelated to quality of care or professional competence."[36] The Medical Society of the State of New York, similarly, has long taken the position that hospitals should not restrict or terminate medical staff privileges "based upon economic criteria unrelated to the quality of patient care."[37]

In contrast, commentators have argued that economic credentialing is nearly impossible to resolve into a purely economic issue.[38] More often, they assert, the issues underlying economic credentialing are ones of quality and control. There are a few court cases illustrating this point.

In the 1984 case of *Belmar v. Cipolla*,[39] a group of anesthesiologists in New Jersey attacked a hospital's exclusive arrangement with a competing group, asserting antitrust and contractual violations. The complaints were dismissed by the trial court. On appeal, the Supreme Court of New Jersey delved into the "nature and function of a modern hospital" in its analysis of the parties' respective rights. After recognizing that hospital privileges are crucial to a physician's practice and, therefore, subject to judicial protection,[40] the New Jersey Supreme Court went on to state that

> No matter what arrangement a hospital may have with doctors, its primary purpose remains to serve the public. As long as those entrusted with the management and governance of a hospital make reasonable decisions consistent with the public interest, their decisions should be respected. Consequently, courts normally do not interfere with a reasonable management decision concerning staff privileges as long as that decision furthers the health care mission of the hospital.
>
> Additionally, a hospital has a right and a duty not only to review the qualifications of doctors, but also to consider the need for an impact of additional doctors on the hospital's staff and patients.[41]

After surveying applicable regulations, policy statements, and the hospital's bylaws, the appellate court found that "[t]he evidence points to the conclusion that the decision to enter an exclusive contract for the provision of anesthesia services was motivated by the hospital's desire to insure [sic] a high standard of medical care."[42]

In a somewhat more recent South Dakota case, *Mahan v. Avera St. Luke's*,[43] an orthopedic surgeon challenged a hospital board's decision to close its medical staff to physicians requesting privileges for three specific spinal procedures. The trial court granted judgment to the surgeon, finding that the hospital had breached its medical staff bylaws by closing its medical staff. The South Dakota Supreme Court reversed, finding that the ultimate authority over corporate decisions remained with the hospital's board of trustees, and that the decision to partially close the medical staff was a corporate decision:

> When making these decisions, the Board specifically determined that the staff closures were in the Aberdeen community's best interests, and were necessary to insure [sic] 24-hour neurosurgical coverage for the Aberdeen area. By preserving the profitable neurosurgical services at [the hospital], the Board also insured [sic] that other unprofitable [hospital] services would continue to be offered.[44]

These two cases illustrate that medical staff determinations are intricately related to the quality of the services offered by the hospital and the financial viability of the hospital as a whole.

It is possible, perhaps, that both sides of this argument are right, but more likely that both sides are wrong. While one might be able to cobble together an esoteric argument that admitting privileges have no value, in practice few could deny that clinical privileges indeed are valuable. At the same time, it is difficult to imagine how institutions would effectively manage their medical staffs if all credentialing decisions had to be made within the framework of the anti-kickback statute. The proponent's response to AMA's position is, in effect, not so much a gainsay as it is a justification of the practice.

The concept of justifying certain economic credentialing practices, rather than denying that privileges are a form of remuneration, is an important one because it points towards the need for a safe harbor instead of a special fraud alert as AMA requested. The existing safe harbors all embody common business practices essential to the health care industry which, but for the safe harbor, would run afoul of the anti-kickback restrictions. Personal service arrangements, for example, are necessary for hospitals to secure the administrative expertise of their physician staff. Yet in the absence of a safe harbor, personal service arrangements would quite clearly violate the statute.[45]

Some legal commentators readily regard the establishment of a safe harbor as a likelihood.[46] Others scour HHS publications, hunting for clues to OIG's position. In recent compliance guidance for hospitals, for example, OIG suggested that conditioning privileges on referrals beyond the volume necessary to ensure clinical proficiency "potentially raises substantial risks" under the anti-kickback statute.[47] Some commentators seized on such statements as evidencing OIG's belief that economic credentialing violates the anti-kickback statute.[48] But OIG's statement in the compliance guidance is nothing new. In fact, one could argue that the language used in the compliance guidance—"potentially raising substantial risks"—is less of an indictment of the practice than "appearing to be suspect," which is how OIG characterized conditioned privileges in 2002.

A Shot in the Arm, or the Foot?

The AMA has been agitating for OIG action on economic credentialing for five years. If, as some envision, OIG ends up promulgating a safe harbor to address credentialing, AMA may well end up with more than what it bargained for. The one aspect of economic credentialing which OIG has been fairly clear about is its position on categorical exclusions. In its recent compliance guidance, OIG repeated a position taken in the 2002 request for comments: "a credentialing policy that *categorically* refuses privileges to physicians with significant conflicts of interest would not appear to implicate the statute in most situations."[49] OIG's position is not surprising. "Discretion" is often code for "favoritism"; policies which lack discretion are, therefore, more likely to genuinely further the "objectives of the institution." Objective, categorical exclusions are likely to form a core component of any safe harbor or other guidance on hospital credentialing. A bright line test of what constitutes a "significant" conflict of interest should not be too difficult to devise. Similar tests were developed for what constitutes permissible and impermissible investment arrangements.[50]

The result of AMA's push for an OIG guidance, therefore, is likely to be fairly specific, bright-line protection for hospitals engaging in categorical exclusions of physicians that invest in competing facilities. For physicians, this may be far worse of an alternative than the gray murk in which hospitals currently operate. The irony of this result is notable.

Wait, or Move?

Until OIG guidance appears, hospitals are left with little guidance and little comfort that their choices will not expose them to potential anti-kickback charges.

In the most conservative route, a hospital seeking to adopt certain economic credentialing practices could pursue an OIG advisory opinion. A favorable advisory opinion would protect the hospital against anti-kickback charges (assuming the facts disclosed to the OIG in order to obtain the opinion are truthful and accurate). An advisory opinion does require modest investments of time and money. There is also always the possibility that the opinion could be unfavorable; though rare, it occasionally does happen.

An advisory opinion may be a good option for two reasons. First, the issue is ripe. OIG is probably not inclined to outlaw all forms of economic credentialing. There is too much of a history of the practice and the concept of privileges as remuneration reaches too far into the fundamental credentialing process to permit an outright ban. Accordingly, a favorable opinion is probably achievable. The matter is also a pressing one. The AMA continues to seek aggressive OIG action on the issue. If OIG is not inclined towards AMA's view, it may well seize on the opportunity to create an unfavorable precedent by issuing a favorable opinion.

If the hospital is not inclined to pursue an advisory opinion, the next best means of protecting against an anti-kickback charge is to build the record exclusively on quality issues.[51] This is an imperfect defense, of course, because of the "one purpose" rule. If it is found that one purpose of the arrangement is the unlawful inducement of referrals, then no amount of other "good" purposes will protect against a charge.

Quality issues that have found favor in commentary or cases thus far include:

- ensuring the availability of appropriate personnel and equipment
- better use of operating room personnel
- the ability to process more operative procedures
- protecting against the loss of skilled physicians to competing facilities
- protecting against adverse selection (where physicians send low acuity/high reimbursement cases to one facility and high acuity/low reimbursement cases to another)
- protecting against loss of cases that are useful for skill development and teaching
- addressing schedule and coverage concerns

Other factors may become apparent from the particular facts and circumstances at hand.

Physicians opposing economic credentialing have little recourse in the courts or other forums such as the Public Health Council. A successful defense in this case actually requires a good offense, and one that is planned and executed well before the issue foments into an actual determination. Early organization presents a unique set of challenges, including the need for proactivity and the ability to surmount lack of awareness, collective apathy, and cultural inertia.

AMA suggests developing bylaw provisions which clearly articulate membership and privilege criteria, including a provision prohibiting economic credentialing.[52] This may be easier said than done. In New York, the hospital board of directors must ultimately approve the medical staff bylaws and any change to them.[53] Thus a resolution of the medical staff securing an anti-economic credentialing provision in the bylaws may still be blocked by the hospital board. Successfully adopting an anti-economic credentialing provision will thus require—in addition to technical knowledge—an aptitude for politics as well.

Conclusion

It would be Pollyannish to pretend that hospital credentialing decisions are devoid of economic considerations. If ever there was such a time (which I doubt), it is true no longer. It would be equally naïve, however, to believe that physician opposition to economic credentialing is motivated exclusively out of concern for patient choice and quality of care. The first step in advancing the dialogue between the two camps may well be to recognize that both sides have a legitimate and respectable financial stake in the criteria applied to clinical privileging determinations. Both sides can then cease their efforts to outdo each other in claiming the moral high ground.

Refocusing the debate in this manner may lead to some frank concessions. Few physicians would disclaim the value a hospital brings to a community. Ambulatory surgery centers and specialty hospitals typically do not have emergency departments and typically do not provide a broad array of services like most hospitals. The hospital serves a community need by supporting unprofitable services which are necessary but which would not be available on a standalone basis. Hospitals, meanwhile, might readily concede that a new, efficient ambulatory surgery center could better serve the community of physicians and, by extension, the patients they operate upon. Such a refocusing does not guarantee a happy outcome, or even a correct outcome. But it at least permits the discussion to proceed in an honest fashion.

Although New York law favors some forms of economic credentialing, hospitals should not blithely venture into the field without careful consideration of the issues. The actual risk of an economic credentialing decision translating into an anti-kickback violation is probably quite low. The severe consequences of such a translation, however, merit a great deal of caution. Unfortunately, there is no solid guidance available to hospitals attempting to manage their medical staff in this manner. The best alternative is to obtain an advisory opinion from the Office of Inspector General. Secondarily, an emphasis on quality and patient care issues will dilute a charge that the hospitals' motivations were primarily financial.

Physicians seeking a means to defeat economic credentialing before it starts should consider whether and how the battle lines are to be drawn. Hospitals and physicians have a mutual interest in the survival of the hospital as an institution. Adroit planning in the early stages can align the interests of the hospital and the physicians and prevent the issue from becoming a polarizing one. If the debate does devolve into a battle, physicians—at least in New York—are more likely to emerge as the losers.

Endnotes

1. Paul Starr, SOCIAL TRANSFORMATION OF AMERICAN MEDICINE, 425-26 (1982), as cited in Elizabeth Weeks, "The New Economic Credentialing: Protecting Hospitals from Competition by Medical Staff Members," 36 Hosp. Law Weekly 247 (2003). Starr's book won the 1984 Pulitzer Prize for General Non-fiction.
2. The American Society of Anesthesiologists, for example, resolved in 1993 that "[t]he Society condemns the practice known as 'economic credentialing,' by which decisions related to medical staff privileges are based on considerations unrelated to quality of care." American Society of Anesthesiologists, "Statement on Economic Credentialing," October 15, 1993.
3. *See*, *e.g.*, Kevin E. Grady, "Current Topics in Medical Staff Development and Credentialing," 26 Journal of Health & Hospital Law 193 (Jul. 1993) ("The economic 'squeeze' which the government and third party payers have imposed on providers has had the particularly unfortunate consequence of increasing tension between hospitals and physicians over privileging decisions."); Jane C. Taber & Janna P. King, "Caught in the Crossfire: Economic Credentialing in the Health Care War," 1994 Detroit College of Law Review 1179 ("In today's rapidly changing health care environment, hospitals have been placed in the combat zone of market crossfire, replete with economic and quality of care aresenals. This crossfire is particularly evident in the area of granting or denying staff privileges."); Brad Dallet, "Economic Credentialing: Your Money or Your Life!," 1994 Health Matrix 325, 327 ("As economic credentialing has posed the latest threat to physicians receiving and renewing their hospital privileges, it is sure to receive its share of litigation in the future. These economic factors will add fuel to the fire in the already volatile arena of physicians suing hospitals for the denial or revocation of hospital privileges.").
4. *See* Health Care Reform Working Group, Initial Recommendations for Reform, at p. 14 (Nov. 17, 2004).

5. 67 Fed. Reg. 72894 (Dec. 9, 2002).
6. *Rome Ambulatory Surgery Center v. Rome Memorial Hospital*, 5:01-CV-23, 2004 U.S. Dist LEXIS 25659 (N.D.N.Y.).
7. American Heritage Dictionary of the English Language, New College Ed. (1979).
8. *See* N.Y. Public Health Law § 2801-b(1).
9. Paul Danello, "Economic Credentialing: Where Is It Going?," available as of this writing at http://articles.corporate.findlaw.com/articles/file/00989/009358 ("There is no generally accepted definition of 'economic credentialing', [sic] although the concept has been widely discussed in the literature of medical ethics and accreditation standards.")
10. American Medical Association Policy H-230.975 ("AMA Policy") (available as of this writing at http://www.ama-assn.org/ama/pub/category/10919.html).
11. American College of Medical Quality, Policy 23 (available as of this writing at http://www.acmq.org/profess/policy23.pdf). The policy goes on to explain that economic credentialing "involves the use of economic criteria by a health care organization as the *only* factor which determines a physician's or other health care professional's qualifications for initiation, continuation, or revocation of medical care or peer review privileges."
12. American Heritage Dictionary of the English Language, New College Ed. (1979).
13. N.Y. Public Health Law § 2801-b(1).
14. Letter from Michael D. Maves, M.D. to Kevin McAnaney, Esq., Office of Counsel to the Inspector General, Sept. 30, 2002, accessible at http://www.ama-assn.org/ama1/pub/upload/mm/395/sept_ltr_oig.doc.
15. According to the commentary accompanying the AMA policy, after OIG's initial refusal AMA "had several conferences with OIG over the ensuing two years regarding the request and in September 2002 submitted another request for a fraud alert." AMA Policy, *supra* note 10.
16. 67 Fed. Reg. 72894 (Dec. 9, 2002).
17. *Id.*
18. 67 Fed. Reg. 72895.
19. *Id.* (emphasis added).
20. 67 Fed. Reg. 72896 (emphasis added).
21. Soc. Sec. Act § 1128B(b)(2), 42 U.S.C. § 1320a-7b(b)(2).
22. The lack of a safe harbor does not necessarily mean the proposed conduct is unlawful. Actions may fall outside of the safe harbor and still be lawful under the Anti-kickback statute.
23. Letter from Michael D. Maves, M.D. to Janet Rehnquist, Inspector General, Feb. 6, 2003, accessible at http://www.ama-assn.org/ama1/pub/upload/mm/395/rev_oig_comments.doc ("AMA Comments") ("Clinical privileges have both a monetary value and a professional value.").
24. Robin Nagele, "Hospital Privileges as Kickbacks? The Economic Credentialing Debate Commands Renewed Attention," Health Law Handbook 2003 at 315 (Am. Health Law. Assoc. 2003) (hereinafter, "Nagele").
25. AMA Comments, *supra* note 23.
26. *Id.* at 2 ("Absent the ability to utilize clinical privileges, many physicians cannot realistically practice medicine").
27. Nagele, *supra* note 24, at 337-43.
28. *Id.* at 358-59.
29. 760 F.2d 68 (3rd Cir.), *cert. denied*, 474 U.S. 988 (1985).
30. *Id.* at 71.
31. Nagele, *supra* note 24, at 360. "The 'rule of lenity' requires that any ambiguities in a criminal statute are to be resolved in the defendant's favor."
32. 874 F.2d 20 (1st Cir. 1989).
33. *Id.* at 29 (emphasis added).
34. *Cf.*, Letter of Daniel M. Mulholland III to Office of Inspector General, February 4, 2003 ("Far from being 'remuneration' unilaterally conferred by the hospital, any value conferred on a physician by virtue of appointment to a hospital medical staff is part of a 'two-way street' of corresponding obligations owed back to the hospital—obligations that go directly to the hospital's cooperate responsibility to its patients. The benefits of medical staff appointment are not extended to physicians without any corresponding obligations, and certainly not for the purpose of inducing the physician to refer to the hospital.").
35. AMA Comments, *supra* note 23, at 2.
36. AMA Policy, *supra* note 10.
37. Medical Society of the State of New York, Position 150.988, "Economic Credentialing and Medical Staff Privileges," available as of this writing at http://www.mssny.org/position/hospitals.htm.
38. Nagele, *supra* note 24, at 324. "Most commentators who have examined the issue of economic credentialing have recognized that economic factors and quality issues are not mutually exclusive criteria, but rather, are closely intertwined in virtually every hospital decision."
39. 96 N.J. 199, 475 A.2d 533 (1984).
40. The "protection" asserted was one of due process.
41. *Belmar*, *supra* note 39, at 208.
42. *Id.* at 211.
43. 2001 S.D. 9, 621 N.W.2d 150 (2001).
44. *Id.* at 15, 621 N.W.2d 156.
45. Avoiding, as OIG does in all of its advisory opinions, the issue of "intent."
46. Danello, *supra* note 9.
47. 70 Fed. Reg. 4858 (Jan. 31, 2005).
48. Eve H. Goldstein, "An Analysis of Medical Staff Credentialing As Remuneration Under the Anti-Kickback Statute," Health Lawyer News August 2004, at 6, 7.
49. 70 Fed. Reg. 4869.
50. 42 C.F.R. § 1001.952(a).
51. Section 2801-b of the New York Public Health Law makes it an "improper practice" for a hospital to deny staff privileges for reasons other than standards of patient care, patient welfare, the objectives of the institution or the character or competency of the applicant. "Objectives of the institution" has been read as a clear nod towards economic credentialing, but casting the analysis in issues of quality would be better.
52. AMA Policy, *supra* note 10.
53. 10 N.Y.C.R.R. § 405.4(a). *See also* Joint Commission on Accreditation of Healthcare Organizations, 2005 Hospital Accreditation Standards, MS 1.20, 1.30.

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Protection Amid the Pitfalls? The Shifting Role of the Attorney-Client Privilege in Compliance Investigations

By Thomas S. D'Antonio and Catherine A. Corlett

Introduction

Compliance programs.
Work plans.
Self-audits.
OIG advisories.
Voluntary disclosures.
Treble damage awards.
Civil monetary penalties.
Qui tam litigation.
Grand jury investigations.
Indictments.

That these terms, as much as any clinical phrase or descriptor, are common parlance in the healthcare world of today is perhaps the most obvious and notorious sign that the world in which healthcare providers operate has undergone a fundamental and dramatic shift over the past decade or so. To paraphrase the wide-eyed Dorothy upon finding herself in the strange surroundings of Oz, "I don't think we're in Kansas anymore, Toto."[1]

The changing healthcare climate has had far-reaching implications on many levels, including specifically the role that lawyers must play in the provider's compliance-related activities, and the nature and extent to which provider-counsel communications can continue to enjoy privilege from disclosure. This article will provide an overview of certain basic tenets applicable to the privilege, examine the current healthcare landscape and its impact on the attorney-client privilege, and provide some practical tips for preserving confidentiality as providers and their counsel navigate the rocks and shoals of compliance activities and governmental investigations in 2005 and beyond.

The Attorney-Client Privilege Generally

Before turning to the role of the attorney-client privilege in today's enforcement climate, some background on the privilege generally, and on some common issues that arise in the area, is in order. The attorney-client privilege is considered the oldest and among the most sacrosanct of the common law privileges; it has been a recognized part of the fabric of our common law for centuries.[2] As noted by New York's Court of Appeals, the privilege serves to "foster[] the open dialogue between lawyer and client that is deemed essential to effective representation."[3] The protection afforded by the attorney-client privilege gives a client easier access to advice that serves the important societal interest of promoting compliance with the law, and affords for the client the added assurance that he or she may fully and freely confide in the attorney during that process, without fear that the confidences subsequently will be exposed or used to the client's disadvantage.[4] Generally speaking, the privilege shields from disclosure both communications made to an attorney or communications from counsel, where those communications relate to the solicitation or furnishing of legal advice, or to the provision of legal services to a client or prospective client.[5] Once the privilege has been found to attach, absent a waiver by operation of law or by election of the client, disclosure of the privileged communications generally can neither be compelled, nor voluntarily made by the attorney.[6]

By broadly and completely shielding a client's confidences from disclosure, however, the privilege often has been criticized for impeding the truth-finding process, and precluding the disclosure of otherwise relevant and often crucial information.[7] Thus, as a general proposition courts often seek to limit the application of the privilege, and often to its narrowest possible form, so as not to contravene the interests of justice.[8] Courts also draw a sharp distinction between communications centered on the privileged provision or receipt of legal advice, as compared to business or operational communications, or to the compilation of strictly factual, nonprivileged information or documentary material.[9]

To qualify for protection under the attorney-client privilege, courts customarily apply the following analysis to lawyer-client communications in determining their eligibility for the privilege:

- The communications must be confidential and between lawyer and client, and the client must *intend and expect* confidentiality;[10]

- The communication must be made for the purpose of obtaining or conveying legal advice or services.[11]

Absent satisfaction of these stated requirements, which the proponent of the privilege must establish by competent proof,[12] the communications are not privileged or exempt from disclosure.

In New York, the source and scope of the attorney-client privilege has been codified in the CPLR. Under CPLR 4503, all "confidential communications made between the attorney or his or her employee and the client in the course of professional employment" are protected from disclosure in "any action, disciplinary trial or hearing, or administrative action, proceeding or hearing conducted by or on behalf of any state, municipal or local governmental agency or by the legislature or any committee or body thereof." Federal Rule of Evidence 501 adopts this state standard in federal diversity cases in New York, while privilege issues in federal question cases are governed by federal common law.[13]

Some Examples of Limits on the Privilege

The precise contours of the attorney-client privilege in a given circumstance are governed by highly fact-sensitive inquiries, but some common misperceptions in this area warrant special mention. The mere involvement of a lawyer in the process does not, standing alone, give rise to a privilege. For instance, in a controversial decision the Appellate Division, First Department held that the report of an investigation into alleged overcharges to a bank, authored by the bank's outside lawyers, was not privileged because their report was, in essence, what an investigator (as opposed to a lawyer) would produce. The report, in the Appellate Division's view:

> Contain[ed] communications to the client which were not clearly made by counsel in their role as attorneys. . . . Since the role of [the outside lawyers] was that of an investigator retained to develop facts, rather than to render legal opinions, their work product [was] not exempt from disclosure. . . . A privilege is not created, where none exists, by hiring the attorney to do the work of an investigator.[14]

The New York Court of Appeals ultimately modified the Appellate Division's holding in that case, noting that the report set forth, in addition to facts, "the firm's assessment regarding a possible legal claim, its approximate size and weaknesses. As a confidential report from lawyer to client transmitted in the course of professional employment and conveying the lawyer's assessment of the client's legal position, the document has the earmarks of a privileged communication."[15] While this particular report, on these particular facts, ultimately was deemed to be an attorney-client communication that was privileged in its entirety, the Court of Appeals stressed that would not necessarily be the outcome in other contexts. Attorney communications, the Court noted, are "not cloaked with privilege when the lawyer is hired for business or personal advice, or to do the work of a nonlawyer."[16] Where a provider's inside counsel is involved in the communication, "nettlesome questions" also arise about the precise line between the staff counsel's role as legal counselor, as opposed to his or her role as a corporate agent or business counselor, and the blurring of this line can make the asserted privilege much more susceptible to a successful challenge.[17]

The presence of counsel at a corporate meeting is customarily sufficient to give rise to the privilege where legal issues are discussed or potentially implicated, but it is not sufficient to create a privilege where the attorney's role is that of a "mere scrivener," or where there has been no consultation or anticipated consultation for legal advice from counsel.[18] Similarly, copying counsel on written communications that neither seek legal advice nor result in the provision of such advice does not cloak them with a privilege, even where they are labeled as "attorney-client communications" or "attorney work product."[19] This is because even the broadest application of the privilege requires that the communication be made for the purpose of giving or obtaining *legal* advice.[20] Where the conversation or correspondence at issue does not seek or furnish legal advice (but rather outlines a party's view as to the issues in dispute, for instance, or recounts facts relevant to the discussion but neither offers nor implicates legal analysis), the communications are not privileged.[21] Information of a strictly factual nature, in particular, cannot be shielded from disclosure by the attorney-client privilege. Facts are not communications, and while lawyer and client cannot be forced to disclose the sum and substance of a conversation about legal strategy or advice, "confidential facts" provided by a client or a witness do not become cloaked with privilege simply because they have been revealed to an attorney.[22] Also not protected by the privilege is the fact of a client's representation by counsel, the fact that she or he has consulted with counsel, or even the client's identity.[23]

Waiver of the Privilege

The large bulk of the litigated issues with respect to privilege address the critical issue of waiver. Even

where the attorney-client privilege properly has been established and asserted, by operation of law or on the facts of any particular case an otherwise applicable attorney-client privilege can be waived. For example, the law is quite plain that no communications to third parties, and no communications made in the presence of third parties, can give rise to a valid privilege claim when that third party is not necessary to the provision of legal advice or services. In this regard, counsel must distinguish between retained experts or consultants, client employees, and similar individuals, on the one hand, and third parties that play no role in the case strategy or defense, on the other.[24] Any discussion of privileged material in the presence of an "unrelated" third party waives the privilege, as does an after-the-fact dissemination of otherwise confidential legal advice to such third parties.

While the circumstances giving rise to a waiver of the privilege often are quite plain, such as where the communication is made to an adversary or in the presence of a complete stranger to the lawyer and his or her client, many other circumstances triggering a potential waiver are far less obvious to many lawyers and clients. As an example, the participation of a lawyer at meetings where that lawyer was not acting in a "representative" capacity has been held to waive the privilege,[25] as have the presence of consultants who have not been engaged to assist in the provision of legal advice or to assist counsel as non-testifying experts.[26] While lawyers can commission non-lawyers to interview witnesses, the results of those interviews will not be privileged absent a determination that the nonlawyer was acting as the lawyer's agent.[27] Similarly, while the interruption of a lawyer-client conversation by the lawyer's secretary or paralegal certainly will not waive the privilege,[28] some perhaps less obvious intrusions do serve to waive the privilege. Indeed, even where a client seeks to have a privileged, private discussion with her lawyer but unwittingly blurts out confidential information within earshot of a law enforcement official who is in the process of leaving the room, a waiver of the privilege has been found.[29] A useful rule of thumb is that the "magic circle" of individuals[30] who properly can receive privileged material is quite small, and any one not acting as an agent or representative of either the lawyer or the client will cause the privilege to be waived.[31]

With regard to so-called "voluntary waivers," only the client has the authority to knowingly waive the privilege.[32] The lawyer has no right or ability to do so, in the absence of criminality or fraud, or a handful of other limited circumstances.[33] Other more recent developments have favored the expansion of the privilege in certain classes of cases. As an example, the so-called "common interest privilege" has found greater acceptance, and broad general recognition by the judiciary. That privilege allows the exchange of selected, otherwise privileged material among counsel from different firms or entities who represent parties with similar interests in multiparty litigation.[34] However, numerous recent cases have sharply divided over the extent to which a "selective waiver" of the privilege can occur, in circumstances where otherwise privileged material is disclosed to a governmental entity (as in the case of a production to a grand jury or a settlement with the government), and yet still remain shielded from discovery in subsequent litigation with private parties.[35]

Specific Privilege Issues in the Healthcare Compliance Arena

All these principles, of course, have direct application in the healthcare compliance context, and counsel is well advised to carefully consider, among other things, the structure, scope and preservation of the attorney-client privilege as the compliance investigation unfolds. The task in this area is complicated by the fact that, when a potential False Claims Act matter presents itself, the applicable timelines are short and the necessary breadth of inquiry often is great. In 2005, the OIG issued its most recent "Compliance Program Guidance for Hospitals,"[36] and in that Guidance mandated:

> Where the compliance officer, compliance committee or a member of senior management discovers credible evidence of misconduct form any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the hospital should promptly report the existence of misconduct to the appropriate Federal and State authorities within a reasonable period, but not more than 60 days after determining that there is credible evidence of a violation.[37]

The self-reporting requirements assume, and in fact require, that the result of the hospital's internal investigation will be turned over to the "appropriate . . . authorities" in short order. Neither the compliance guidelines nor the OIG's Self-Disclosure Protocol[38] contemplate, however, the effect that such disclosures may have on the attorney-client privilege. And, frankly stated, neither the OIG, the governmental payors nor their representatives particularly care if a provider's privilege is vitiated in connection with any particular disclo-

sure, and often will demand that it be waived in the context of a particular settlement.[39]

Some Practical Suggestions for Establishing and Maintaining Privilege

What steps, therefore, should a provider and its counsel take when faced with a report of potential overbillings to Medicaid, with alleged research malfeasance in a sponsored program, with purported fiscal improprieties affecting a cost report, or with a similar set of circumstances that require a prompt but thorough investigation that may well culminate in a disclosure to the payor, to the Department of Justice or to the OIG? Should they be concerned with the attorney-client privilege if a voluntary disclosure is almost a certainty at the conclusion of the process? Can they avoid disclosing all they learn during that process?

There is, of course, no single appropriate answer to those questions, or any "one size fits all" solution when these issues arise. However, the following twelve principles (we resist the temptation to label them the "Dirty Dozen") should be considered as the provider and its attorney pursue an investigation and map out their strategy, to maximize the chance that they will create, identify and preserve privilege as appropriate:

A. Identify All the Issues—If this suggestion sounds rudimentary, that's because it is. However, a failure at the outset to think through all the issues presented, and to create appropriate strategies for investigating and analyzing each issue, can be highly detrimental to the provider and to the ultimate outcome of the investigation. As an example, consider the situation where a teaching hospital learns that certain attending physicians have not been properly supervising residents, and the hospital at the same time learns that one or more of the attending physicians have not been documenting adequately in the charts, raising what the payors euphemistically call "medical necessity" issues. To investigate these issues, two universes of facts (with some but relatively little overlap) must be examined. The former may require significant numbers of interviews of residents, compliance team members, attending physicians and administrators to determine not only whether the challenged conduct took place as alleged but how the supervision rules were disseminated, what the institution "knew," if anything, about the problem, and whether the requisite institutional culpability under the False Claims Act can be argued to exist. The latter issue almost surely will require some expert assistance in connection with chart reviews and the universe of interviewees will likely be substantially smaller and significantly different. As a result, different "teams" with different skill sets will be required to assist the provider in evaluating those issues, and different needs for the creation and maintenance of privilege will arise. Identifying those needs at the outset can avoid problems as the investigation unfolds.

B. Pick Your Teams—Once the issues are identified and a strategy is developed, then counsel (in consultation with the provider) should determine which people will be responsible for which specific tasks. In this regard, the lawyer essentially "quarterbacks" the effort, and should structure the investigation in such a way as to create and preserve privilege where that is important. For example, the interviews may well unearth information that is not directly relevant to the billing conduct that the provider likely will be disclosing, but is potentially damaging to the institution in other ways. Assuming that the interviews do not yield information that would otherwise need to be disclosed in connection with the subject billing conduct, properly structured interviews in which counsel participates, or which counsel directs,[40] can maximize the chance that the privilege is created and preserved.

C. Create and Preserve the "Magic Circle"—Lawyers should directly retain required consultants and experts where the creation and maintenance of privilege for their work is a consideration, and the retainers should be properly drawn so that their role in assisting counsel is particularly and effectively delineated.[41] In any interview, meeting, debriefing session or strategy caucus, consider at the outset who is attending, and whether any attendee or participant can be considered as an "unrelated third party." In other words, always keep focused on the "magic circle," and who can breach the protections afforded within that circle.

D. Identify Those With the "Need to Know"—Strategy meetings should not become conventions. Interviews are not group affairs. The number of participants in the process should be kept to an appropriate minimum, and they should be told what they need to know to assist the provider and counsel effectively in the investigation. For example, the consultant performing chart reviews need not necessarily be told all the information that has been unearthed in the interviews of the provider's employees, and the participants in strategy sessions should be limited to those who will be expected to plan and formulate (as opposed to those who will be directed to execute) the strategy. A consultant's "work papers" also should not include documentation not strictly necessary for the consultant to perform her or his function. Among the reasons counsel must consider the "need to know," in addition to efficiency, are that the greater the number of persons made

privy to confidential communications, the greater the likelihood that the communications will be disclosed beyond the confines of the "magic circle." Remember that while the corporation controls the privilege,[42] individuals can give rise to a waiver by improvident or innocent "leaks," or by the inclusion of otherwise privileged information in audit "work papers."[43]

E. Document the Scope and Role of All Consultants and Refined Experts—No consultant or expert should be engaged by the provider, as opposed to counsel, where a privilege may need to be asserted with respect to their work. That retention, moreover, should be in writing, and the retainer documents should reference the role that *counsel* expects the consultant/expert to play in assisting the lawyer to assess legal risk and to advise the provider accordingly. So-called "*Kovel* letters,"[44] or similar documentation, should be fully executed *before* any work starts.

F. One Investigation or Two?—There is no hard and fast rule about whether, or how, to segment a compliance inquiry. Some points of separation are obvious—personnel/human resources issues and reimbursement audits are a good example. Others are less clear, but not necessarily less important insofar as privilege considerations are concerned. For instance, it is often fairly evident at the outset of a self-audit that a provider will disclose the results of that effort if overpayments are identified. A corollary inquiry into institutional practices, the "recklessness" question and similar issues may, or may not, yield additional information to be disclosed, and mechanisms to protect the confidential information developed during the attorney's investigation of that latter issue should be implemented.

G. To Write or Not to Write?—Lawyers, in general, love to write, and busy senior administrators prefer to receive written summaries they can ponder as time permits. That may not be advisable in the context of a compliance investigation. Counsel should carefully consider what is to be committed to writing, whether drafts are to be saved, and the universe of recipients of any reports generated during the process.

H. E-Mail is *Not* a Friend of Privilege—As Bill Gates and many others can attest, e-mails often create problems for their authors. This is not only because the "informal, unguarded" exchanges are preserved literally forever, but also because the author cannot control the universe to whom her or his message is disseminated. E-mail is, without doubt, a useful tool, but it also is a tool that should be used deliberately and sparingly in the compliance investigation context.

I. Carefully Choose What You Disclose—Disclosure of an overpayment to a governmental payor or to a government attorney involves, generally speaking, a specific set of facts and a limited inquiry. Counsel should endeavor to assist the provider in making a forthright and full disclosure, but one that is bracketed within sharp and well-defined limits where appropriate. If certain procedures or physicians were evaluated, for instance, and there is a good faith basis for limiting the compliance inquiry only to those procedures or physicians, identify the limits and stay strictly within them. Similarly, there customarily are temporal limits that are appropriate in an investigation, either because the provider hired a key person or changed a protocol at a specific time, or because a limitations period governs the claim. Counsel should stay within those temporal limits, and disclose only information related to the issues arising therein.

J. Focus on "Selected Waiver" Considerations—As noted, this is an unsettled area of the law, and one in "hopeless confusion."[45] That is no excuse for counsel being unfamiliar with the governing law in the jurisdiction in which the provider operates, and for ensuring that all necessary steps are taken to maximize the chance that privilege is preserved to the maximum extent possible, and that the effect of any waiver be limited.

K. Negotiate the Scope of Any Waiver Requested in a Settlement Context—The initial position taken by government attorneys in this area, not infrequently, is that the provider must agree to waive privilege as a precondition to a settlement. While that is not an uncommon request, provider counsel should assess which areas may be particularly sensitive for the institution, in a given case, and negotiate toward a mutually acceptable compromise that serves the provider's needs as well as the government's.

L. Wear the White Hat—In this area, more than in any other, the ability to avoid overreaching demands for broad waivers depends upon the credibility of the provider and the provider's counsel. If the issue has been identified by the provider (as opposed to a whistleblower, the OIG, MFCU or CMS, for instance), greater latitude generally will be available to the provider in terms of what must be reviewed and disclosed. The qualitative nature of what is disclosed, moreover, and the thoroughness (or lack thereof) evident in the disclosure will affect significantly the provider's ability to negotiate effectively in this area.

Quite clearly, the particular facts will dictate the specific steps that counsel will need to (or be asked to) take. However, following the dozen tips suggested

above, the provider should be able to maximize its ability to create and preserve the attorney-client privilege in the areas most important to it.

Endnotes

1. This shopworn phrase finds particular application given the venue of an infamous, hopelessly misguided and overly aggressive prosecutorial effort targeting, among others, two Midwestern healthcare lawyers. *See United States v. Anderson*, 55 F. Supp. 2d 1163 (D. Kan. 1999); *see also United States v. Anderson*, 2004 WL 624966, *1, n.1 (D. Kan. Mar. 24, 2004).
2. *See, e.g., Swidler & Berlin v. United States,* 524 U.S. 399, 403, 118 S. Ct. 2081, 2084, 141 L. Ed. 2d 379 (1998); *In re Grand Jury Investigation*, 399 F.3d 527, 531 (2d Cir. 2005).
3. *Spectrum Sys. Intern. Corp. v. Chemical Bank*, 78 N.Y.2d 371, 377 (1991) (citing *In re Vanderbilt [Rosner—Hickey]*, 57 N.Y.2d 66, 76 (1982) and *In re Priest v. Hennessy*, 51 N.Y.2d 62, 67–68 (1980)); *see also* WIGMORE, EVIDENCE § 2290 (McNaughton rev. 1961) [WIGMORE].
4. *See Upjohn Co. v. United States,* 449 U.S. 383, 389, 101 S. Ct. 677, 682, 66 L. Ed. 2d 584 (1981) (the purpose of the attorney-client privilege is "to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice"); *United States v. Bilzerian,* 926 F.2d 1285, 1292 (2nd Cir. 1982) ("sound legal advice or advocacy serves the public ends and . . . such advice or advocacy depends on the lawyer's being fully informed by the client") (*quoting Upjohn*, 449 U.S. at 389, 101 S. Ct. at 682); *Priest*, 51 N.Y.2d at 68 (the privilege allows the client to "confide fully and freely" in his or her attorney, while remaining "secure in the knowledge that his confidences will not later be exposed to public view to his embarrassment or legal detriment"); *see generally* N.Y. JUR. EVIDENCE § 864.
5. *Upjohn,* 449 U.S. at 390–91, 101 S. Ct. at 683; *Rossi v. Blue Cross and Blue Shield of Greater New York,* 73 N.Y.2d 588, 592 (1989); *see generally* CPLR 4503.
6. *Campinas Foundation v. Simoni*, 2004 WL 2709850, *2 (S.D.N.Y. Nov. 23, 2004) (The privilege "permits a client to both refuse to disclose and prevent others from disclosing confidential communications between himself and his legal representative(s)[.]").
7. *See Priest*, 51 N.Y.2d at 68 (*citing In re Jacqueline F.*, 47 N.Y.2d 215, 219 (1979)). As the Second Circuit has commented, "the privilege stands in derogation of the public's right to every man's evidence," and therefore "ought to be strictly confined within the narrowest possible limits consistent with the logic of its principle." *In re Grand Jury Proceedings*, 219 F.3d 175, 182 (2nd Cir. 2000) (citations omitted).
8. *Id.*; *see also United States v. International Brotherhood of Teamsters,* 119 F.3d 210, 214 (2nd Cir. 1997); *Rossi,* 73 N.Y.2d at 593; *People v. O'Connor*, 85 A.D.2d 92, 94–94 (4th Dept. 1982); WIGMORE § 2291.
9. *Women's InterArt Ctr., Inc. v. NYC Economic Dev.*, 223 F.R.D. 156, 159–60 (S.D.N.Y. 2004) ("Under the attorney-client privilege, it is the communication between the client and the attorney, that is protected, not the underlying facts"); *accord, WLIG-TV, Inc. v. Cablevision Sys. Corp.*, 879 F. Supp. 229, 233 (E.D.N.Y. 1994); *Niesig v. Team I*, 76 N.Y.2d 363, 372 (1990). *See also Woman's IntArart,* 223 F.R.D. at 160 (*citing In re Grand Jury Subpoena Duces Tecum Dated September 15, 1983,* 731 F.2d 1032, 1037 (2nd Cir. 1984) (noting that the privilege applies only to communications for legal, not business, advice)).
10. *See Priest*, 51 N.Y.2d at 68; *National Educ. Training Group, Inc. v. Skillsoft Corp.*, 1999 WL 378337, *4 (S.D.N.Y. Jun. 10, 1997).
11. *Doe v. Poe*, 92 N.Y.2d 864 (1998); *see generally United States v. United Shoe Mach. Corp.,* 89 F. Supp. 357, 358–59 (D. Mass. 1950).
12. *See Spectrum Sys. Intern. Corp. v. Chemical Bank,* 78 N.Y.2d 371, 372 ("the burden of establishing any right to protection is on the party asserting it; the protection claimed must be narrowly construed; and its application must be consistent with the purpose underlying the immunity") (*citing Priest,* 51 N.Y.2d at 62, 69; *In re Jacqueline F.,* 47 N.Y.2d at 218–19 and *Koump v. Smith,* 25 N.Y.2d 287, 294 (1969)); *accord, Sackman v. Liggett Group, Inc.,* 920 F. Supp. 357, 364 (E.D.N.Y. 1996).
13. "Except as otherwise required by the Constitution of the United States or provided by Act of Congress . . . the privilege of a witness . . . shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience. However, in civil actions . . . as to which State law supplies the rule of decision, the privilege of a witness . . . shall be determined in accordance with State law." Fed. R. Evid. 501; *see also United States v. Goldberger & Dubin, P.C.,* 935 F.2d 501, 505 (2nd Cir. 1991) (applying federal common law of privilege to case alleging violation of federal law); *California Union Ins. Co. v. National Union Fire Ins. Co.,* 1989 WL 48413, *1 (N.D.N.Y. Apr. 27, 1989) (applying New York privilege law in a diversity action).
14. *Spectrum Sys.,* 157 A.D.2d at 447, 448, *modified* 78 N.Y.2d 371 (1991); *see also B.C.F. Oil Refining, Inc. v. Consolidated Ed. Co. of New York,* 168 F.R.D. 161, 165 (S.D.N.Y. 1996) ("the attorney-client privilege simply does not extend to facts known to a party that are central to that party's claims, even if such facts came to be known through communication with counsel who had obtained knowledge of those facts through an investigation into the underlying dispute"); *New York Times Newspaper Div. of New York Times Co. v. Lehrer McGovern Bovis, Inc.,* 300 A.D.2d 169, 171–72 (1st Dept. 2002) (report to counsel analyzing potential claims against client held to be privileged; the court, reversing the finding that no privilege had attached, considered as a factor the oral request by counsel for the report).
15. *Spectrum Sys.,* 78 N.Y.2d at 378.
16. *Id.* at 379 (*citing People v. Belge,* 59 A.D.2d 307, 308–09 (4th Dept. 1977)).
17. *See, e.g., Rossi v. Blue Cross and Blue Shield of Greater New York,* 73 N.Y.2d 588, 592–93 (1989) ("unlike the situation where a client individually engages a lawyer in a particular matter, staff attorneys may serve as company officers, with mixed business-legal responsibility; whether or not officers, their day-to-day involvement in their employers' affairs may blur the line between legal and non-legal communications; and their advice may originate not in response to the client's consultation about a particular problem but with them, as part of an ongoing, permanent relationship with the organization"); *see also ABBKent-Taylor, Inc. v. Stallings & Co.,* 172 F.R.D. 53, 55 (W.D.N.Y. 1996) ("Privilege issues with respect to communications between in-house corporate counsel and the corporate client have proven to generate thorny discovery and disclosure problems for the courts").
18. *See Rossi,* 73 N.Y.2d at 593 (the "mere participation of an attorney" cannot be used to "seal off disclosure"); *see also 40 Gardenville LLC v. Travelers Prop. Cas.,* 2004 WL 1055821, *3 (W.D.N.Y. April 22, 2004); *Aetna Cas. & Sur. Co. v. Certain Underwriters at Lloyd's London,* 176 Misc. 2d 605, 608–609 (Sup. Ct. New York Cty. 1998).

19. *California Union Ins. Co. v. Nat'l Union Fire Ins. Co.*, 1989 WL 48413,*2 (N.D.N.Y. Apr. 27, 1989) ("The corporate attorney-client privilege is not available to allow a corporation to funnel its papers and documents into the hands of its lawyers for custodial purposes and thereby avoid disclosure. . . . This Court finds that the attorney-client privilege is not available merely by stamping a document that was contained by an attorney, which contains solely business advice, 'PRIVILEGED AND CONFIDENTIAL,' 'Advice of Counsel'"); *see also Spectrum Systems*, 78 N.Y.2d at 381.

20. The narrowest interpretation of the attorney-client privilege refuses to protect a legal opinion or advice given *by* the lawyer *to* a client if the communication would not reveal client confidences. *See Natta v. Hogan*, 392 F.2d 686, 692–93 (10th Cir. 1968). While this overly restrictive application is not favored in the majority of jurisdictions, including New York, even under the so-called "broad" view communications running *between* the lawyer and client are protected only if related to the giving or receiving of professional advice. *See generally Rossi*, 73 N.Y.2d at 592 ("while the cases largely concern communications by clients to their attorneys, CPLR 4503 speaks of communications between the attorney and the client and the privilege thus plainly extending as well to the attorney's own communications to the client") (internal citations omitted).

21. Certain investigator's work, where it reveals the thought processes or trial strategy of counsel, can be protected under the attorney-work product doctrine, but that protection is qualified and this privilege is narrowly construed in New York. *See, e.g., Klinge v. State*, 302 A.D.2d 667, 670 (3rd Dept. 2003); *Salzer v. Farm Family Life Ins. Co.*, 280 A.D.2d 844, 846 (3rd Dept. 2001); *Zimmerman v. Nassau Hosp.*, 76 A.D.2d 921 (2nd Dept. 1980).

22. *See Upjohn*, 449 U.S. at 395–96; *Kenford Co, Inc. v. County of Erie*, 55 A.D.2d 466, 469 (4th Dept. 1977).

23. *See* J. Kane and D. Bucci, *Elements of the Attorney Client Privilege*, 32 SPG Brief 12,*4 (Spring 2003).

24. *Doe v. Poe*, 92 N.Y.2d 864, 867 (1998) ("Communications between a client and an attorney made in the presence of third parties are not privileged"); *Britton v. Lorenz*, 45 N.Y. 51 (1871); *Occidental Chem. Corp. v. OHM Remediation Servs. Corp.*, 175 F.R.D. 431, 436-37 (W.D.N.Y. 1997).

25. *Doe v. Poe*, 92 N.Y.2d at 867.

26. *United States Postal Serv. v. Phelps Dodge Refining Corp.*, 852 F. Supp. 156, 160–61 (E.D.N.Y. 1994); *see also Occidental Chem.*, 175 F.R.D. at 436–37. *See generally United States v. Kovel*, 296 F.2d 918 (2nd Cir. 1961).

27. *See, e.g., Carter v. Cornell Univ.*, 159 F.3d 1345 (2nd Cir. 1998).

28. Statements made by a client to the employees of the lawyer are privileged. *See People v. Osorio*, 75 N.Y.2d 80 (1989). Also, the presence of an agent or employee of the client does not waive the privilege. *See, e.g., Kovel*, 296 F.2d at 921–22 (presence of translators and accountants will not waive the privilege); *In re Grand Jury Subpoenas Dated March 9, 2001*, 179 F. Supp. 2d 270, 283 (S.D.N.Y. 2001); *Bowne of New York City, Inc. v. AmBase Corp.*, 161 F.R.D. 258 (S.D.N.Y. 1995); *Bruce v. Christian*, 113 F.R.D. 554 (S.D.N.Y. 1986).

29. *People v. Harris*, 57 N.Y.2d 335, 342–43 (1982).

30. *In re Lupron Marketing and Sales Practices Litigation*, 313 F. Supp. 2d 8, 9–10 (D. Mass. 2004) (*citing United States v. Massachusetts Inst. of Tech.*, 129 F.3d 681 (1st Cir. 1997)).

31. *See* text note 28, *supra.*

32. CPLR 4503(a)(1).

33. Here, the lawyer's ethical duty to keep confidential all client secrets overlaps with the evidentiary rule of privilege. In New York, the lawyer's ethical obligation is codified at 22 N.Y.C.R.R. 1200.19 (DR 4-101) and permits disclosure by the lawyer of a client's secrets and confidences, for example, where it is necessary to collect the lawyer's fee, when the lawyer has been accused of wrongdoing, to prevent the commission of a future crime and when it is "implicit in withdrawing a written or oral opinion or representation previously given by the lawyer." *Id.*; *see, e.g., Nesenoff v. Dinerstein & Lesser, P.C.*, 12 A.D.3d 427 (2nd Dept. 2004) (attorneys permitted to disclose confidential information about former clients where the attorneys were accused of wrongful conduct); *People v. DePallo*, 275 A.D.2d 60 (2nd Dept. 2000) (attorney not sanctioned for revealing to the court client's intention to commit perjury).

34. *See United States v. Schwimmer*, 892 F.2d 237, 243 (2nd Cir. 1989); *Campinas Foundation v. Simoni*, 2004 WL 2709850, *2 (S.D.N.Y., Nov. 23, 2004); *Aetna Cas. and Sur. Co. v. Certain Underwriters and Lloyd's London*, 176 Misc. 2d 605, 611–12 (Sup. Ct. New York Cty. 1998).

35. *Compare MIT*, 129 F.3d 681, 684–86; *In re Steinhardt Partners*, 9 F.3d 230, 234–35 (2nd Cir. 1993); *and In re Columbia/HCA Healthcare Corp. Billing Practices Lit.*, 293 F.3d 289, 293–303 (6th Cir. 2002) (collecting cases in area of the law deemed to be in "hopeless confusion") *with Diversified Ind. v. Meredith*, 572 F.2d 596 (8th Cir. 1978) (*en banc*). *See generally* Ashok M. Pinto, *Cooperation and Self-Interest are Strange Bedfellows: Limited Waiver of the Attorney-Client Privilege Through Production of Privileged Documents in a Government Investigation*, 106 WEST VA. L. REV. 359 (Winter 2004).

36. 70 Fed. Reg. 4858 (Jan. 31, 2005).

37. *Id.* at 4876.

38. 63 Fed. Reg. 58399 (Oct. 30, 1999).

39. *See, e.g., Memorandum from Deputy Attorney General Larry D. Thompson: Principles of Federal Prosecution of Business Organizations* (Jan. 20, 2003), *available at* http://www.usdoj.gov/dag/cftf/business_organizations.pdf.

40. *See, e.g., Carter v. Cornell Univ.*, 159 F.3d 1345 (2nd Cir. 1998).

41. *See* Issue E, *infra.*

42. *See, e.g., Commodity Futures Trading Comm'n v. Weintraub*, 471 U.S. 343, 348-49, 105 S. Ct. 1986, 1990–91 (1986).

43. *See, e.g., Jonathan Corp. v. Prime Computer, Inc.*, 114 F.R.D. 693 (E.D.Va. 1987).

44. *See United States v. Kovel*, 296 F.2d 918 (2nd Cir. 1961).

45. *See* note 35, *supra.*

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Legislation Report: In Support of The Family Health Care Decisions Act

NYSBA Health Law Section

May 20, 2005

A.5406 By Assemblyman Gottfried et al.

S.4296 By Senator Seward

AN ACT to amend the public health law, in relation to establishing procedures for making medical treatment decisions on behalf of persons who lack the capacity to decide about treatment for themselves and to repeal certain provisions of such law relating thereto

LAW AND SECTION REFERRED TO: Public Health Law, Article 29-C
REPORT PREPARED BY THE HEALTH LAW SECTION

THE BILL IS APPROVED

The Health Law Section hereby restates its support of the Family Health Care Decisions Act. We previously wrote in support of this proposal in 1995, 1997 and 2000. As we stated in 1997:

> Existing law imposes needless suffering on dying patients and their families by requiring the provision of treatment that runs contrary to the patient's wishes and best interest. New York is among a handful of states in the nation that continues to deny family members and others close to the patient the authority to forgo life-sustaining measures for incapable patients in accord with appropriate safeguards. Or laws on this matter are unreasonable and unsound.

Much has changed in health care in recent years, but New York's rule on end-of-life care, unfortunately, has remained in place. We urge the Legislature to finally recognize the harshness of that rule, and to replace it with the more reasonable, more humane and more respectful principles set forth in the Family Health Care Decisions Act.

For the foregoing reason, this bill is APPROVED.

Chair of the Section: Philip Rosenberg. Esq.

Legislation Report: In Support of Kendra's Law

NYSBA Health Law Section

May 20, 2005

S.3664, Governor's Program Bill No. 40

By: Senator Morahan
Committee: Mental Health and Developmental Disabilities
Effective Date: Immediately
Status: Referred to Committee 03/25/05

S.3903, Attorney General's Program Bill No. 5

By: Senators Morahan and Padavan
Committee: Mental Health and Developmental Disabilities b
Effective Date: June 30, 2005
Status: Referred to Committee 04/01/05

PURPOSE:

Both bills would eliminate the June 30, 2005 expiration date of Chapter 408 of the Laws of 1999, known as **"Kendra's Law."** S.3664, the "Governor's bill," eliminates the expiration and repeal of Kendra's Law and makes no other changes in the law. S.3903, the "Attorney General's bill," also would make the law permanent but also would make changes in the existing law.

SUMMARY OF PROVISIONS:

S.3664

AN ACT to amend chapter 408 of the laws of 1999 amending the mental hygiene law relating to enhancing the supervision and coordination of care of persons with mental illness in community-based settings by providing assisted outpatient treatment, in relation to the effectiveness thereof.

Section 1 of the bill would amend Chapter 408 of the Laws of 1999 to eliminate the June 30, 2005 expiration date and related language.

S.3903

AN ACT to amend the mental hygiene law, in relation to improving the functionality of assisted outpatient treatment hearings and programs and to amend chapter 408 of the laws of 1999 amending the mental hygiene law relating to enhancing the supervision and coordination of care of persons with mental illness in community-based settings by providing assisted outpatient treatment, in relation to making permanent the provisions thereof.

LAW AND SECTIONS REFERRED TO:

Mental Hygiene Law, Section 9.60;
Laws of 1999, Section 18 of chapter 408

KENDRA'S LAW SHOULD BE MADE PERMANENT AND SERIOUS INDEPENDENT STUDY MADE OF ISSUES RAISED

Existing Law

New York State recently enacted legislation that provides for assisted outpatient treatment for certain people with mental illness who, in view of their treatment history and present circumstances, are unlikely to survive safely in the community without supervision. This new law is commonly referred to as "Kendra's Law" and is set forth in Section 9.60 of the Mental Hygiene Law (MHL). It was named after Kendra Webdale, a young woman who died in January 1999 after being pushed in front of a New York City subway train by a person whose mental illness was inadequately treated.

Overview of Assisted Outpatient Treatment

Kendra's Law establishes a procedure for obtaining court orders for certain individuals with mental illness to receive and accept outpatient treatment. The prescribed treatment is set forth in a written treatment plan prepared by a physician who has examined the individual. The procedure involves a hearing in which all the evidence, including testimony from the physician, and, if desired, from the person alleged to need treatment, is presented to the court. If the court determines by clear and convincing evidence that the individual meets the criteria for assisted outpatient treatment ("AOT"), an order is issued to either the director of a hospital licensed or operated by the Office of Mental Health ("OMH"), or to a director of community services who oversees the mental health program of a locality (i.e., the county or the City of New York mental health director). The court orders require the appropriate director to provide or arrange for those services described in the

written treatment plan which the court finds necessary. The initial order is effective for up to 6 months and can be extended for successive periods of up to one year. The legislation also establishes a procedure for admission to an inpatient setting in cases where the patient fails to comply with the ordered treatment and poses a risk of harm.

The legislation also requires the Office of Mental Health to designate "program coordinators" who are responsible for monitoring and overseeing AOT programs. Hospitals licensed or operated by OMH are authorized (but not required) to operate AOT programs; county directors of community services are required to operate AOT programs, either separately or jointly with other counties. The directors of local assisted outpatient treatment programs report to the program coordinators regarding the operation of their AOT programs and also supply the program coordinators with information on every assisted outpatient treatment order. All AOT programs must be approved by the Commissioner of Mental Health.

Petitioners

The process for issuance of assisted outpatient treatment orders begins with the filing of a petition in the supreme or county court where the person alleged to be mentally ill and in need of AOT is present (or is believed to be present). The following may act as petitioners:

- an adult (18 years or older) roommate of the person;
- a parent, spouse, adult child or adult sibling of the person;
- the director of a hospital where the person is hospitalized;
- the director of a public or charitable organization, agency or home that provides mental health services and in whose institution the person resides;
- a qualified psychiatrist who is either treating the person or supervising the treatment of the person for mental illness;
- the director of community services, or social services official of the city or county where the person is present or is reasonably believed to be present; or
- a parole officer or probation officer assigned to supervise the person.

The petition must show that the subject of the petition meets the criteria for AOT and must be supported by a sworn statement of a physician who has examined the person within the last 10 days attesting to the need for AOT. The required physician's affidavit may state in the alternative that unsuccessful attempts were made in the past ten days to obtain the consent of the person for an examination, and that the physician believes AOT is warranted. In the latter case, the court may request the person to consent to examination. If the person refuses and the court finds reasonable cause to believe the allegations in the petition are true, the court may order peace officers or police officers to take the person into custody for transport to a hospital for examination by a physician. Any such retention shall not exceed twenty-four hours.

AOT Eligibility

No person may be placed under an AOT order unless the court finds by clear and convincing evidence that the subject of the petition meets all of the following criteria:

- is at least 18 years old; and
- is suffering from a mental illness; and
- is unlikely to survive safely in the community without supervision, based on a clinical determination; and
- has a history of lack of compliance with treatment for mental illness that has: (a) at least twice within the last 36 months been a significant factor in necessitating hospitalization or receipt of services in a forensic or other mental health unit in a correctional facility or local correctional facility (not including any period during which the person was hospitalized or incarcerated immediately preceding the filing of the petition), or (b) resulted in one or more acts of serious violent behavior toward self or others, or threats of or attempts at serious physical harm to self or others within the last 48 months (not including any period in which the person was hospitalized or incarcerated immediately preceding the filing of the petition); and
- is, as a result of his or her mental illness, unlikely to voluntarily participate in the recommended treatment pursuant to the treatment plan; and
- in view of his or her treatment history and current behavior, the person is in need of assisted outpatient treatment in order to prevent a relapse or deterioration which would be likely to result in serious harm to self or others as defined in § 9.01 of the Mental Hygiene Law; and
- it is likely that the person will benefit from assisted outpatient treatment; and
- if the person has executed a health care proxy as defined in Article 29-C of the Public Health Law, that any directions included in such proxy shall be taken into account by the court in determining the written treatment plan.

A court may not issue an AOT order unless it finds that assisted outpatient treatment is the least restrictive alternative available for the person.

Service of the Notice and Petition

Notice of the petition must be served on a number of people or entities, including the person, his or her nearest relative, the Mental Hygiene Legal Services ("MHLS"), the AOT program coordinator appointed by OMH, any health care agent appointed in a proxy executed by the person, and the appropriate AOT program director.

The Court Hearing

Upon receipt of the petition, the court is required to set a hearing date that is no more than 3 days later, although adjournments can be granted for good cause. The examining physician must testify at the hearing and must state the facts and rationale supporting the need for AOT as well as the conclusion that such treatment is the least restrictive alternative. The subject of the petition has the right to legal representation by Mental Hygiene Legal Services, or by other counsel at the subject's expense, and at all stages of the proceeding. The person may also testify (but is not required to do so), and he or she may call witnesses and examine any adverse witnesses. A proposed written treatment plan must also be furnished to the court before an order for AOT will be issued. If the petitioner is a director of community services or a director of a hospital operating an AOT program, the treatment plan is required to be provided to the court by the date of the hearing. If the patient has previously refused to be examined, the court may order officers to take the person into custody for transport to a hospital for examination.

Written Treatment Plan

The treatment plan submitted to the court is prepared by an examining physician appointed by the local director of community services (or the director of a hospital with an approved AOT program). The examining physician must permit the person, his or her treating physician, and, if requested by the person, a relative, close friend or other concerned individual to actively participate in the development of the treatment plan. The treatment plan must include case management or assertive community treatment ("ACT") team services to provide care coordination. It will also set forth the other categories of services recommended by the examining physician. If the plan includes alcohol or substance abuse counseling, then it may include a provision for relevant testing for alcohol or illegal substances. Such testing may be recommended only if the physician's clinical basis for the recommendation shows facts sufficient for the court to find that (1) the person has a history of alcohol or substance abuse that is clinically related to his or her mental illness, and (2) the testing is necessary to prevent a relapse or deterioration which would likely result in serious harm to the person or others.

A physician (not necessarily the same one who testifies regarding the satisfaction of the AOT criteria) must also explain the treatment plan in testimony to the court demonstrating that the proposed treatment is the least restrictive alternative. If the treatment plan includes a recommendation for medication, the testimony must include the types or classes of medication recommended, the beneficial and detrimental physical and mental effects of the medication, and whether the medication should be self-administered or administered by authorized professionals.

Disposition of the Proceeding

If the court concludes that all the criteria for AOT are not met, the petition must be dismissed. If, however, the court finds by clear and convincing evidence that the subject of the petition meets the criteria and a written treatment plan has been filed, the court may order the subject to receive assisted outpatient treatment. If the treatment plan and testimony explaining it have not been provided to the court by the time of such a finding, the court will issue an order to the appropriate director of community services to provide the written treatment plan and testimony within 3 business days.

The initial assisted outpatient treatment order may extend for a period of up to 6 months. The order must specifically state findings that the proposed treatment is the least restrictive treatment that is appropriate and feasible, and must state the categories of treatment required. No treatment may be ordered unless it is recommended by the examining physician and included in the written treatment plan. The order must also require the appropriate director (either a hospital director or the local director of community services) to provide or arrange for the services described in the order.

The initial order can be extended for additional successive periods of up to one year. The same procedure used to commence the proceeding is used to secure an order for extension. Appeals of AOT orders are taken in the same manner as specified in MHL § 9.35 relating to retention orders.

Failure to Comply with AOT Order

If in the clinical judgment of a physician the assisted outpatient has failed or refused to comply with the treatment ordered by the court and may be in need of involuntary admission to a hospital, the physician may request the director of community services, his designee, or other physician designated under § 9.37 of

the MHL to arrange for the transport of the patient to a hospital. If requested, peace officers, police officers or members of an approved mobile crisis outreach team shall take the patient into custody for transport to the hospital. An ambulance service may also be used to transport the patient. There the patient can be held for up to 72 hours for care, observation and treatment and to permit a physician to determine whether involuntary admission under the standards set forth in Article 9 of the MHL is warranted.

Other Provisions of Kendra's Law

A. Grants for Medication Programs

Note: It is important to mention that the population targeted by this medication grant program may be quite different from the group of individuals who potentially qualify for assisted outpatient treatment. While there will likely be some overlap, the eligibility requirements for individuals under the grant program are substantially different from the eligibility criteria for assisted outpatient treatment under § 9.60(c) of the MHL.

Kendra's Law also addresses the need to ensure that people with mental illness who are transitioning from hospitals or correctional facilities to the community receive necessary psychiatric medications without interruption. To this end, the legislation establishes a grant program administered by OMH (effective April 1, 2000) that provides funding to localities for medications to treat mental illness, and the services necessary to prescribe and administer such medications, during the period that an individual's eligibility for medical assistance is being determined. Grants may be used to provide medications and such related services to individuals for whom the process of applying for medical assistance has commenced within one week after discharge or release, and who have either:

1. been discharged from a hospital as defined in § 1.03 of the MHL; or
2. been released from a correctional facility or local correctional facility and have received services from or in a forensic or similar mental health unit of such a facility.

The grants available under the legislation are subject to the approval of the State Commissioner of Mental Health based on a plan by the locality explaining:

1. the process for improving the timeliness of filing medical assistance applications for the individuals who will receive such medications;
2. the process by which such medications will be made available at or near the time of release or discharge;
3. the process by which these individuals will be referred to a city or county provider of medications or to a provider under contract with a locality to supply such medications; and
4. the process by which the Office of Mental Health will be provided information necessary to file medical assistance claims.

The program will also provide grants to assist localities in the development of the plans required to be furnished to the Commissioner of Mental Health. The grants may also assist in the preparation of plans to be used at local correctional facilities to improve coordination between individuals for whom the medications are targeted and providers of the medications, as well as to help such individuals in applying for medical assistance and other public benefits.

B. Termination of Conditional Release

The legislation also amends § 29.15 of the Mental Hygiene Law regarding the termination of conditional release for involuntary patients who leave State operated psychiatric centers. Conditional release may be used for these patients as a means of ending the inpatient period of service to them without ending the State facility's ties to the person under the MHL. The "conditions" usually involve the facility providing or arranging for services on an outpatient basis and the person agreeing to accept such services.

If a director of an OMH inpatient facility determines that conditional release is no longer appropriate, and a physician on the staff of the hospital determines that the conditionally released individual may have a mental illness and may be in need of involuntary hospitalization, the director may require the person to be retained for observation, care and treatment at a hospital for up to 72 hours. Any continued retention beyond this initial period will be in accordance with the provisions of the Mental Hygiene Law relating to involuntary admissions.

C. Information Sharing

The legislation also provides that clinical information on patients shall be available to mental health facilities throughout the State. Kendra's Law amends § 33.13 of the Mental Hygiene Law, the confidentiality provision, to clarify that OMH licensed or operated facilities may share confidential patient information (but only information that is necessary in light of the reason for disclosure).

Furthermore, upon prior approval of the Commissioner of OMH, general hospital emergency room services are permitted to share patient information with other hospital emergency room services, as well as with hospitals licensed or operated by OMH.

D. Planning for AOT Programs and High-Need Patients

Kendra's Law also requires each local governmental unit, as part of its local or unified services plan, to plan for the provision of services to individuals who may be included in an AOT program administered, supervised or operated by the locality. Furthermore, each local governmental unit is required under the legislation to plan for the provision of mental health services to "high-need patients" as that term is defined by the Commissioner of Mental Health.

Experience During the Five Year Trial Period

Since the law became effective in 1999, OMH has carefully tracked its implementation and impact on individuals who have been made subject to the law's provisions. Complying with the statute, OMH released an interim report in January 2003 and a final report in March 2005 which updated the interim report. The report presented findings on: (i) outcomes of AOT judicial proceedings, (ii) number of individuals who have received AOT, (iii) length of time individuals typically remain under court-ordered treatment, (iv) characteristics of AOT recipients, (v) outcomes for AOT recipients and (vi) opinions of AOT recipients about court-ordered treatment and its impact. The findings in each of those areas are summarized below:

(i) Through December 31, 2004, there were a total of 10,078 referrals/investigations of individuals out of a total state population of nearly 19 million.

(ii) From those referrals/investigations, petitions were filed for 4,041 individuals. Petitions were granted for 3,766 individuals. Of the 3,493 individuals whose court orders were eligible for renewal upon expiration of the initial period (almost always 6 months), 64%, or 2,236 were renewed. The two major reasons for non-renewal of orders were that the recipient was no longer in need of AOT (67%) or was re-hospitalized (10%).

(iii) Of the 3,766 individuals who have received AOT services, 36% spent 6 months under order and 64% remained under order for more than 6 months. The average length of time under court order for all recipients was 16 months.

(iv) Characteristics of AOT recipients included the following: the mean age was 37.5 years and 66% were male and 34% female. Black (non-Hispanic) individuals accounted for 42% of recipients, 34% white (non-Hispanic), 21% Hispanic, 2% Asian and 1% other ethnicity. Seventy-five percent were single/never married, 17% divorced/widowed and 8% were married or cohabitating with a significant other or domestic partner. Thirty-eight percent lived with others, 37% lived in supervised housing, 13% lived alone and 12% lived in some other arrangement. Schizophrenia was the diagnosis in 71% of recipients and 52% had a coexisting alcohol and/or substance abuse disorder.

(v) Outcomes for AOT recipients were substantial and positive: incarcerations during AOT order were reduced by 87% over the pre-AOT rates, arrest rates dropped 83%, psychiatric hospitalizations dropped by 77% and homelessness was reduced by 74%. Average days hospitalized were also significantly reduced, going from an average of 50 days prior to AOT, to 22 during AOT and, perhaps most significantly, dropping to 13 days after being in AOT. Services provided to recipients during AOT as compared to their pre-AOT rates increased dramatically: participation in case management services increased by 89%; medication management, individual or group therapy and day program participation each increased by 47%; substance abuse service participation increased by 65% and housing or housing support services use went up by 63%. Recipients' adherence to medication increased from 34% prior to AOT to 69% during AOT. Reduced incidence of harmful behaviors was also substantial, with self harm/attempted suicides reduced by 55%, alcohol abuse by 49%, drug abuse by 48% and physical harm to others reduced by 47%. AOT recipients also saw significant improvements in numerous measures of self help/community living; improvements in social, interpersonal and family functioning; and improvements in task performance.

(vi) The opinions of AOT recipients, based on a limited sample, were telling. Fifty-four percent were angry by the experience of court-ordered treatment and 53% were embarrassed by it. Yet 62% felt that, all things considered, court-ordered treatment had been a good thing for them and 90% said it made them more likely to keep appointments and take prescribed medications. Eighty-one percent said AOT helped them to get and stay well and 75% said it helped them gain control over their lives. Within the sample population, 88% said they agreed with their case manager on what is important for them to work on and 87% were confident in their case manager's ability to help them.

PROVISIONS OF S3903, "the Attorney General's Bill"

The following material is excerpted from the Attorney General's memorandum in support:

"PURPOSE:

This bill makes certain technical changes to "Kendra's Law" to ensure the proper implementation and administration of assisted outpatient treatment programs.

SUMMARY OF PROVISION:

This bill makes the following technical and other changes to "Kendra's Law":

- The bill expands the definition of "assisted outpatient treatment" [MHL § 9.60(a)(1)] to encompass the many patients who currently participate in AOT programs through voluntary agreements rather than court orders, and provides guidelines for such agreements under § 9.60(q).
- The bill adds a procedure under MHL § 9.60(*l*) for transferring a current AOT order to another county when the patient relocates.
- The bill adds accountability provisions to the current responsibility of counties to investigate reports of persons in need of AOT. Specifically, the bill requires counties to implement procedures to notify reporting persons of the results of investigations [MHL § 7.17(f)(2)], and adds oversight of the procedures for such investigations to the monitoring role of OMH program coordinators [MHL § 9.47(b)].
- MHL § 9.60(h)(4) currently requires a physician testifying on behalf of the petitioner at the initial hearing to state "the recommended assisted outpatient treatment," while other provisions of the statute require the petitioner to allege in the petition and prove at the initial hearing that the subject of the petition is unlikely to voluntarily participate in the treatment recommended "pursuant to the treatment plan." However, in the case of a private petitioner such as a family member, the treatment plan cannot yet exist at the time of the petition filing or initial hearing: under § 9.60(j)(3), the treatment plan is not developed until *after* the court finds the subject of the petition in need of AOT. The bill therefore amends § 9.60 to ensure that private petitioners will not be required to address the recommended treatment plan prior to the possible existence of such plan.
- In order to be eligible for AOT, MHL § 9.60(c)(4) requires that a person must either have been hospitalized twice within the prior 36 months or have had one violent incident within the past 48 months, not including any period of hospitalization "immediately preceding the filing of the petition." Unfortunately, this wording would appear to only exclude a period of hospitalization that "immediately" preceded the filing of the petition, and not one that ended prior to the filing of the petition, in counting back 36 or 48 months to identify the qualifying hospitalizations or incident. This bill therefore amends § 9.60(c)(4) to conform the statutory language to the intent of the Legislature. It makes clear that the look-back periods extend back to the subject of the petition's most recent 36 or 48 months spent outside of a hospital setting.
- The bill increases the maximum term for an initial AOT order under MHL § 9.60(j)(2), from six months to one year.
- The bill amends MHL § 9.60(k) to allow a private petitioner such as a family member to petition to renew an expiring AOT court order. Currently, only a director of community services may petition to renew, even if a private party was the petitioner for the original order.
- The bill eliminates the current requirement for unnecessary and wasteful hearings by amending MHL § 9.60(k) to permit the court to continue an AOT order without a hearing if the patient so agrees.
- MHL § 9.60(e)(1)(iv) currently permits an AOT petition by the director of a public or charitable organization only if the agency provides mental health services *and* shelter to the subject of the petition. Obviously, many organizations provide services but not shelter, and others provide shelter but not services. The bill amends § 9.60(e)(1)(iv) to permit all such organizations to file petitions.
- The bill amends MHL § 33.13 to ensure that directors of community services and patient attorneys will have access to hospital treatment records in investigating or challenging the need for AOT, and makes clear that parties with legal access to such records may present them to the court in support of an AOT petition.
- Finally, the bill improves the structure and readability of MHL § 9.60 by, *inter alia*: (1) moving the provision requiring consideration of a health care proxy in the formulation of an AOT plan from the subdivision stating eligibility criteria to that concerning development of the treatment plan; and (2) moving the provision governing the modification of a court-approved AOT plan from the subdivision entitled "Disposition" to that concerning petitions to stay, vacate or modify."

Hearings were held by the New York State Assembly on Kendra's Law on April 8, 2005 in New York City and on April 21, 2005, in Buffalo. A variety of views were presented.

Other organizations in addition to the Office of Mental Health have also monitored and reported on the experience of the existing law over its initial 5-year period, including advocacy organizations such as the National Alliance for the Mentally Ill of New York State which published a "white paper" report on "Assisted Outpatient Treatment Through Kendra's Law" in early March 2005. That report drew upon both the OMH reports and its own systematic interviews of 20 families across the State who have had first-hand experience with Kendra's Law involving members of their families. Family reactions ranged from relief and satisfaction to frustration over bureaucracy or inaction. The report endorses making Kendra's Law permanent but also identified some areas where the law could be improved. These areas of improvement fall generally into administrative and enforceability issues. Some of those recommendations are included in the Attorney General's bill.

Other groups have issued reports supportive of certain other changes in Kendra's Law as it pertains to providers of services, including the Association for Community Living. Still other groups have issued reports opposing Kendra's Law and calling for it to be allowed to sunset. The New York Lawyers for the Public Interest issued a report that alleges that the law is flawed in its implementation because it has been disproportionately applied to persons of color, including specifically African-Americans and Hispanics.

These various reports have sparked a debate over whether the individuals covered by Kendra's Law are "victims" whose personal liberties have been infringed or "beneficiaries" of a public program of enhanced mental health benefits and services. Almost all major stakeholders to the debate, however, agree that some consumers of mental health services in New York State are in need of enhanced access to services and that if Kendra's Law is extended, carefully crafted, independent and nonpartisan studies should be undertaken to examine those issues identified in the public debate.

New York is not alone on this subject. Nationwide, 42 states and the District of Columbia have similar laws allowing for assisted outpatient treatment, and 2 of the 8 states that do not are currently considering AOT legislation.

Conclusion

In conclusion, the NYSBA Health Law Section supports passage of legislation to make "Kendra's Law" permanent before the current law expires. The law has been positive in its effect on AOT recipients and its impact on public safety, and the Section has seen no evidence of its overuse, abuse or inappropriate use. However, enough concerns and questions have been raised by the various stakeholders during the hearing process to convince the Section that more careful and independent examination is warranted. Therefore, while calling for Kendra's Law to be made permanent, the Section recommends that such legislation include within it a specific requirement that an independent study of all relevant issues raised during the hearings be undertaken during a period of 3 to 5 years following re-enactment. The study may include recommendations for future amendment of the law.

Further, in approving this report, the Health Law Section Executive Committee added its view that the Legislature should consider the need to reimburse or compensate outside entities such as hospitals, that must bear the expense of AOT proceedings.

Chair of the Section: Philip Rosenberg, Esq.

REPORT WAS PREPARED BY THE COMMITTEE ON MENTAL HEALTH ISSUES
Co-Chairs of the Committee: Henry A. Dlugacz, Esq.[1] and J. David Seay, Esq.

1. **Please note:** Henry Dlugacz recused himself from all votes related to this Legislative Report.

Report and Recommendation of the Health Care Provider Committee on the External Appeals Law

The New York State Departments of Insurance and Health (the "Departments") consistently have interpreted New York's "external appeals" law (N.Y. Pub. Health Law § 4900; N.Y. Ins. Law § 4900) (the "Law") in a manner that limits the rights of health care providers to exercise external appeals, and they have adopted regulations and imposed administrative requirements regarding such appeals that are flatly inconsistent with the Law. These regulations and requirements are, however, consistent with the Departments' stated views that providers should not have a right to external appeal of managed care decisions, even though the Law clearly intended to provide such a right. We believe that the Law should be amended to clarify the rights of providers to pursue external appeals. At the end of this report, we provide suggested language for such amendments.

I. The External Appeals Law

The External Appeal Program grew out of New York's 1996 Managed Care Reform Act, specifically the Act's requirement that health plans have a utilization review process if medical necessity determinations are made. New York State (NYS) Ins. Dept. and NYS Dept. of Health (DOH) External Appeal Program Annual Report, July 1, 1999-June 30, 2000 ("1999-2000 Report"), at 2. Utilization review is a determination of the medical necessity of "health care services that have been provided, are being provided or are proposed to be provided to a patient, whether undertaken prior to, concurrent with or subsequent to the delivery of such services." N.Y. Pub. Health Law § 4900(8); N.Y. Ins. Law § 4900(h).

The External Appeal Program provides for appeal of utilization review determinations involving medical necessity or the experimental or investigational nature of the services. Coverage denials must first go through the health plan's internal appeal process, unless the health plan and patient jointly agree to waive the internal process. N.Y. Pub. Health Law § 4910(2); N.Y. Ins. Law § 4910(b). The party requesting the external appeal must do so within 45 days of receipt of the health plan's final adverse determination. N.Y. Pub. Health Law § 4914(2)(a); N.Y. Ins. Law § 4914(b)(1). The law was designed to "level the playing field" and assure patients and providers that they would have access to an independent external review of medical necessity, regardless of limitations otherwise placed on such rights by contract.

The Insurance Department is responsible for processing requests for external appeals. After determining whether the request is complete and obtaining further information from the requesting party, if necessary, the Insurance Department randomly assigns the request to one of three external appeal agents for review. There is a two-track system for expedited and standard appeals, with the agent having three days to issue a decision in expedited (concurrent review) cases (N.Y. Pub. Health Law § 4914(2)(c); N.Y. Ins. Law § 4914(b)(3)) and 30 days (plus five, if additional information is requested) in standard (retrospective review) cases. N.Y. Pub. Health Law § 4914(2)(b); N.Y. Ins. Law § 4914(b)(2). *See also* 1999-2000 Report, at 1.

The external appeal law allows three classes of people to request appeals: health plan enrollees, the designee of an enrollee, and, with respect to retrospective adverse determinations, an enrollee's health care provider. N.Y. Pub. Health Law § 4910(2); N.Y. Ins. Law § 4910(b).

A. What is "Retrospective" Utilization Review?

"Retrospective" utilization review, which triggers providers' appeal rights under the Law, is not defined as such in the Law. However, although the statute does not define concurrent or retrospective utilization review, it does distinguish between the review of "continued or extended health care services, or additional services for an enrollee undergoing a course of continued treatment" (N.Y. Pub. Health Law § 4903(3); N.Y. Ins. Law § 4903(3)) and review of "health care services which have been delivered." N.Y. Pub. Health Law § 4903(4); N.Y. Ins. Law § 4903(d). Utilization review is recognized to occur "prior to, concurrent with or subsequent to the delivery of . . . services. . . ." N.Y. Pub. Health Law § 4900(f); N.Y. Ins. Law § 4900(h). The Law's definition of utilization review plainly distinguishes between situations in which health care delivery is anticipated or pending and those in which health care services already have been received. The Law does not explicitly define a review that commences concurrently with a service delivery, but as to which the provider only receives a determination of non-payment subsequent to the delivery of such service. Nevertheless, we believe that such a determination is a "retrospective" review within the meaning and intent of the Law.

In "concurrent" review, a sick patient is waiting to receive care. The time frame is urgent, and the provider

has not yet taken a financial risk. The statute refers to "*a determination* involving continued or extended health care services, or additional services for an enrollee undergoing a course of continued treatment prescribed by a health care provider. . . ." (N.Y. Pub. Health Law § 4903(3) (emphasis added)); N.Y. Ins. Law § 4903(c). For these types of reviews, utilization review "*determinations*" must be made within one business day of receipt of the necessary information, and the enrollee's health care provider and the enrollee or designee notified of the decision by telephone and in writing. N.Y. Pub. Health Law § 4903(3); N.Y. Ins. Law § 4903(c). The Law further provides that if a decision is not reached, in the concurrent review context, the failure to review within one day may be deemed a denial permitting the patient to appeal. The focus is on a timely "determination," which allows appropriate planning by all parties. N.Y. Pub. Health Law § 4903(7); N.Y. Ins. Law § 4903(7).

In contrast to concurrent situations, in regard to retrospective review determinations, the patient has already received health care services. Thus, the time urgency is gone, and the provider has already rendered care in anticipation of being paid. The statute refers to "*a determination* involving health care services which have been delivered. . . ." N.Y. Pub. Health Law § 4903(4) (emphasis added); N.Y. Ins. Law § 4903(d). For these types of reviews, utilization review determinations must be made within 30 days of receipt of the necessary information. N.Y. Pub. Health Law § 4903(4); N.Y. Ins. Law § 4903(d). Allowing providers to appeal only from retrospective review determinations recognizes the legitimate claims of providers who have already borne the financial risk of treating patients (which applies in retrospective review situations), as opposed to concurrent review situations, where health care providers have not yet taken the risk.

B. Who May Be a Designee? When May a Designee be Designated?

Under the Law, health plan enrollees and their designees may appeal adverse determinations. N.Y. Pub. Health Law § 4910(2); N.Y. Ins. Law § 4910(b). (The statute does not specifically define "designee," but the accompanying regulations define a designee as "a person authorized in writing by an enrollee to assist . . . in obtaining access to health care services." 10 N.Y.C.R.R. § 98-2.2(c); 11 N.Y.C.R.R. § 410.2(d).) The Law neither places limitations on a designee's authority nor on the time when a designee may be so designated.

The 2001 Insurance Department Regulations

Unlike the Law, the regulatory scheme adopted by the Insurance Department limits the definition of "designee." The regulations state that "for the purpose of requesting an external appeal," a designee is "a person authorized in writing by an enrollee to assist such enrollee in obtaining access to health care services," but excludes an insured from authorizing a designee if the insured has already received health care services. 10 N.Y.C.R.R. § 98-2.2(c); 11 N.Y.C.R.R. § 410.2(d). We are advised that, historically, the Department of Insurance did not accept designations occurring prior to the delivery of the health care services (e.g., upon admission to the provider) and, given the prohibition on post-hoc designations, this practice effectively excluded health care providers, the designees most likely to be appointed after the enrollee has received health care services, from being designated.

Whereas the Law does not define concurrent and retrospective review as such, the regulations do define these terms. "Concurrent review" is defined as "an initial determination involving continued or extended health care services or additional services for an enrollee undergoing a course of continued treatment prescribed by a health care provider. . . ." 10 N.Y.C.R.R. § 98-2.2(h); 11 N.Y.C.R.R. § 410.2(i). In contrast, "retrospective adverse determination" is "a determination for which utilization review was initiated after health care services have been provided. . . ." 10 N.Y.C.R.R. § 98-2.2(h); 11 N.Y.C.R.R. § 410.2(i).

Unlike the Law, the regulations narrowly construe retrospective review, defining concurrent and retrospective review not in terms of the time frame for the *determination*, *i.e.*, before service provided versus after service provided, but rather in terms of when the review is done, regardless of the date of determination. According to the Departments, "Utilization Review may be concurrent even if the utilization review determination is rendered after health care services have been provided, depending upon when the necessary information is reviewed by the utilization review agent." 1999-2000 Report, at 32, citing N.Y. Pub. Health Law § 4903(3) and N.Y. Ins. Law § 4903(c). Thus, under the regulatory scheme, if "concurrent" review results in a post-treatment *determination*, providers could neither appeal on their own—because the review was not deemed "retrospective"—nor be designees—because the insured has already received the service.

The statute allows for health care providers to appeal retrospective adverse determinations without limitations. In contrast, the regulations specify that health care providers (as providers, rather than as enrollees' designees) can appeal such determinations only if they have obtained the signature of the *insured* on a form for external review requests to be developed by the Departments and a consent from the insured to the release of medical and treatment records for purpose of the external appeal. 10 N.Y.C.R.R. § 98-2.3(b); 11 N.Y.C.R.R. § 410.3(b).

II. The *HANYS v. Serio Case*

A. The Challenge

In May 2001, a group of not-for-profit health care trade associations, including the Healthcare Association of New York State, Western New York Health Care Association, Rochester Regional Hospital Association, Nassau-Suffolk Hospital Council, Iroquois Healthcare Alliance and Northern Metropolitan Hospital Association, joined by a consumer advocacy organization, Citizen Action of New York, commenced an Article 78 proceeding against the New York State Departments of Health and Insurance, seeking a judgment declaring null and void the regulations promulgated pursuant to the Law. 1998 N.Y. Laws Ch. 586: 10 N.Y.C.R.R. § 98-2 and 11 N.Y.C.R.R. § 410. The petitioners alleged that the regulations were beyond the authority of the respondents to promulgate, were arbitrary and capricious and were an abuse of respondents' discretion. The petitioners further contended that the regulations, in a number of significant instances, altered the statutory scheme of the Law.

The petitioners offered both broad legislative intent arguments to challenge the regulations as well as a number of focused challenges to specific elements of the regulations. In terms of the broad legislative intent arguments, the petitioners contended that the statute itself authorized the respondents to implement regulations in very specific instances. In this regard, the grant of rule-making power by the Legislature to the respondents was, petitioners argued, "very narrow and particularized in nature." Petitioners' Memorandum of Law, at 4.

One of the particular focused challenges in the Article 78 petition was directed to the respondents' definition of "retrospective adverse determination." As noted above, the applicable regulations at 10 N.Y.C.R.R. § 98-22(h) and 11 N.Y.C.R.R. § 410.2(i) define retrospective adverse determination as follows: "a determination for which utilization *review was initiated after health care services* have been provided." (Emphasis supplied.) Through this definition, petitioners argued that respondents improperly narrowed the statute, treating as "concurrent," and not retrospective, any external appeal where the review was initiated during the course of a patient's medical treatment, regardless of when the final adverse determination was made. The regulation, it was argued by petitioners, improperly focuses on the time the review was initiated rather than when the determination is made, which was the focus of the statute. The Departments, however, contend that "the definition of retrospective adverse determination is consistent with the distinction between preauthorization, concurrent and retrospective determinations currently in law. . . ." New York State (NYS) Ins. Dept. and NYS Dept. of Health (DOH) Report on External Appeals in New York, January 1, 2002–December 31, 2002 ("2002 Report"), at 60. Such practice of treating as concurrent, and not retrospective, any external appeal where the review was initiated during treatment, regardless of when the final adverse determination was made, has the effect of denying health care providers the right to an external appeal when the adverse determination is made after services have ended.

A second focused challenge of the Article 78 petition was addressed to the restrictive definition of "designee" in the implementing regulations. It was contended by petitioners that the definition of "designee" operated to prevent otherwise entitled enrollees, their designees and health care providers from exercising their statutory rights to external review of adverse determinations regarding health coverage. Where the statute is silent, the regulations provide that "[i]f the enrollee has already received health care services, a designee shall not be authorized for purposes of requesting an external appeal." 10 N.Y.C.R.R. § 98-22(c); 11 N.Y.C.R.R. § 410.2(d). According to the Departments, this limited definition "is necessary because there had been cases when a provider whose own application was rejected as ineligible because the utilization review determination was not retrospective, resubmitted the appeal as the patient's designee." 2002 Report, at 60.

It was stated that this provision effectively limits those instances in which an enrollee, for whatever reason, cannot or does not want to exercise the external appeal right himself, but instead needs a designee. In this regard, the petition charges that the regulation's designee restriction "has no basis in the statutory scheme," as the statute "does not provide any limitation on the authority of a designee." Petitioners' Memorandum of Law, at 8. Instead, under the statute, "[a]n enrollee, the enrollee's designee and, in connection with retrospective adverse determinations, an enrollee's health care provider, shall have the right to request an external appeal." N.Y. Pub. Health Law § 4910(2); N.Y. Ins. Law § 4910(b). The argument is that the Legislature granted the designee the right to act for the enrollee in any case in which the enrollee could act.

Petitioners also challenged the regulations at 10 N.Y.C.R.R. § 98-2.3(b) and 11 N.Y.C.R.R. § 410.3(b) that require enrollees to sign the request and consent to release of medical records for the health care provider to be eligible for the (retrospective) external appeal. The statute provided that "in connection with retrospective adverse determinations, an enrollee's health care provider shall have the right of external appeal," thereby placing no limitation on the provider's eligibility. *Id.*

B. The Decision

In a decision dated February 8, 2002, the Court, utilizing a rational basis standard of review, upheld the

regulatory definition of "retrospective adverse determination" as contained in the regulations. *Healthcare Association of New York State v. Gregory v. Serio*, Decision and Order Index No. 3133-01, RJI No. 0101ST1857 (New York State Supreme Court, Albany County, 2002). The Court also upheld the regulatory requirement that an individual provide a signed consent to the release of medical records. 10 N.Y.C.R.R. § 98-2.7(a)(3)(v); 11 N.Y.C.R.R. § 410.7(a)(3)(v). The Court opined that state agencies must be afforded a high degree of deference in promulgating regulations. Such regulations "will be upheld as valid if [they have] a rational basis, that is, if [they are] not unreasonable, arbitrary or capricious." Decision, at 4.

The Court held, however, that respondents acted improperly in their definition of "designee." The Court stated, "the definition appears to be drafted solely to restrict the right of an enrollee to appoint a designee." Decision, at 5. The Court found that the restriction both materially changed the statute and directly contradicted the Law as written. Neither party appealed the Court's decision, and the time to appeal has passed.

III. Implementation Issues

Despite the decision in the *Serio* case discussed above, in practice, the Insurance Department continues to interpret the regulations extremely narrowly in regard to retrospective appeals.

First, the Insurance Department continues to enforce its bizarre regulatory interpretation of retrospective review—*i.e.*, excluding from such definition those determinations based on reviews that commenced at or prior to the rendering of a service even where a determination and action of denial is not made or provided until after the service has been delivered. Moreover, such appeals continue to require the written consent of the insured, even though the statute does not mandate such consent, and the Departments appear to require that, at the time of the appeal, a letter be sent to the insured by the provider advising the insured of the appeal and the release of health information it requires.

In addition, in yet another example of a regulatory nullification of an otherwise plain statutory right recognized by the *Serio* court and anticipated by the regulations, we have been advised by providers that the Insurance Department has been unwilling to accept an insured's authorization of a provider as a designee and to the release of information made upon admission to the provider.

Officially, the Departments say that "providers *are* permitted to obtain this consent at the time of treatment so that the provider does not have to locate the patient after treatment has been rendered." (emphasis added) 2002 Report, at 61. Providers report, however, that in each instance in which a provider requests an external appeal as a patient's designee, the Insurance Department asks the patient to confirm the designation in writing to make sure that the patient has given informed consent and understands that the external appeal means that his or her medical record will be released to a third party (the external appeal agent). Consequently, even though providers have rendered services prior to a utilization review determination, and have obtained a designation from the patient to whom the services were rendered, they may not seek external review without such patient's contemporaneous consent. Representatives of the Insurance Department have told us that while nothing specifically prohibits a patient from designating a provider as designee upon admission to the provider, the Department has concerns about this type of designation in terms of whether the patient is truly giving an informed consent.

Three annual reports prepared by the Insurance and Health Departments (as required by the Law) provide critical insight into their narrow view of the statute. The Insurance Department has received over 5,000 requests for external appeals since July 1, 1999 when the external appeal program took effect. 2002 Report, at 9. The vast majority of the requests have been related to medical necessity determinations. 2002 Report, at 26.

Of the more than 5,000 requests, 2,971 were decided by the external appeal agent. 2002 Report, at 14. One thousand four hundred twenty-seven (1,427) of the requests were rejected, *i.e.*, not forwarded to an external appeal agent. *Id.* The main reason for the rejections was applicants' failure to provide missing information in the application. 2002 Report, at 15.

Fifty-one (51) of the rejections for the years 2001 and 2002 were due to the "ineligibility" of a provider making the request. 2002 Report, at 16. In their first annual report, the Departments reported that there were 74 rejections of provider requests and 47 determinations of provider requests. *See* unpaginated table, "Reasons for Rejection of External Appeal Applications July 1, 1999-June 30, 2000," following p. 19, 1999-2000 Report, at 32. Therefore, the rejection rate for provider requests in the program's first year was approximately 61%. A rejection rate for provider requests for the program's second and third years cannot be calculated based on the information provided by the Departments. It appears, however, that providers have not been able to benefit from the External Appeal Law, and it has not served as the fair and efficient dispute resolution forum it was intended to be.

In their first annual report, the Departments acknowledged that "questions have arisen as to when providers may request an external appeal on their own

behalf." 1999-2000 Report, at 32. Relying on the regulatory definition of retrospective adverse determination, the Departments rejected a proposal by providers to allow them to request appeals in cases where notification of an adverse determination is received after services are initiated. 1999-2000 Report, at 32. The Departments suggested that the focus should be on when the utilization review was conducted, not when the determination was rendered, supposedly because doing otherwise would eliminate the category of concurrent utilization review. *Id.* at 33. (Of course, the key to concurrent utilization review is concurrent *determinations*.) The Departments also expressed concern that providers' rights to external appeal not be expanded beyond the statute's intent. *Id.*

Similarly, the Departments have rejected requests from providers acting as their patients' designees. While acknowledging that "designee" is not defined in the statute, the Departments have concluded that the designee provision "was intended to enable the patient to designate a person to assist them [sic] in making an external appeal request in order to obtain access to health care services . . . not . . . to permit disputes between providers and health plans that were not based on upon a retrospective adverse determination to be subject to the external appeal process." 1999-2000 Report, at 33. This reflects a clear misunderstanding of the Law's intent, and ignores the Law's grant of authority for external appeals directly to providers in the case of retrospective review determinations, and its allowance of "designees" to pursue appeals on behalf of insured persons, without limiting the ability of providers, the likely designees, to be so designated.

The Departments expressed two concerns about provider appeals in their first year report. They contended that "broadening" the scope of provider appeals would shift focus of the external appeal program away from patients and would potentially increase premium costs since health plans are responsible for costs of external appeals, regardless of outcome. The Departments also suggested that payment dispute arbitration is an adequate forum for addressing provider disputes, which, they implied, involve solely payment issues. 1999-2000 Report, at 34. Again, this reflects the intent of the Departments of Health and Insurance to nullify the Law in its application to providers.

The Departments' reliance on arbitration as an adequate forum for addressing provider disputes is shortsighted. Arbitration is quite expensive, invariably requires counsel, and is often not a workable solution for individual coverage disputes. Arbitration is also a function of the provider's contract with the payor, and there is substantial variability in the parties' respective bargaining power. A statutory review process levels the playing field and assures efficiency and economy. Concerns regarding patient liability in the context of provider appeals could be resolved by requiring the provider to release the patient from liability if the provider pursues an appeal, whether in its own right or as a designee. The existence of this type of neutral and fair process would lead to better judgments at the outset.

IV. Conclusion and Recommendation

Health care providers appear to be the step-children of the implementation of the External Appeals Law. The Departments have made clear that they do not believe that providers should be able to use independent external review in accordance with the Law, presumably, because they may rely on contractual remedies. The Departments' insistence on maintaining the regulatory position that the timing of a utilization review determination (in advance of, simultaneously with, or subsequent to the service) is irrelevant for purposes of defining whether the review is concurrent or retrospective, as long as the review commenced prior to or simultaneously with the service, and their historical (and, perhaps, current) practice of requiring that the patient's designee authorization and consent to release of medical information be confirmed in writing after the denial of payment and contemporaneous with the appeal, are flatly inconsistent with the intent and purpose of the Law. It also defeats one of the Law's central purposes: affording an independent external appeal to providers who have rendered services, particularly before a utilization review determination was made, regardless of the contractual terms of the agreement with the managed care payor.

In this regard, the *Serio* court deferred to the Departments' judgment in their adoption of the regulation, and sustained the definition of retrospective review. We believe that in so holding, the court erred. (As a lower court decision, it is not binding on other courts, and, in any event, we believe it would not have been sustained on appeal.)

Moreover, the Departments' historical (and, perhaps, continuing) application of regulatory (*i.e.*, the restriction on when a provider can appeal by itself) and extra-regulatory (the practice of requiring a specific consent by the patient to the provider's appeal and to the release of information on a post-treatment designee appeal form) limitations on a provider's right to challenge a managed care denial reflects an admitted bias against such appeals that is both inexplicable and inconsistent with the statute.

While numerous bills dealing with external appeals have been proposed recently, none have passed. We strongly believe, however, that the Law should be amended to overrule these problematic regulations and practices. The Law should explicitly define a "retrospec-

tive adverse determination," from which a provider may appeal, to clarify that the classification is based on when the adverse determination is made, rather than when the utilization review process was initiated. "Retrospective adverse determination" should be defined as "review of an adverse determination made during or after the provision of health care services or treatment to an enrollee." Further, the Law should be amended specifically to allow patients to designate providers as designees for external appeals *at any time* without further approval, on the condition that providers release patients from financial liability.

Below is a marked copy of the Law with proposed changes as well as a copy of the Law as it stands presently.

NY CLS Pub Health § 4904 (2002)

§ 4904. Appeal of adverse determinations by utilization review agents

1. An enrollee, the enrollee's designee and, in connection with retrospective adverse determinations, an enrollee's health care provider may appeal an adverse determination rendered by a utilization review agent. *Retrospective adverse determinations are those determinations by a utilization review agent that are first conveyed to the provider after the services at issue have been rendered. An enrollee may appoint a designee and consent to the disclosure of health information as necessary for an appeal at any time (including upon admission to the provider) and such appointment shall remain valid unless revoked, and no further consent, approval or notice shall be required to effectuate such designation. If a provider appeals on its own behalf, or as an enrollee's designee, such appeal shall release the enrollee from any liability to that provider for the health care services, but such release shall not extend the obligation at issue in the appeal, and shall not extend to any third party payor who may be liable to pay for such services.*

(Proposed additions to statutory language are italicized.)

Health Care Provider Committee
Edward Kornreich, Chair
Health Law Section, New York State Bar Association

Mason v. Central Suffolk Hosp., 3 N.Y.3d 343 (2004) 786 N.Y.S.2d 413, 819 N.E.2d 1029 ***Roger Mason, Appellant v. Central Suffolk Hospital et al., Respondents***

No. 143.
Court of Appeals of the State of New York.
Argued October 12, 2004.
Decided November 18, 2004.

Appeal, by permission of the Court of Appeals, from an order of the Appellate Division of the Supreme Court in the Second Judicial Department, entered May 19, 2003. The Appellate Division reversed, on the law, so much of an order of the Supreme Court, Suffolk County (Robert W. Doyle, J.), as had denied defendants' motion pursuant to CPLR 3211 (a)(7) to dismiss the complaint for failure to state a cause of action, (2) granted the motion, and (3) dismissed the complaint. *Mason v. Central Suffolk Hosp.*, 305 A.D.2d 556, affirmed. Robert G. Spevack, New York City, and Michael P. Barnes for appellant.

Michael S. Cohen, James Fabian and Christopher J. Porzio of counsel, for respondents.

Chief Judge KAYE and Judges G.B. SMITH, CIPARICK, ROSENBLATT, GRAFFEO and READ concur.

OPINION OF THE COURT R.S. SMITH, J.

In *Gelbard v. Genesee Hosp.* (87 N.Y.2d 691, 698 [1996]), we left open the question "whether a breach of contract action can be predicated on a violation of medical staff by-laws." We now answer that question in part, holding that no action for damages may be based on a violation of medical staff by-laws, unless clear language in the by-laws creates a right to that relief.

Facts

Doctor Roger Mason was a member of the medical staff of Central Suffolk Hospital and a specialist in laparoscopic surgery (surgery performed by means of a narrow tube called a laparoscope inserted through the abdominal wall). On February 3, 1998, the Hospital suspended Dr. Mason's privileges to perform "advanced" laparoscopic procedures, and required him to obtain a concurring second opinion before performing certain other kinds of surgery. The Hospital based its decision on a review of Dr. Mason's cases by another doctor, who reported that in some of those cases Dr. Mason's skills and judgment appeared to be flawed, and that his failings may have caused patients to be injured.

Dr. Mason sought internal review of this decision pursuant to the Hospital's by-laws. Lengthy proceedings followed, with the net result that the Hospital found the initial suspension to be justified; discontinued the requirement for a second opinion, but required a period of monitoring of certain procedures; and provided for reinstatement of Dr. Mason's advanced laparoscopic surgery privileges on certain conditions. Dr. Mason then complained to the Public Health Council of the Department of Health, pursuant to Public Health Law 2801-b. The Public Health Council rejected his complaint.

After the Public Health Council's ruling, Dr. Mason brought this action against the Hospital and Dr. Jon Zelen, a former employee of Dr. Mason's surgical practice group who had left before February 1998 to form a competing group. Dr. Mason alleged that Dr. Zelen had stood to gain from restrictions being placed on Dr. Mason's privileges, and that he had therefore made false accusations and stirred up an unwarranted investigation by the Hospital. Dr. Mason claimed that the Hospital's by-laws were a contract between him and the Hospital, and that the Hospital breached that contract by failing to follow the procedures the by-laws required and by suspending him "without legitimate cause." He sought damages from the Hospital for breach of contract, and from Dr. Zelen for inducing the breach.

Defendants' motion to dismiss the complaint for failure to state a cause of action was denied by Supreme Court. The Appellate Division reversed and ordered the complaint dismissed. We now affirm the Appellate Division's order.

Discussion

A number of our cases reject claims by doctors complaining of the denial of hospital privileges. One of these was *Leider v. Beth Israel Hosp. Assn.* (11 N.Y.2d 205, 208 [1962]), in which we held "that the plaintiff, a surgeon, has no vested right to the use of the hospital's facilities for the care and treatment of his private patients." In *Guibor v. Manhattan Eye, Ear and Throat Hosp., Inc.* (46 N.Y.2d 736, 737 [1978]), we cited *Leider* for the broad proposition that "(a)t common law, absent a contractual obligation to the contrary, a physician's continued professional association with a private hospital was within the unfettered discretion of the hospital's administrators."

We noted in *Guibor* that "this seemingly harsh common-rule" had been "tempered" by the enactment of Public Health Law 2801-b. The statute provides that it "shall be an improper practice" for a hospital's governing body to "curtail, terminate or diminish in any way a physician's . . .

professional privileges in a hospital, without stating the reasons therefor, or if the reasons stated are unrelated to standards of patient care, patient welfare, the objectives of the institution or the character or competency of the applicant" (§ 2801-b[1]). It also provides that any person "claiming to be aggrieved by an improper practice as defined in this section" can make a complaint to the Public Health Council, which, if it upholds the complaint, shall direct the hospital's governing body to review its actions (§ 2801-b[2],[3]); and that the statute's provisions "shall not be deemed to impair or affect any other right or remedy" (§ 2801-b[4]). Public Health Law 2801-c provides that Supreme Court "may enjoin violations or threatened violations of any provisions of this article." In *Guibor*, we held that an action seeking an injunction under § 2801-c was premature where the doctor had not first presented his claim to the Public Health Council.

In *Gelbard v. Genesee Hosp.* (87 N.Y.2d 691 [1996]), a physician sought an order restoring his staff privileges, relying not on the Public Health Law, but on the hospital's by-laws. Dr. Gelbard claimed, as Dr. Mason does here, that the by-laws were a contract, and he sought an injunctive remedy for their breach. Without reaching the merits of Dr. Gelbard's claim we held that the lawsuit, as in *Guibor*, was premature; even where a doctor who is seeking reinstatement sues for breach of contract, his claim must first be presented to the Public Health Council, for otherwise the "statutory requirement of threshold PHC review" might be "circumvented by artful pleading" (*Id.* at 697).

This case differs from *Gelbard* in two ways: Dr. Mason is not seeking reinstatement, but damages, and he has already presented his claim to the Public Health Council. No argument can be or is made that Dr. Mason's suit is premature, and therefore we must decide in this case, as we did not need to do in *Gelbard*, whether the claim is legally sufficient.

While we have never decided whether hospital by-laws constitute a contract for breach of which a doctor may sue, several Appellate Division decisions have dealt with that question, producing mixed and perhaps inconsistent results. Some cases decline to dismiss complaints alleging breach of medical staff by-laws, holding them legally sufficient as suits for injunctive relief (*e.g., Chalasani v. Neuman*, 97 A.D.2d 806 [2d Dept 1983]) or damages (*Giannelli v. St. Vincent's Hospital and Med. Ctr. of New York*, 160 A.D.2d 227 [1st Dept 1990]); *Chime v. Sicuranza*, 221 A.D.2d 401 [2d Dept 1995]). Other decisions, however, appear to limit the effect of these holdings in damages actions by rejecting complaints for wrongful termination of staff privileges based on alleged by-law violations (*Falk v. Anesthesia Assoc. of Jamaica*, 228 A.D.2d 326 [1st Dept 1996]; *Gelbard v. Gennesee Hosp.*, 255 A.D.2d 882 [4th Dept 1998]). There appears to be no appellate case in which a damages award for breach of medical staff by-laws has been upheld after trial.

The decisions of our Court, and many of those of the Appellate Division, are consistent with an important, though generally unexpressed, policy consideration: It is preferable for hospital administrators who decide whether to grant or deny staff privileges to make those decisions free from the threat of a damages action against the hospital. It is not just in a hospital's interest, but in the public interest, that no doctor whose skill and judgment are substandard be allowed to treat or operate on patients. A decision by those in charge of a hospital to terminate the privileges of, or deny privileges to, a doctor who may be their colleague will often be difficult. It should not be made more difficult by the fear of subjecting the hospital to monetary liability.

This does not mean, of course, that the hospital may not expose itself to such liability if it chooses to do so. A clearly written contract, granting privileges to a doctor for a fixed period of time, and agreeing not to withdraw those privileges except for specified cause, will be enforced. But the by-laws in this case are not such a contract.

Not a word in the by-laws that are now before us says or implies that doctors have a vested right to hospital privileges. The most relevant provisions of the by-laws are procedural, not substantive: They are contained in Article V (Procedures for Appointment and Reappointment) and Article VI (Hearing and Appeal Procedures). It is most unlikely that these by-law provisions were intended by anyone to create a monetary claim in favor of a doctor for wrongful termination or suspension of privileges. Dr. Mason also relies on Section 7.4 of the by-laws, which provides that no representative of the Hospital or staff shall be liable for action taken "in good faith and without malice." Dr. Mason claims that the Hospital acted in bad faith and with malice, and that therefore he may sue. It is far-fetched, however, to suggest that Section 7.4, entitled "Immunity from Liability," was intended to create a liability where one would otherwise not exist.

Dr. Mason claims that a rule imposing liability for a breach of institutional by-laws can be traced to our decision in *Tedeschi v. Wagner Coll.* (49 N.Y.2d 652 [1980]), but *Tedeschi* actually supports the rejection of Dr. Mason's damages claim. We held in *Tedeschi* that the plaintiff, a college student, was entitled to a judgment directing the college that was seeking to suspend her to comply with its own written guidelines; but we also held that "[s]o much of the complaint as sought money damages . . . was properly dismissed . . . ." (49 N.Y.2d at 661-62). In *Maas v. Cornell Univ.* (94 N.Y.2d 87 [1999]), we distinguished *Tedeschi* in a case brought by a professor challenging a university's disciplinary action. We held that the professor could not sue for breach of contract based on the university's "failure to observe bylaws and procedures" (*Id.* at 90). We see no reason why the by-laws of the Hospital here should be read to confer more rights on Dr. Mason than the institutional documents in *Tedeschi* and *Maas* did on the plaintiffs in those cases.

Accordingly, the order of the Appellate Division should be affirmed, with costs.

Recent Section Programs

The Health Law Section sponsored three educational programs so far this year:

- *External Appeals for Insurance Denials: Implementation and Practical Issues*. Panelists addressed the External Appeals program in Action, emerging issues including recent litigation and the experimental treatment issue, and the perspective of an external appeals agent. The Program, held at the Princeton Club in NYC on March 11, 2005 was organized by Robert P. Borsody of the Law Offices of Robert P. Borsody, and Harold N. Iselin of Greenberg Traurig.
- *Senior Housing Industry—An Evolving Business.* This unique program, held in Albany in April and New York City, addressed the legal issues in the growing Senior Housing Industry. The program included presentations on the regulation of various housing options, the interplay of housing providers with home health services, long term care insurance, financing senior housing, zoning issues and employment issues. Sandra C. Maliszewski was the Overall Planning Chair.
- *Hospital Tax Exemptions: Preparing to Defend Litigation*. There are over 50 class action litigations brought against hospitals claiming failure to fulfill their obligations under their 501(c)(3) tax exemptions. This program, held in New York City on March 16, 2005, examined the issues in these cases, summarized the status of the defensive actions taken, and proposed steps which hospitals can take prepare to defend themselves. The overall planning chairs were Robert Borsody of the Law Firm of Robert P. Borsody, Chris Stern Hyman, Esq. of Medical Mediation Group LLC, and Joan Shipman Esq. of the Law Office of Joan Shipman.

Upcoming Programs

- When Your Client's Health Law Problems Become Your Own and Meet the AUSA's. On Friday, September 23, 2005, the Fraud, Abuse and Compliance Committee will host a full day presentation in New York City with a morning session by representatives of the Southern and Eastern District Health Care Civil and Criminal Fraud Units. The morning program will include presentations by each of the Coordinators of the Civil and Criminal Fraud Units on the federal health care laws including the Stark Self-Referral Laws and the Fraud and Abuse Anti-kickback Laws. This will be the fourth year of this program which will include a luncheon presentation by the United States Attorney for the Eastern District of New York, Roslyn R. Mauskopf. The morning presentation will conclude with a panel discussion by all four of the Assistant U.S. Attorneys on a hypothetical which will offer a chance for participation by meeting attendees.

  The afternoon session will be on the topic of when "advising becomes structuring." This will discuss the recent rash of cases and the very complex and delicate issue of when a consultant of any kind, a lawyer, accountant, or healthcare consultant, can become so involved and take such actions as to incur civil or criminal liability arising out of his relationship with a client who, generally, would have been charged and found to have violated some healthcare fraud laws. Robert P. Borsody is the Overall Planning chair of this Program.
- Fall Retreat—Friday and Saturday, Oct. 28-29. The Section has booked the Sagamore Hotel on picturesque Lake George in Bolton Landing, NY for its first Fall Retreat. The retreat will include practical training for health lawyers in conducting administrative hearings such as Medicaid hearings. But it will also include ample time for socializing and exploring the Lake George area and the Adirondack State Park. Further information will be posted on the NYSBA website.

Upcoming Special Editions of the *Health Law Journal*

The NYSBA *Health Law Journal* is published triannually—in the Spring, Summer/Fall and Winter. The Summer/Fall issue will be a regular edition, with a variety of topics, and persons wishing to contribute articles are still invited to do so. The Winter issue will be a special edition on legal issues in long term care, and Ari Markenson, Chair of the Long Term Care Committee will be the Special Edition Editor. The Spring 2006 issue will be a special edition on legal issues in mental health care, with Henry A. Dlugacz, Co-Chair of the Mental Health Committee, as Special Edition Editor. Persons wishing to contribute articles to those special editions should contact the Special Edition Editor—the contact information is on the last page of this *Journal*.

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

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