

Health Law Journal

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

Published in cooperation with Pace University School of Law Health Law and Policy Program

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

in cooperation with

PACE UNIVERSITY SCHOOL OF LAW
HEALTH LAW AND POLICY PROGRAM

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A Message from the Section Chair

It is a pleasure and a privilege to assume the chairmanship of the Health Law Section. Among other aspects of Section membership that I have enjoyed these past years has been the opportunity to work with colleagues on the Executive Committee and in Section Committees on issues of importance to the public and to health care practice. I look forward to doing so again this year as we build on the Section's strengths.



Among those strengths are the Section Web site and the revised and expanded *Journal*, two important legacies of my predecessor, Robert Swidler. On behalf of the Section, I want to thank Robert for the exceptional leadership and commitment he brought to these and other initiatives.

The Bar Association will soon be conducting a survey of its members to find out how to improve the content and format of information available from the Association online. We welcome suggestions from you either through your participation in the survey or directly to the Section throughout the year. We are in the process of adding a suggestions page to the Section Web site to facilitate input and ideas from you about the Web site and the Section's activities and committees more broadly.

Responding to the extraordinary developments related to the provision of health information and provider-related services online, I have established a new Section Committee on the Health Care Internet. This Committee, chaired by Linda Fentiman, Director of the Center for Health Law and Policy at Pace University Law School, will examine the legal, ethical, and policy issues posed by mounting reliance on the Internet as a source of information for patients, as a means of connecting patients and providers, and as a vehicle to enhance core administrative tasks for the delivery of health care.

The health care Internet is the fastest growing sector online. By the close of 1999, an estimated 33% of all American adults were online, and of these an estimated 38% had used the Internet for health and medical information during the previous 12 months. Spurred by consumers' desire to play a more active role in their health care decisions and management, the rapid growth in use of health information and medical services online portends significant change for the practice of medicine,

the patient-physician relationship, and health care delivery. These changes pose critical challenges for health law and policy. Following on the success of the Section program on the health care Internet last year, we are planning another program for the upcoming year to cover emerging market, regulatory, and policy developments.

In conjunction with the Medical Society of New York State, the Section will also offer a program on October 11, 2000 on federal and state fraud and abuse laws governing physicians and small group practices, including compliance guidelines recently released by the HHS Office of Inspector General. Due to the popularity of the health care primer program, we will offer the primer again in three cities in the fall: in Rochester on Wednesday, October 25, 2000 with Sally True as Program Chair; in Albany on Friday, October 27, 2000 with Philip Rosenberg as Program Chair; and in New York City on Thursday, November 2, 2000 with Frank Serbaroli as Program Chair. We also anticipate that the Section will conduct a program in early spring on critical legal issues for health care delivery systems, under Robert Wild's leadership.

I want to take this opportunity to thank the outgoing committee chairpersons for their service, and to welcome and introduce the new chairpersons. Joseph Baker, III has joined Susan Slavin as Co-Chair of the Committee on Consumer Protection. Joe is Executive Vice-President of the Medicare Rights Center, a national advocacy group for Medicare beneficiaries. Jerrold Ehrlich has assumed the chairmanship of the Committee on Health Care Providers. Jerry provides legal counsel to diverse provider organizations through his legal practice at Epstein Becker and Green. Jim Horan, Administrative Law Judge for the New York State Department of Health, is the new Chair for the Committee on Professional Discipline. Peter Millock, a partner at Nixon Peabody, LLP, will chair the Nominating Committee for the Section. Finally, the Committee on Payment Issues has been disbanded; the shift to a deregulated payment system curtailed the scope and immediacy of the Committee's mission. Ross Lanzafame, a partner at Harter, Secrest and Emery, who was Chair of the Committee on Payment Issues, is now Chair of the Committee on the Uninsured.

These Committee Chairs will add to the exceptional strength in health law and policy on the Executive Committee and in the Section. I look forward to working with the Executive Committee and the Section's members in the year ahead.

Tracy E. Miller

In the New York State Courts

Appellate Court Holds that Plastic Surgeon Committed Malpractice by Failing to Refer Patient to a Mental Health Professional Before Obtaining Informed Consent for Multiple Cosmetic Surgeries

Lynn G. v. Hugo, 2000 WL 863129 (1st Dep't, June 29, 2000). The plaintiff in this case is a woman who was a long-time patient of plastic surgeon Dr. Norman Hugo; she underwent at least 50 cosmetic procedures over a seven-year period. After having two liposuction procedures and a full abdominoplasty in 1993, the patient complained to Dr. Hugo that she was dissatisfied with the appearance of her abdomen. She then brought this malpractice action alleging that Dr. Hugo failed to advise her of less invasive alternatives and that she was incapable of giving informed consent. The patient claimed she lacked capacity to give informal consent because she was suffering from a psychiatric disease known as Body Dysmorphic Disorder, a disproportionate preoccupation with minor or imaginary physical flaws.

Plaintiff claimed that Dr. Hugo was aware from 1986 to 1990 that she was under the care of a psychiatrist for depression, and was taking at least two mood elevators. Plaintiff contended that her psychiatric history, combined with her unusually high demand for surgical correction of slight or imagined physical defects, should have alerted Dr. Hugo to the presence of a mental disorder that fueled her demand for unnecessary surgery and prevented her from assessing the risks and benefits of such surgery. At the very least, plaintiff contended, Dr. Hugo should have consulted with a mental health professional before performing another invasive procedure.

The trial court denied defendant's motion for summary judgment seeking dismissal of the informed consent claim, and the

First Department affirmed. The appellate court stated that, "in the area of cosmetic surgery, when there is no medical need for the operation and only the patient's subjective aesthetic opinion determines her view of whether surgery is to be undertaken, a physician should have some responsibility to provide objective guidance to a patient whose capacity for self-assessment is clearly disordered. The court then reasoned that her history of psychiatric problems and her medications should have warned Dr. Hugo that there was a possibility of impaired judgment regarding cosmetic surgery. According to the court, this notice should have resulted in his referral of the patient to a mental health professional.

Blood Fractionators Immune from Liability Under Blood Shield Statute

In re Blood Factor Litigation v. Armour Pharmaceutical Co., (N.Y.L.J., April 27, 2000, p. 28, col. 6) (Sup. Ct., New York Co., April 27, 2000). The defendants are "blood fractionators, i.e., they process and distribute blood clotting factors. Plaintiffs alleged that they were injured because of the defective design, manufacture and sale of blood clotting factors infected with viruses, including the human immunodeficiency virus. The plaintiffs alleged that as manufacturers of defective products, defendants were liable under theories of strict liability and breach of warranty.

Defendants moved to dismiss plaintiffs' claims under the blood shield statute found in Public Health Law § 508(4). Public Health Law § 508(4) provides, in pertinent part that:

the collection, processing, storage, distribution or use of blood, blood components or blood derivatives for the purpose of diagnosis, pre-

vention or treatment of disease is hereby declared to be a public service and shall not be construed to be, and is declared not to be, a sale of such blood, blood components or blood derivatives, for any purpose or purposes whatsoever.

In rejecting plaintiffs' argument that the above statute applied only to laboratory services, the Court concluded that the Legislature did not intend such a narrow effect, which would also exclude protection to hospitals and doctors who transfuse patients. Finding further that the manufacture and sale of clotting factors were an integral part of "the collection, processing, storage, distribution or use of blood or a blood derivative," the Court held that the fractionator defendants were performing a public health service as defined under Public Health Law § 508(4), and were therefore protected from claims of strict liability or implied warranty.

Surrogate's Court Grants Hospital's Cy Pres Petition to Lift Restrictions on Testamentary Bequests

In re the Application of the Long Island College Hospital, File No. 5101/95 (Surrogate's Ct., Kings Co., May 30, 2000). Petitioner hospital was a beneficiary under the wills of a husband and wife of bequests totaling approximately \$135 million. The terms of such bequests established an endowment fund ("Fund") whereby the principal would be held in perpetuity and the income only could be used for general purposes. While the Fund generated annual income of approximately \$10 million, such amount was insufficient, in light of the hospital's dire financial condition, to permit it to make certain capital improvements and acquisitions it believed were necessary for it to continue as a viable institution in a changing health care

environment. In addition, petitioner had exhausted its borrowing capacity and wished to use a portion of the Fund to secure additional financing for working capital and other purposes.

The hospital therefore petitioned the court for *cy pres* relief under § 8-1.1 of the Estates Powers and Trusts Law (EPTL) in the form of an order modifying the restrictions in the wills to permit the use of a portion of the Fund for the foregoing purposes. The petition was uncontested and the Attorney General, the only other interested party, submitted an affidavit in support of the hospital's application.

The *cy pres* doctrine as codified in the EPTL permits a court to modify the terms of a bequest to effectuate a testator's *general* charitable intent when the *specific* terms of the bequest cannot be followed, or are no longer practicable. The three-prong test for relief requires a court to find that (1) the gift in question is charitable in nature; (2) the language of the will, when read in light of all attendant circumstances, indicates that the donor had a general, rather than a specific, charitable intent; and (3) the purpose for which the gift was made has failed or become impossible or impracticable to achieve.

In this case, the court granted the petition in full, holding that the hospital had met each prong of the three-part test for *cy pres* relief under the EPTL. Specifically, it found that (1) the gifts were charitable in nature because petitioner is a charitable hospital and gifts for the promotion of health or medicine have always been recognized as being charitable in nature; (2) the donors possessed the requisite general charitable intent because they (a) left the bulk of their sizable estate to various charitable institutions and (b) gave petitioner substantial discretion in the application of the Fund's income, directing only that it be used for "general purposes;" and (3) the purpose of the

bequest would become impracticable if petitioner were forced to cease operations and stop performing its charitable function.

The court also noted the testators' long-standing charitable commitment to petitioner in the form of sizable *inter vivos* gifts and board service and found, in accordance with § 8-1.1(c) of the EPTL, that the testators' general intent, which was to enhance petitioner's ability to provide medical services to the community in furtherance of its charitable mission, would best be accomplished by lifting the restrictions in the testators' wills and granting petitioner's application.

Physician's Defamation Claim Barred by HCQIA Immunity

Gelbard v. Bodary, 706 N.Y.S.2d 801 (4th Dep't, 2000). This is the third in a series of court decisions that resulted in the dismissal of a physician's claims against a hospital and the individual physicians who participated in a peer review process that terminated the physician's clinical privileges. (For background, see *Gelbard v. Genesee Hospital*, 87 N.Y.2d 691 (1996)) and *Gelbard v. Genesee Hospital*, 255 A.D.2d 882 (4th Dep't 1998). At issue this time was plaintiff's defamation claim based on a letter published and subsequently republished to the Hospital's peer review committee.

The court held that pursuant to its prior determination, the defendants were immune from liability under the Health Care Quality Improvement Act (HCQIA). Because the alleged defamatory letter was published by a member of the hospital's medical staff during the peer review process, the court dismissed the claim under HCQIA immunity.

The court also held that the defamation claim was time barred, because the claim was commenced more than one year after the letter was initially published. Significantly, the court held that later republications of the letter to the peer review

committee did not give rise to a new claim; otherwise, a new cause of action would accrue each time the "letter is provided to other individuals involved in a professional review process months or even years later."

Court Dismisses Suspended Physician's Damage Claims Against Hospital

Wasserman v. Maimonides Medical Center, 702 N.Y.S.2d 88 (2nd Dep't, 2000). This suit arose from a hospital's two-week suspension and subsequent reduction of plaintiff's surgical privileges. The hospital imposed these limitations based on a complication and patient death in one of the physician's cases. The physician sued to recover damages for breach of contract, injurious falsehood and intentional infliction of emotional distress.

The Appellate Division affirmed dismissal of the suit. The court upheld dismissal of the breach of contract claim, which alleged that the hospital had violated its medical staff bylaws, because it was based upon an alleged failure to act in good faith rather than a breach of a specific bylaw. The court also held that the claim for injurious falsehood was properly dismissed for failure to allege special damages, and that the claim for intentional infliction of emotional distress failed because the defendant's actions did rise to the level of outrageous conduct.

The court also noted that the physician was not required to pursue his administrative remedy with the Public Health Council, because he was seeking only money damages and not an order lifting his suspension or reinstating his privileges. (Ed. note: This holding may be inconsistent with other reported appellate cases on that issue).

Family Leave Act Claim Against Medical Group Held Collaterally Estopped by Administrative Ruling

Kosakow v. New Rochelle Radiology Associates, P.C., 88 F. Supp. 2d 199 (S.D.N.Y. 2000). Plaintiff was ter-

minated from her job as a part-time x-ray technician while she was out on disability leave. In response, she filed discrimination charges with the New York State Division of Human Rights (DHR) and the federal Equal Employment Opportunity Commission (EEOC), alleging violations of the Americans with Disabilities Act (ADA). Both agencies found that the employer had acted for legitimate business reasons having to do with the need to reduce staff because of a fiscal crisis. After her time to appeal these decisions lapsed, plaintiff sued her former employer—a group medical practice—for alleged violations of the Family and Medical Leave Act (FMLA). FMLA is a 1993 law that permits eligible employees to take 12 weeks of job-protected leave to care for their own or a family member's "serious medical condition."

After discovery, the employer moved for summary judgment. It asked that the Court dismiss the complaint on the grounds that: (i) plaintiff had not worked the number of hours (1,250) required to be eligible for FMLA leave or protections; and (ii) the findings of the state and federal agencies that the employer acted legitimately, and not in violation of the ADA, should collaterally estop the FMLA claim.

The District Court agreed with the employer's collateral estoppel theory, and granted summary judgment dismissing the FMLA claim. The court held that the plaintiff had had a full and fair opportunity to litigate before the DHR and EEOC, that the issues decided therein were material and necessary to the decision in the administrative proceeding, and would be material and necessary to any decision to be rendered in the federal court lawsuit.

The Court declined, however, to dismiss an alleged violation of ERISA based on the employer's failure to pay severance to this employee. This alleged violation was premised on the Court's finding that a one-line provision in an employee

manual that severance shall be paid to terminated employees, "where applicable," constituted an ERISA Plan. The Court remanded to the employer for a determination as to whether severance, in this instance, was "applicable." (Ed. note: Garfunkel, Wild & Travis represented the employer in this case).

Physician's Sexual Relationship with Patient Constitutes Moral Unfitness Sufficient to Uphold License Suspension, Even Though Statutory Proscription Is Directed Only at Psychiatrists

Miller v. Commissioner of Health, 703 N.Y.S.2d 830 (3d Dep't, 2000). The Administrative Review Board for Professional Medical Conduct suspended petitioner's license based upon a finding of moral unfitness to practice medicine. The charge was based upon petitioner's 16-month consensual sexual relationship with a patient, during the same period that he provided medical treatment to the patient. The petitioner commenced an action seeking to overturn the Administrative determination upon the ground that it was arbitrary and capricious. Petitioner argued that he could not be found guilty of moral unfitness because the statute proscribing any physical contact of a sexual nature with a patient (Education Law § 6530[44]) was expressly applicable only to psychiatrists, which petitioner was not.

The Appellate Court "strenuously" disagreed, stating that although the statute is expressly applicable to psychiatrists, "the absence of a corollary proscription in the practice of all other areas of medicine does not ipso facto constitute approval by the Legislature." The Court further found that in view of petitioner's admission regarding his concerns about the patient's psychological condition at the time he was having sexual relations with her, and his acknowledgment that his sexual relationship with the patient impaired his judgment, that such conduct support a

final and moral unfitness under Education Law § 6530[20]. Thus, the Court was "loath to find" that the administrative suspension of the physician's license was arbitrary and capricious.

Court Allows Claim Against Medical Corporation for Negligent Disclosure of Confidential Patient Information

Doe v. Community Health Plan - Kaiser Corporation, et al., 2000 WL 571431 (App. Div. 3d Dep't, 2000). Plaintiff, who received services from a certified psychiatric social worker at a facility owned and operated by Community Health Plan—Kaiser Corporation (CHP), filed suit alleging negligent disclosure of confidential information contained in her patient file by a medical records clerk employed by CHP. The Supreme Court granted CHP's motion for summary judgment based on the doctrine of respondeat superior, since the disclosure by the clerk was not within the scope of her employment.

The Appellate Division reversed, reasoning that although the plaintiff's claim was characterized as negligence, it essentially was based on the breach of the fiduciary duty of confidentiality. The common law privilege protecting patient-doctor communications has been codified, and the Court noted other statutory protections arising from this privilege. CPLR 4504 specifically protects the disclosure of medical records. As a Public Health Law article 44 medical corporation, CHP is bound by CPLR 4504. In CPLR 4508, the legislature extended this protection to other health and mental health professionals, including social workers, as well as to clerks working for the same employer as the certified social worker. Public Health Law § 4410(2) also prohibits the disclosure of confidential information acquired while providing professional services.

Although the Court acknowledged that these statutes do not cre-

ate a private right of action for improper disclosure of confidential information, such disclosure is nonetheless actionable as a tort.

One justice dissented in part, and disagreed with the majority's decision to reinstate the plaintiff's claim. The justice acknowledged that case law recognizes a tort claim in these circumstances, but such a claim sounds only in malpractice and can be asserted only against a professional, not a corporation, for breach of the duty of confidentiality. The dissenting justice also found the cause of action fashioned by the majority to be inconsistent with the statutory scheme applicable to health maintenance organizations.

Physician Employed by Hospital as Clinic Director Owes Duty of Loyalty to Employer

Bronx-Lebanon Hospital Center v. Wiznia, Bronx County Index No. 13325/99. Plaintiff Bronx-Lebanon

Hospital Center sued three physicians it had employed to staff its Pediatric Aids Treatment Center. While still employed by the hospital and without the hospital's knowledge, the defendants took steps to transfer grant funding, physician staff, support staff, and patients to another hospital. Bronx-Lebanon sued the physician employees for breach of fiduciary duty and tortious interference with business relations.

After an evidentiary hearing, the Court granted the Hospital's motion for summary judgment against Dr. Wiznia (the physician employed as Director of Bronx-Lebanon's Pediatric Aids Treatment Center), finding that he had breached his fiduciary duty with respect to his solicitation of staff, his redirection of grant monies, and his wrongful attempt to divert Bronx-Lebanon patients to another hospital, all while still employed by Bronx-Lebanon. The Court did not credit Dr. Wiznia's

attempts to argue that his duty to patients outweighed the general rule that prohibits employees from acting in a manner contrary to the trust placed in him by the employer.

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

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In the New York State Legislature

The New York State Legislature is known for its contentious legislative sessions and the 2000 legislative session was no exception. Perhaps distinguishing the 2000 legislative session was the extent to which the most serious battles involved intra-party struggles. During the early weeks of the session, relations between Governor George Pataki and the Republican Senate Majority Leader Joseph Bruno threatened to derail timely budget or legislative agreements. Toward the close of the session, the Assembly Majority Leader Michael Bragman attempted to overthrow his fellow Democrat Speaker Sheldon Silver.

Notwithstanding the Legislature's bumpy ride through the year, the legislative session proved to be a productive one, generally, with significant health legislation agreed to by both houses in the last weeks of the session. At deadline, a substantial number of bills await action by the Governor in the health arena, including an important and controversial initiative to provide more information to consumers on the quality of their health care providers. In addition to describing the so-called "physician profiling" legislation in some modest detail, this report summarizes a number of other bills of interest to the health care legal community.

Physician Profiling (S.8127/A.1401-D)

In the waning hours of the 2000 legislative session and after a persistent lobbying effort by patient organizations, the Legislature passed the Patient Health Information and Quality Improvement Act of 2000. The bill, commonly referred to as the "physician profiling bill," will provide consumers with additional information on physicians, hospitals and health plans and tighten existing laws to promote patient safety.

Inspired by the Institute of Medicine's (IOM) report on the prevalence of medical errors and some well-publicized instances of malpractice committed by physicians with records for negligence or misconduct, the legislation is intended to facilitate consumers' ability to assess the qualifications, experience and track record of physicians, hospitals and health plans. Consistent with the recommendations of the IOM study, the bill would also establish a Patient Safety Center within the Department of Health to coordinate efforts within the Department to improve health care quality and consumer access to health care information.

The bill directs the Department of Health (DOH) to collect and disseminate individual profiles on licensed physicians. The profiles must be made available to the public on the Department's Web site and in hard copy that can be ordered over a toll-free telephone number. Among other information, the profiles will contain:

- A statement of any criminal convictions within the last ten years;
- A statement of any state disciplinary actions within the last ten years;
- A statement of any loss or involuntary restriction of hospital privileges or a failure to renew professional privileges at hospitals within the last ten years (for reasons related to the quality of patient care);
- A statement indicating the number of medical malpractice court judgments, arbitration awards and malpractice settlements within the last ten years in which a payment is awarded to a complaining party. As for malpractice settlements, a contentious issue for physician

organizations, reporting occurs only after two settlements are reached or "if the commissioner determines that any such settlement could be relevant to patient decisionmaking concerning health care quality." Judgments, awards and settlements must be reported in graduated categories indicating the level of significance, date and place of action. Pending malpractice claims are not to be disclosed to the public.

The DOH must provide each licensee with a copy of his or her profile prior to dissemination to the public and provide an opportunity for the physician to correct inaccuracies in the profile. The physician may also submit a statement concerning information contained in the profile that will be disseminated along with the profile. Any physician who knowingly provides materially inaccurate information will be guilty of professional misconduct.

In addition to physician profiles, the legislation also requires the DOH to collect data on hospital performance, largely resurrecting the provisions from the first Health Care Reform Act (HCRA) that had expired earlier this year. Legislators intended to continue the effort to assemble "hospital report cards" that was underway pursuant to the health care quality and information initiatives authorized by HCRA, through the collection of utilization and performance data and the development of statewide performance data comparing utilization and selected performance measures to accepted norms and benchmarks.

The Legislature then focused on the health plans and imposed a similar quality initiative designed to ensure the dissemination of health plan data collected pursuant to the existing quality assurance reporting

requirements (QARR) developed by DOH in conjunction with the National Committee on Quality Assurance (NCQA).

In an effort to reduce medical errors and improve health care quality, the legislation tightens current laws and penalties related to the reporting of adverse incidents, malpractice and misconduct and requires the Board of Professional Medical Conduct within the Department of Health to get approval from the Board of Regents prior to restoring a revoked physician's license. In addition, when a patient undergoes a non-emergency treatment, procedure or surgery under local or general anesthesia, the bill now subjects the practitioner to professional discipline if he or she fails to inform the patient of every physician, podiatrist and dentist reasonably anticipated to be actively involved in the patient's treatment. Medical residents in certified training programs are not required to be disclosed to the patient under these circumstances.

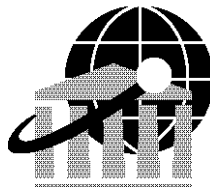
Finally, in provisions that respond directly to recommendations in the IOM report, the legislation establishes a Patient Safety Center within the Department of Health to improve data reporting, collection, analysis and dissemination on the health care performance of health care providers and professionals.

Other Health Care Bills of Interest

In addition to the physician profiling bill, the Legislature reached agreement on the following additional bills, all of which will be subject to the Governor's approval or veto:

- **Sharps Safety** (A.7144-C/S.4936-B): The bill would provide for regulations from the Department of Health to prevent and reduce needle-stick injuries by using safer technologies, including engineered sharps injury protection.
- **Whistleblower Protection** (A.11435/S.8133): The legislation would prohibit retaliatory personnel actions by health care employers against employees who provide information to a public body concerning alleged violations of law, rule or regulation.
- **Deregulation of contingency fees in medical malpractice actions** (A.8762/S.554): The existing sliding scale fee limitations on contingency fees on medical malpractice actions, enacted as part of the malpractice reforms of the mid-1980s, would be repealed by this bill.
- **Insurance Mandates:** Bills have been passed that would require coverage of prostate cancer screening (A.5037/S.976), licensed home care services (A.2426-A/S.2535-A), and occupational therapy in like manner as coverage for physical therapy (A.6834-A/S.1580-A) and that would expand coverage for family members of alcohol and substance abusers (A.9528-A/S.3946-A).
- **Mini-Stark Law Expansion** (A.3573-A/S.5415-A): The bill would extend the state's anti-self-referral law to include physical therapy services.

Compiled by James W. Lytle, resident partner, and Ami Schnauber, legislative coordinator, from the Albany office of Kalkines, Aaky, Zall & Bernstein, LLP, a firm that devotes a substantial part of its practice to health care and government relations.



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In the New York State Agencies

The New York State Department of Health and the New York State Department of Insurance have recently promulgated these regulations of note:

External Appeal Program

- Department of Health issued a Notice of Continuation of regulations governing the external appeal program. *See* N.Y.S. Register, May 17, 2000.
- Proposed amendments by the Department of Insurance to implement the external appeal program. These amendments provide guidance to providers, insureds, and external appeal agents in implementing the external appeal program. *See* N.Y.S. Register, May 17, 2000.
- This addition to Subpart 98-2 to Title 10 N.Y.C.R.R. has been adopted pursuant to the Department of Health's emergency rulemaking power. The Department of Health intends to adopt these emergency rules. These rules provide guidance to health care plans, enrollees of health care plans, and external appeal agents in implementing the requirements of Chapter 586 of the Laws of 1998. These additions include various definitions and information to be included in the external appeal process. In addition, these provisions include requirements for notification; timeframes for making external appeal determinations; certification of the clinical peer review; and responsibility for payment of the appeal. Filing date: February 10, 2000. Effective date: February 10, 2000. *See* N.Y.S. Register March 1, 2000 and May 31, 2000.
- Additions to Part 410 (Regulation 166) to Title 11 N.Y.C.R.R. These rules were promulgated

on an emergency basis by the Insurance Department to implement the external appeal program. The rules provide guidance to insurers, insured, and external appeal agents for implementing the external appeal process. Filing date: February 10, 2000. Effective date: February 10, 2000. *See* N.Y.S. Register March 1, 2000.

§ 410.1: Defines an insured's rights to an external appeal and the appeal process applies to health care plans defined as insurers subject to Article 32 or 43 of the Insurance Law and external appeals agents.

§ 410.2: Includes definition of "attending physician," "commissioner," "confidential HIV information," and "final adverse determination."

§ 410.3: Specifies the type of information to be included in the standard description of the external appeals process which must be provided to all insured. The standard description must include: a statement of the insured's right to an external appeal; the eligibility requirements for an appeal; notification of the timeframes in which an external appeal agent must make a determination; and instructions on how to complete and file the appeal request with the Department of Insurance.

§ 410.4: Outlines the standards which need to met in order to qualify for certification as an external appeal agent. The agent must demonstrate access to a sufficient pool of clinical peer reviewers and an ability to comply with the applicable laws and rules.

§ 410.5: Outlines the information required in the application for certification as an appeal agent. The applicant must provide information regarding affiliations with health care plans, health care providers, health care facilities and/or developers or manufacturers of health services; a description of the clinical peer reviewer network; a description of the applicant's external appeal process; and the fees to be charged.

§ 410.6: Provides standards for evaluating conflicts of interest between the external appeals agent and clinical peer reviewers. A description of the disqualifying criteria as well as a sworn statement by applicants attesting to the absence of material affiliations which may constitute a conflict must be provided to the Department of Insurance. An applicant must also provide a description of the written policies and procedures for ensuring that no conflict exists.

§ 410.7: Outlines the process and standards for determining the eligibility of requests by insured for an external appeal. Health care services covered by Medicare are not subject to external appeal. The insured is required to attach all the documentation necessary to evidence his/her eligibility for appeal. The State is required to notify the insured and the insured's health care plan when a request for appeal is determined eligible.

§ 410.9: Provides that health care plans provide information regarding the appeals process to the insured.

§ 410.10: It is the responsibility of the certified external appeal agent to notify the insured, the insured's physician, and the health plan upon receiving an appeal. The agent must also provide a time-frame for making a determination. The medical director of the certified external appeal agent must certify that the clinical peer reviewers followed the appropriate procedures and that each reviewer provided a sworn statement that no prohibited material affiliation existed with respect to the appeal.

§ 410.11: The insured must file complete requests for an appeal within the statutory timeframes and is responsible for paying the fee as prescribed by the insured's health plan.

§ 410.12: Gives a description of the confidentiality requirements which must be followed by health care plans, certified appeal agents, and clinical peer reviewers regarding the insured's medical treatment.

§ 410.13: Describes the record-keeping requirements for health care plans, certified appeal agents, and clinical peer reviewers.

Health Care Initiatives Pool

The Insurance Department has adopted an addition to § 68.6 to Title 10 N.Y.C.R.R. The text of the amendment was promulgated in the N.Y.S. Register, March 1, 2000. *See below.* Filing date: April 25, 2000. Effective date: May 10, 2000. *See N.Y.S. Register, May 10, 2000.*

Pooling Mechanisms for Individual and Small Group Health Insurance

Amendment of Part 361 (Regulation 146) of Title 11 N.Y.C.R.R. The Legislature pursuant to L. 1992, ch.

501, required New York State health insurers and HMOs to make changes in the marketing and rating of health insurance coverage sold to individuals and small groups. The Legislature has established open enrollment and community rating requirements to facilitate increased access to affordable and equitable health insurance to individuals and small groups. Chapter 501 provides for a pooling mechanism that allows insurers and HMOs to share the risk of high cost claims for individual and small groups. These rules implement a medical condition-based pool rather than the former demographic-based pooling mechanism. These regulations establish new standards for the distribution of specified medical condition pooling funds. Filing date: February 15, 2000. Effective date: February 15, 2000. *See N.Y.S. Register, March 1, 2000.*

Adult Day Health Care Programs

The Department of Health has adopted this emergency rule. These rules repeal emergency adoption number 129, filed with the Department of State on February 8, 2000, which repealed Parts 425, 426, and 427, and added a new part 425, and amended § 86.29 to Title 10 N.Y.C.R.R. New standards of operation are created to regulate adult day health care programs. These rules were adopted to prevent fiscal abuse and fraud within these programs. Filing date: April 14, 2000. Effective date: April 14, 2000. *See N.Y.S. Register, May 3, 2000.*

Amendment of § 860-2.9 to repeal Parts 425-427 and addition to Part 425 of Title 10 N.Y.C.R.R. The Department of Health has issued this emergency regulation in response to allegations of Medicaid fraud by adult day health care programs. The emergency regulations establish additional standards for the operation and reimbursement of adult day health care providers. Filing date: February 8, 2000. Effective date: February 8, 2000. *See N.Y.S. Register, February 23, 2000.*

Public notice to amendment to Title XIX of the Medicaid State Plan for adult day health care programs. All adult day health care programs must submit a new budget to the Department of Health. The new budgets are being required because the program service delivery requirements have been revised. *See N.Y.S. Register, February 23, 2000.*

Finger Imaging for Medicaid Applicants and Recipients

Proposed rule promulgated by the Department of Health to amend §§ 360.3.2, 360-6.2, and 384.3 of Title 18 N.Y.C.R.R. These proposed regulations would implement provisions of the Welfare Reform Act of 1997, requiring finger imaging as a condition of eligibility for certain Medicaid applicants and recipients. *See N.Y.S. Register, April 26, 2000.*

Nursing Home Resident Discharge Appeals

These proposed rules seek to amend § 415.3 of Title 10 N.Y.C.R.R. regarding nursing home discharges. It requires nursing home facilities to provide a notice of transfer or discharge at least 30 days prior to the action. It also provides that if the resident appeals the transfer or discharge to the Department of Health within 15 days of being notified, the residents may remain in the facility pending the determination of the appeal. *See N.Y.S. Register, April 12, 2000.*

Medicaid Payment Rates for OMH Psychiatric Centers

The Office of Mental Health and the Department of Health are proposing to change the trend factor used in Medicaid inpatient rates to a "full market basket." The Department feels that this trend factor is more consistent with the trend factors given to other hospital providers in the state. It is expected that these methodology changes will increase the aggregate Medicaid payments to OMH facilities by 2.5%. *See N.Y.S. Register, April 5, 2000.*

Medicaid Payments for Inpatient Hospital Services

The Department of Health has proposed to amend Title XIX (Medicaid State Plan for Inpatient Hospital Services) to comply with proposed State legislation. For the period beginning April 1, 2000 through March 31, 2001, the State is authorized to make additional payments of \$103 million in aggregate medical assistance disproportionate share inpatient hospital services payments to public general hospitals located in cities with a population greater than one million. State and SUNY facilities will not be eligible for a portion of these payments. *See* N.Y.S. Register, March 29, 2000.

HIV Reporting and Contact Notification

Regulations §§ 63.1-63.11. Adoption of proposed amendments affecting 10 N.Y.C.R.R. Part 63 regarding HIV Reporting. These regulations authorize HIV reporting and contact notification. These regulations are not retroactive. Physicians and other diagnostic providers must provide laboratories with the names and addresses of the sources of specimen. Informed consent to an HIV test must include information concerning the mandated reporting of HIV tests and also inform the patient that if the test is positive, he/she will be asked to cooperate in the contact notification process. Physicians and other diagnostic providers must report cases of HIV infection, AIDS, or HIV-related illness as soon as possible after post-test counseling but no later than 21 days after receiving the positive test result. Three mechanisms are also set forth for contact

notification: (1) for contacts identified through Article 21 reporting; (2) for contacts identified by physicians and other diagnostic providers in the course of their practice; and (3) when an exposure incident occurs to staff in the performance of their professional duties. The regulations also set forth the requirement of initial employee education and annual in-service education. Filing date: March 2, 2000. Effective date: June 1, 2000. *See* N.Y.S. Register, December 15, 1999 and March 22, 2000.

Risk Transfer Agreements

Addition of Part 101 (Regulation 164) to Title 11 N.Y.C.R.R. This proposed regulation has been promulgated by the Department of Insurance. This regulation assesses the financial responsibility and capability of health care providers to perform their obligation under certain financial risk-sharing agreements, and sets forth standards pursuant to which providers may adequately demonstrate such responsibility and capability to insurers. *See* N.Y.S. Register, March 1, 2000.

Community-Based Mental Illness Programs

Amendment of Parts 506, 587, and 595 of Title 14 N.Y.C.R.R. These regulations were promulgated by the Department of Health in order to implement the provisions of Kendra's Law. The regulations set forth guidelines to enhance the supervision and coordinate the care of persons with mental illness in community-based settings. Filing date: February 7, 2000. Effective date: February 7, 2000. *See* N.Y.S. Register, February 23, 2000.

Patient Review Instrument (PRI) Instructions

Emergency amendments to §§ 2803(2), 2807(3), and 2808. These amendments were proposed by the Department of Health to give nursing facilities incentive to provide quality cost-effective care to patients. The proposed regulations allow for a new admission qualifier in claiming medical treatments and they also allow nursing facilities to use nurse practitioners or physician assistants where a physician is currently required. Filing date: January 21, 2000. Effective date: January 21, 2000. *See* N.Y.S. Register, February 9, 2000.

Compiled by Francis J. Serbaroli, Esq. Mr. Serbaroli is a partner in Cadwalader, Wickersham & Taft's 20-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 Committee. 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 Mr. David Quirolo, a third year law student at the New York University School of Law and a summer associate at Cadwalader, Wickersham & Taft, in compiling this summary is gratefully acknowledged.

In the Law Journals

1. Clark C. Havighurst, *Vicarious Liability: Relocating Responsibility for the Quality of Medical Care*. 26 Am. J. of Law and Medicine (2000).
2. Kathleen A. Peterson, *First Nursing Homes, Next Managed Care?: Limiting Liability in Quality of Care Cases under the False Claims Act*. 26 Am. J. of Law and Medicine (2000).
3. Tiffany F. Theodos, *The Patients' Bill of Rights: Women's Rights Under Managed Care and ERISA Preemption*. 26 Am. J. of Law and Medicine (2000).
4. Kurt Machemer, *Recent Development in Health Law: Select Recent Court Decisions: Consent: Physician Not Authorized to Release HMO Members' Medical Records Unless HMO has Secured Members' Express Written Consent*. 26 Am. J. of Law and Medicine (2000).
5. Heather N. Burghardt, *Recent Development in Health Law: Select Recent Court Decisions: Constitutional Law: Tax Assessments on Residential Health Care Facility's Gross Receipts for Medicaid Patient Care Declared Constitutional*. 26 Am. J. of Law and Medicine (2000).
6. Diane Serritella, *Recent Development in Health Law: Select Recent Court Decisions: Disability & ADA: Employers and Insurers Not Obligated by the ADA to Provide Equal Benefit Plans for Physical and Mental Disabilities*. 26 Am. J. of Law and Medicine (2000).
7. John Kindley, *Abortion, Breast Cancer, and Informed Consent*, 15 Issues Law & Med. 243 (2000).
8. Perspectives Current Enforcement, "Sentinel Effect" Shows Freud Control Effort Works, 32 J. Health & Hospital L. 445 (1999).
9. Infertility Treatment: An Argument for Mandated Courage, 32 J. Health & Hospital, 475 (1999).
10. Notes and Comments: *Free Care Provided by Hospices*, 32 J. Health & Hospital 475 (1999).

A Primer on Health Law

Co-sponsored by the Health Law Section and the Committee on Continuing Legal Education of the New York State Bar Association

**Wednesday, October 25, 2000
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**Friday, October 27, 2000
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The New York State Bar Association's Health Law Section and Committee on Continuing Legal Education are pleased to present a basic overview of health law and its practice. The program will offer presentations on legal and regulatory rules governing health care providers and practice-oriented pointers on substantive matters that health care attorneys regularly encounter. This balanced approach incorporating fundamental legal principles and practical problems and concerns faced by health care providers should provide valuable information and guidance to persons 1) just entering this field or 2) looking to stay up-to-date in this rapidly changing area.

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For Your Information

By Claudia O. Torrey

"First do no harm" is the phrase most people associate with the Hippocratic Oath.¹ The oath, named for the Greek physician Hippocrates, but of uncertain authorship, serves as a guide to ethical conduct for physicians. Some form of the oath is usually incorporated into the medical school graduation ceremony.

Since the increase of "managed care" into the health care arena, more attention has been given to many health-oriented issues. However, very little attention has been given to the issue of medical errors—until recently!

The Institute of Medicine (IOM), a member of the National Academies, via its Committee on Quality of Health Care in America ("Committee"), recently published a report, in book form, entitled *To Err Is Human: Building a Safer Health System*.² The Committee states in its Executive Summary that "(w)hether a person is sick or just trying to stay healthy, they should not have to worry about being harmed by the health system itself."³ Thus, the Committee calls its report a call to action to make health care safer for patients.⁴ This author's column will highlight some of the concerns and recommendations stated in the report.

Medical error (or quality of care issues) is an issue that will permeate our professional literature more and more as Congress grapples with a "Patients' Bill of Rights," and the alleged right "to sue an HMO."⁵ The Committee defines medical error as the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim.⁶ Recognizing the economics of medical errors, that a high preponderance of medical errors yields high opportunity costs, requires closer scrutiny to prevention techniques and technology preconditions (latent

failures embedded in the system).⁷ Thus, a substantial decrease in medical errors could be generated through preventable suboptimal iatrogenic responses to clinical signs and symptoms, as well as recognizing technology as an enhancement tool, and *not* as a substitute for knowledge. This is especially true as more and more care shifts from hospital settings to ambulatory and home settings.⁸ The use of medical technology by non-health professionals can be expected to increase, thereby creating importance to the "team effort" between both health and non-health professionals.

Particularly controversial Committee recommendations concern the identification of alleged unsafe providers, and the periodic re-examining and re-licensing of health professionals.⁹ Another Committee recommendation creating interest is the proposal for a Center of Patient Safety ("Center") within the federal Agency for Healthcare Research and Quality. This recommendation seeks to address the fact that although multiple agencies are concerned with selected issues that influence patient safety, there is no focal point for patient safety in health care.¹⁰ The activities of such a center would include developing and disseminating tools for identifying and analyzing medical errors, as well as issuing an annual report on the state of patient safety.¹¹

Several entities (not-for-profit and/or state-supported) have studied different measures of performance for preventing and/or reducing medical errors. For example: (1) In 1995, Paul Ellwood (often considered the father of managed care) helped create the Foundation for Accountability (FACCT).¹² The purposes of FACCT are to develop measures of performance that are relevant to consumers, and to educate consumers

about how to use the information;¹³ (2) In Massachusetts, the Coalition for the Prevention of Medical Errors ("Coalition") was established in 1997 to develop and implement a statewide initiative to improve patient safety and minimize medical errors.¹⁴ The Coalition has a wide cross-section of members; and, (3) In New York State, an ad hoc committee emanating from the New York State Public Health Council is currently in the process of creating guidelines for health professionals regarding such topics as emergency care, patient assessment, sedation, and equipment maintenance. This is especially needed with the rise in outpatient and office-based surgery.¹⁵

The Committee concludes their report by identifying five principles that will enable entities to "build a safer health system." The principles are: to provide leadership; to respect human limits in the design process; to promote effective team functioning; to anticipate the unexpected; and, to create a learning environment.¹⁶ This author asserts that the fifth principle is the most important, and necessarily includes the other principles. That is, if the environment is one that is conducive to learning, the intellectual interchange,¹⁷ sincere role responsibility, and team "interaction" will naturally occur.

Building safety into processes of care is a more effective way to reduce errors than blaming individuals.¹⁸ Yet, when one has been hurt/harmed, it is a natural response to blame someone. It is very difficult to forgive when one, or a loved one, has been affected by a medical error. If entities concentrate on the Committee's fifth principle, then perhaps there will be very few times in the health arena when one will have to exercise the second part of an age-

old saying—"Good nature and good sense must ever join; to err is human, to forgive divine."¹⁹

Endnotes

1. "... I will prescribe regimen for the good of my patients . . . and never do harm to anyone. . . ." *Mosby's Medical Dictionary*, 4th edition, St. Louis: The Clarinda Company (1994).
2. Committee on Quality of Health Care in America, Institute of Medicine, *To Err Is Human: Building a Safer Health System* (2000).
3. *Id.* at 3.
4. *Id.*
5. Consider the recent ruling in the United States Supreme Court case of *Pegram et al. v. Henrich*, No. 98-1949 (June 12, 2000) <http://www.cornell.edu>.
6. *Supra* note 2, at 4.
7. *Id.* at 60.
8. *Id.* at 63.
9. *Id.* at 4-14.
10. *Id.* at 70.
11. *Id.* at 7. The New York State Legislature may implement a version of such a center.
12. Thomas Bodenheimer, *The American Health Care System: The Movement for Improved Quality in Health Care*, 340(6) *New England Journal of Medicine* 488, 490 (1999).
13. *Id.*
14. The Massachusetts Coalition for the Prevention of Medical Errors, *MHA Best Practice Recommendations to Reduce Medication Errors* (1999).
15. *Supra* note 2, at 165.
16. *Id.* at 166.
17. *Id.* at 4.
18. *Id.*
19. Alexander Pope, *An Essay on Criticism* (1711). Mr. Pope, an English poet/writer, lived from 1688-1744. He is considered to have been one of the most outstanding satirists of English literature. He is often credited with being the chief architect of the heroic couplet used in English literary technique.

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Health Law Section Executive Committee



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Elder Law Update

By Howard S. Krooks

The Elder Law Update column is designed to provide members of the Health Law Section with information regarding recent legislative changes and case law in the field of elder law. In this edition, I discuss *In re Bipin Shah v. Debuono* and *In re Kashmira Shah v. Helen Hayes Hospital*, two related cases which were recently decided by the New York Court of Appeals. In the lower court decisions, the Appellate Division, Second Department, determined that a) a New Jersey resident injured and institutionalized in New York was a New York resident for Medicaid eligibility purposes, and b) a guardian spouse could effectuate gift transfers on behalf of her incapacitated spouse, who was a patient in a New York hospital, for purposes of allowing the spouse to then refuse to use those assets for the payment of the costs related to the institutionalized spouse's long-term care. Motion for Leave to Appeal was granted by the Court of Appeals on both issues and the Court of Appeals affirmed the Appellate Court decisions on June 8, 2000. I also discuss the decision of the Court of Appeals in *Oxenhorn v. Fleet Trust Company and Estate of Marion F. Judson*, regarding the ability of Medicaid to recover Medicaid benefits from the estate of a deceased Medicaid recipient where, due to Medicaid error, the person was deemed eligible for benefits notwithstanding the availability of trust assets which rendered the person ineligible for benefits. Finally, I discuss certain provisions of the Foster Care Independence Act of 1999, which, among other things, imposes a penalty period on SSI eligibility due to a transfer of assets (similar to the penalty period imposed on Medicaid nursing home eligibility, but with more onerous consequences).

I. *In re Bipin Shah v. Debuono*¹ and *In re Kashmira Shah v. Helen Hayes Hospital*²

In re Bipin Shah and *In re Kashmira Shah* are two cases decided on the same day in July 1999 by the Appellate Division, Second Department. The cases together concerned two issues: 1) whether an out-of-state resident who is institutionalized in New York, who was not placed in the New York facility by another state and who became incapable of forming his or her own intent as to residency, is to be considered a resident of the State of New York for Medicaid eligibility purposes; and 2) whether an institutionalized spouse, acting by way of a guardian, may make a gift of assets to his or her spouse, thereby rendering the institutionalized spouse eligible for Medicaid, and allowing the spouse to then refuse to use those assets for the payment of nursing home costs.

The facts of the case are as follows:

On August 1, 1996, Bipin Shah suffered serious brain damage in a work-related accident that occurred in Amityville, New York.

Mr. Shah was admitted to Stony Brook Hospital in Suffolk County immediately after the accident, and on September 29, 1996, was transferred to Helen Hayes Hospital (HHH) located in Rockland County.

Mr. Shah has been comatose since the accident and is not expected to improve.

At the time of the accident, Mr. Shah resided with his wife and two children in New Jersey.

On January 16, 1997, Mrs. Shah executed a "spousal refusal" form.

On or about January 28, 1997, an application for Medicaid benefits was submitted to the Rockland County Department of Social Services (Rockland County DSS) on behalf of Mr. Shah.

Mrs. Shah then filed a petition pursuant to Mental Hygiene Law article 81 seeking to be appointed guardian for the personal needs and property management of her husband. One of the powers she sought was the power to "transfer all the assets of BIPIN SHAH . . . to his wife KASHMIRA SHAH for her support . . . and to qualify BIPIN SHAH for medical assistance."

HHH opposed the guardianship petition and the request to engage in Medicaid planning, asserting, among other things, that Mr. Shah's Medicaid application would most likely be denied because, at the time of the accident, Mr. Shah was a resident of New Jersey and would not qualify for Medicaid in New York. HHH contended that if Mr. Shah's assets were transferred to his wife and Mr. Shah did not qualify for Medicaid, then there would be no source of funds from which to pay Mr. Shah's medical bills incurred at HHH.

The State of New York also opposed Mrs. Shah's effort to be legally authorized to transfer her husband's assets to herself to support herself and their two children and to make Mr. Shah eligible for Medicaid.

On March 27, 1997, Rockland County DSS forwarded Mr. Shah's Medicaid application to Suffolk County DSS. Rockland County DSS reasoned that Suffolk County should be the responsible district because Mr. Shah's accident occurred in Suffolk County and he was initially hospitalized in Suffolk County.

On March 28, 1997, Rockland County DSS denied Mr. Shah's Medicaid application on the ground that he was not a resident of Rockland County.

On April 23, 1997, Suffolk County DSS also denied Mr. Shah's Medicaid application, but based its decision on the determination that Mr. Shah was not a resident of the State of New York.

On May 2, 1997, the Supreme Court, apparently unaware of Rockland and Suffolk County DSS's denials based upon Mr. Shah's residency, granted Mrs. Shah's guardianship petition and stated that "Federal Medicaid rules provide that for an institutionalized individual, residency is where the individual intends to reside. However, if the person is incapable of forming intent, then residency is where the individual is physically present." Thus, the Court determined that Mr. Shah would, from the standpoint of his residence, qualify for Medicaid in New York.

However, on July 2, 1997, the Commissioner of the New York State Department of Health determined, after a fair hearing, that the determinations of the Rockland and Suffolk County DSSs as to Mr. Shah's ineligibility for New York Medicaid on the basis that he was not a resident of Rockland County or New York State were correct. Thus, it was now determined by the New York State Department of Health that Mr. Shah was *not* entitled to New York Medicaid.

An order and judgment appointing guardian was entered on July 17, 1997, which appointed Kashmira Shah as guardian of Bipin Shah and which authorized the transfer of assets.

A. Discussion of the Case

Following the above sequence of events, Rockland County DSS and HHH appealed from the order and judgment appointing guardian. In addition, on October 14, 1997, in an

effort to challenge the Fair Hearing decision denying Mr. Shah Medicaid benefits, Mrs. Shah commenced a proceeding pursuant to CPLR article 78. This proceeding, by order of the Supreme Court dated February 9, 1998, was transferred to the Supreme Court, Appellate Division, Second Department, for determination. The Appellate Division decisions were appealed by the New York State Department of Health and the Rockland County Department of Social Services (in the case of the residency issue) and Helen Hayes Hospital and the Rockland County Department of Social Services (in the case of the Medicaid planning issue) to the Court of Appeals, which issued its decision on June 8, 2000.³

B. Residency Issue

The Appellate Division, Second Department, held that under the unambiguous terms of the applicable state and federal regulations (18 N.Y.C.R.R. § 360-3.2(g)(5)(iii) and 42 CFR § 435.403(i)(3), respectively), an individual who is institutionalized in the State of New York, who was not placed in a New York facility by another state, and who became incapable of indicating his or her intent at or after the age of 21 years is, for the purposes of Medicaid eligibility, to be deemed a resident of the State of New York. Thus, even though Mr. Shah, along with his wife and their two children, was a resident of New Jersey at the time of his accident, he is now to be considered a resident of New York for Medicaid eligibility purposes, because he is being cared for in a New York institution and is incapable of expressing his intention to live in New York.

The Court of Appeals affirmed, stating that the Appellants did not contend that New Jersey made a placement and therefore, Mr. Shah fell plainly under the core aspects of the residency regulations. Mr. Shah was institutionalized, he became incapacitated after age 21 and he was physically present in New York. According to the Court of Appeals, the State of New York was his resi-

dence for purposes of 42 CFR 435.403(i)(3). The Court also noted that "(1) [t]he agency may not deny Medicaid eligibility because an individual has not resided in the State for a specified period . . ." and "(2) [t]he agency may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution," citing 42 CFR 435.403(j)(1) and (2).

C. Medicaid Planning Issue

The Appellate Division, Second Department, held that a spouse who serves as her husband's court-appointed guardian pursuant to Mental Hygiene Law article 81 may transfer his assets to herself and then refuse to use those assets for his care, thus rendering him eligible for Medicaid. The Court further held that such a transfer constitutes a legitimate and prudent form of Medicaid planning.

The Court of Appeals affirmed, dismissing arguments made by 1) the Rockland County Department of Social Services that only a transfer of a part of the assets was permissible (citing language in the Mental Hygiene Law) and not the entire assets, and 2) the Department of Health's dissatisfaction with the practical complications of its eventual recoupment option (since Mrs. Shah's spousal refusal allows Mr. Shah to qualify for Medicaid initially and forces Medicaid to pursue reimbursement after benefits are paid).

D. Notable Language in *Shah* Regarding Medicaid Planning Guardians

Aside from deciding the residency and Medicaid planning issues favorably to the Shahs, the Appellate Division decisions in *Shah* contain important language that support the premise that a guardian may engage in Medicaid planning on behalf of an incompetent individual under article 81 of the Mental Hygiene Law. While this principal was thought to have

been well-established through a series of lower court decisions and the *John "XX" case* (decided by the Appellate Division, Third Department in 1996),⁴ the Second Department in *Shah* joined the Third Department in so concluding and, after a long line of lower court decisions, the Court of Appeals in *Shah* also has agreed.

In the Appellate Division decision in *Shah*, Justice Bracken wrote that the complexities of the law that come into play as

. . . hapless middle class Americans seek to save themselves from financial ruin as the result of astronomical nursing home costs, should never be allowed to blind us to the essential proposition that a man or a woman should normally have the absolute right to do anything that he or she wants to do with his or her assets, a right which includes the right to give those assets away to someone else for any reason or no reason . . . Mr. Shah, who had the unrestricted right to give up his assets to his wife, or to his children, or to anyone else for that matter, at all times up to the moment of his terrible injury did not . . . lose that fundamental right merely because he is now incapacitated and financial decisions on his behalf must necessarily be made by a surrogate.

Judge Bracken further stated, . . . no agency of the government has any right to complain about the fact middle-class people confronted with desperate circumstances choose voluntarily to inflict poverty upon themselves when it is the government itself which has established the rule that poverty is a prerequisite to the receipt of

government assistance in the defraying of the costs of ruinously expensive, but absolutely essential, medical treatment.

In affirming, the Court of Appeals noted

[w]e agree with the common sense verity uttered by the Appellate Division that the transfer here was properly authorized because '[t]here can be no quarreling with the Supreme Court's determination that any person in Mr. Shah's condition would prefer that the costs of his case be paid by the State, as opposed to his family.'

II. Medicaid Overpayment Is Recoverable Although Payment was Due to Administrative Error (*Oxenhorn v. Fleet Trust Company and Estate of Marion F. Judson*).

We all know that when it comes to paying for long-term care in a nursing home Medicaid is the payor of last resort, meaning that all other available resources must be used before Medicaid will kick in. The "last resort" rule is the underlying policy for several recovery statutes that permit Medicaid to recoup payments made by the state on behalf of recipients. One such statute is Social Services Law § 369(2)(b)(i), which provides that:

Notwithstanding any inconsistent provision of this chapter or other law, no adjustment or recovery shall be made against the property of any individual on account of any medical assistance correctly paid to or on behalf of an individual under this title, except that recoveries must be pursued: (A) upon the sale of the property subject to a lien imposed on account of medical assistance paid to an individual * * * or from the

estate of such individual; and (B) from the estate of an individual who was fifty-five years of age or older when he or she received such assistance.

Thus, Medicaid is precluded from seeking recovery of benefit payments that were "correctly made." Although "correctly made" is not defined in the Social Services Law, Section 106-b of the Social Services Law (entitled "Adjustment for Incorrect Payments") provides:

A social services official shall * * * take all necessary steps to correct any overpayment * * * to a public assistance recipient. * * * For purposes of this section, overpayment shall include payments made to an eligible person in excess of his needs as defined in this chapter and payments made to ineligible persons.

On the flip side, there is no statutory restriction on Medicaid's ability to recover Medicaid benefits that were incorrectly paid.

In *Oxenhorn v. Fleet Trust Company and Estate of Marion F. Judson*,⁵ Appellant, Commissioner of the Department of Social Services for Columbia County, sought to recover Medicaid benefits paid to the decedent, Marion F. Judson, who was the named beneficiary of a self-settled, irrevocable trust. The parties acknowledged that had the Department included the trust principal in its eligibility determination, the decedent would not have been eligible for Medicaid benefits. Respondents contend that because the Department made an administrative error that was not due to misrepresentation or fraud, the benefits should be deemed "correctly paid" to decedent within the meaning of Social Services Law § 369(2)(b)(1) and are therefore not recoverable.

Marion Judson resided in a nursing home from May 1, 1989 until her death on December 26, 1995. For the

first two years, the decedent paid privately for the cost of her nursing home care. Her son submitted a Medicaid application on her behalf on May 1, 1991 to the Columbia County Department of Social Services (the "Department"). On the application, her son disclosed that the decedent was the named beneficiary of a self-settled, irrevocable trust and a copy of the trust agreement was provided. The trust provided that the trustee had discretion to apply "all or such part of the principal of this trust * * * for the support, care and maintenance of [decedent] during [her] lifetime."

Although this first application was denied, the Department granted eligibility to the decedent upon the second application made on September 4, 1991, which contained the same trust information. The department included trust income but did not include trust principal (about \$150,000) as an available resource in determining decedent's eligibility for Medicaid. From October 1991 through December 26, 1995, all income from the trust was paid directly to the Department (during this time the decedent received Medicaid benefits totaling \$121,302).

The Department commenced this action against the trustee and decedent's sons as co-executors of her estate (decedent's sons are the sole beneficiaries of the trust). The action alleged, *inter alia*, a cause of action under Social Services Law § 369(3), asserting that it could recover benefits paid from the trust corpus because the decedent had a "beneficial interest" in the trust corpus at the time she received Medicaid benefits. The Appellate Division held that the benefits at issue were "correctly paid" pursuant to Social Services Law § 369(2)(b)(i) and that the Department was therefore precluded from recovering the payments under Social Services Law § 369(3).⁶ The Appellate Division reasoned that because the Department had found the decedent eligible for Medicaid and there was no claim of fraud or misrepresentation on the application

process, the benefits were "correctly paid."

The Court of Appeals reversed the Appellate Division, holding that the Department paid benefits to an ineligible individual by not including the trust principal in its eligibility determination. The Court further stated that a finding of fraud or misrepresentation was not required to conclude that benefits were incorrectly paid. The Court reasoned that overpaid benefits are not deemed correctly paid when they are not paid "in accordance with lawful authorization."

III. New SSI Provisions Subject Asset Transfers to Penalty Periods for SSI Eligibility Purposes.

A. Introduction

The Foster Care Independence Act of 1999 ("the Act"), signed by President Clinton on December 14, 1999, makes several notable changes to the Supplemental Security Income (SSI) program, as detailed in Title II of the Act, *SSI Fraud Prevention*. Two of the changes will have a significant impact on planning for those elderly and disabled persons who are or will become eligible for SSI: 1) Transfers of assets for less than fair market value will now create a period of ineligibility for SSI benefits, and 2) the income and assets of certain self-settled trusts will now be considered income and resources for SSI eligibility purposes.

B. Disposal of Resources for Less Than Fair Market Value Under the SSI Program

Under the new rules regarding transfers of assets, an SSI applicant/recipient will incur a penalty period during which he or she will be ineligible for SSI benefits based on the value of assets transferred. The Act implements a 36-month look-back period that begins immediately prior to the date the individual applies for SSI or the date of the transfer, whichever date is later. The effective date of the Act is December 14, 1999.

Accordingly, this new rule regarding asset transfers applies only to transfers of assets for less than fair market value made on or after December 14, 1999 and made within the 36-month look-back period. The period of ineligibility is calculated by dividing the amount of the transfer by \$599 (the total of the SSI federal benefit rate of \$512 plus the applicable New York state supplement of \$87). Unlike the Medicaid penalty period, where there is an unlimited penalty period, the maximum penalty period for SSI purposes is 36 months. However, like the Medicaid penalty period, the penalty starts on the first day of the first month "in or after" the month during which resources are transferred. It is not clear whether the Social Security Administration will commence the penalty period in the month of the transfer or the month following the month of transfer. For Medicaid purposes, New York calculates the penalty period from the first day of the first month *after* which resources were transferred.

Example: Mr. Jones applies for SSI on September 1, 2000. He transferred \$11,980 to his son on January 1, 2000. Since the transfer occurred during the 36 months immediately prior to the date of his application and after December 14, 1999, he will be ineligible for SSI benefits for 20 months ($\$11,980 \div \$599 = 20$ months), starting from the first day of the month following the month of the transfer (February 1, 2000).

If an SSI applicant/recipient owns an asset jointly with another person, anything that the applicant/recipient or the other person does that causes the applicant/recipient's ownership or control of the asset to be reduced will be considered a transfer for less than fair market value resulting in a penalty period.

In the case of a transfer by the spouse of an applicant/recipient that results in a period of ineligibility for the applicant/recipient, the Commissioner of Social Security must appor-

tion the period (or any portion of the period) among the applicant/recipient and the applicant/recipient's spouse if the spouse becomes eligible for SSI benefits.

C. Exempt Transfers

The transfers that are exempt for SSI eligibility purposes are the same as those transfers that are exempt from the Medicaid transfer rules. Thus, a period of ineligibility will not be imposed on a transfer by an applicant/recipient or the applicant/recipient's spouse where:

- 1) The resources are a home and title to the home was transferred to:
 - a) a spouse;
 - b) a child under 21, or child of any age who is blind or disabled;
 - c) a sibling who has an "equity interest" in the home and who was residing in the home for a period of at least one year immediately before the date the applicant/recipient became institutionalized; or
 - d) a son or daughter who was residing in the home for a period of at least two years before the date the applicant/recipient became institutionalized and provided care to the applicant/recipient which permitted him or her to live at home; or
- 2) The resources were transferred:
 - a) to the applicant/recipient's spouse or to another for the sole benefit of the applicant/recipient's spouse;
 - b) from the applicant/recipient's spouse to another for the sole benefit of the spouse;
 - c) to the applicant/recipient's child of any age who is blind or disabled;
 - d) to a trust established for the sole benefit of the applicant/recipient's blind or disabled child of any age; or
 - e) to a trust established solely for the benefit of an individual under 65 years of age who is disabled; or
- 3) Satisfactory showing is made to the Commissioner of Social Security that:
 - a) the applicant/recipient intended to dispose of the resources at fair market value or for other valuable consideration;
 - b) the resources were transferred for a purpose other than to qualify for SSI benefits;
 - c) all resources transferred for less than fair market value have been returned to the applicant/recipient; or
- 4) the denial of eligibility would work an undue hardship as determined on the basis of criteria established by the Commissioner of Social Security.

In the Medicaid context, a partial return of transferred assets is permissible and will reduce the applicable penalty period in proportion to the assets transferred.⁷ The SSI legislation would seem to indicate that *all* (see item 3(c) above) assets would have to be returned to reverse a penalty period.

D. Treatment of Assets Held in Trust Under the SSI Program

Under prior law, a person could qualify for SSI benefits by creating a Special Needs Trust into which he or she transferred his or her assets. This

strategy would allow the SSI applicant/recipient to use SSI income to pay for the necessities of food, clothing and shelter, and use the trust assets to pay for items other than those necessities.

Under the new law, if the trust income or assets can be used for the benefit of the SSI applicant/recipient, then the trust income and/or assets will be considered an available resource for SSI eligibility purposes. One exception to the new law, however, allows the income and assets of such Special Needs Trusts to be disregarded when determining SSI eligibility if the trust contains a "pay-back" provision. The "pay-back" provision must provide, upon the beneficiary's death, for reimbursement to the government for any SSI benefits received by the beneficiary. Please note that only trusts established after January 1, 2000 must include a "pay-back" provision. All trusts existing prior to January 1, 2000 will be grandfathered under the prior regulations. Another exception applies to those trusts created by will. Such trusts are not regarded as an available resource to the SSI applicant/recipient.

Aside from the two exceptions just explained, a trust that is established on or after January 1, 2000 with the assets of the applicant/recipient or the applicant/recipient's spouse, whether income or resources, is considered an available resource, regardless of:

- 1) whether the trust is revocable or irrevocable;
- 2) the purpose for which the trust is established;
- 3) whether the trustee(s) has/have or exercise any discretion under the trust;
- 4) any restrictions on when or whether distributions may be made from the trust; or
- 5) any restrictions on the use of distributions from the trust.

A revocable trust will be considered an available resource to the applicant/recipient. An irrevocable trust, where there are circumstances under which payment from the trust can be made to or for the benefit of the applicant/recipient or the applicant/recipient's spouse, will be considered an available resource to the extent of the portion of the trust from which the payment could be made.

The Commissioner of Social Security may waive any penalties if the Commissioner determines that such penalties would work an undue hardship (as determined on the basis of criteria described by the Commissioner) on the applicant/recipient.

E. Recovery of SSI Overpayments

If any payment of more than the correct amount is made to a representative payee on behalf of an individual after the individual's death, the representative payee shall be liable for the repayment of the overpayment. This section of the Act applies to overpayments made 12 months or more after December 14, 1999.

In the case of an individual or eligible spouse to whom a lump sum is payable, one means of recovering any overpayment is to make the adjustment or recovery from the lump sum payment in an amount equal to the lesser of the amounts of the overpayment or 50 percent of the lump sum payment. This section of the Act takes effect on December 14, 2000 (12 months after the enactment date of the Act), and shall apply to amounts incorrectly paid which remain outstanding on or after such date.

With respect to any SSI overpayments, the Commissioner of Social Security may now use the same debt collection practices as those available for collecting Social Security overpayments. Such tools include: credit

bureau reports, private debt collection agencies, and state and federal "intercepts." This amendment applies to overpayments outstanding on or after December 14, 1999.

F. Penalties for False or Misleading Statements

SSI benefits may now be suspended for those individuals who 1) knew or should have known that they were making a false or misleading statement or representation of material fact used in determining eligibility for SSI benefits or 2) have omitted a material fact. The duration of nonpayment of benefits is six months for the first violation, 12 months for the second violation, and 24 months for any additional violations.

G. Exclusion of Representatives and Health Care Providers Convicted of Violations from Participation in Social Security Programs

Penalties have also been added barring representatives (including attorneys) and health care providers from participating in the OASDI and SSI programs if they provide or assist in providing false information for individuals so that such individuals may obtain government benefits. The bar lasts five years for the first offense, ten years for the second offense, and permanently for the third.

H. Computer Matches with Medicare and Medicaid Institutionalization Data

The SSA Commissioner must now conduct periodic computer matches with data maintained by the Secretary of Health and Human Services. This will allow the Commissioner to ascertain whether an applicant/recipient is providing the different agencies with consistent information. If any discrepancies in information are found, the Commissioner would have grounds upon which to further investigate.

I. Access to Information Held by Financial Institutions

SSI applicants and recipients may now be required to authorize SSA to obtain financial information from financial institutions when such information is determined by the Commissioner of Social Security to be necessary to determine the applicant/recipient's eligibility for, or amount of, SSI benefits. If the applicant/recipient refuses to authorize SSA to obtain the financial information or revokes an authorization already given, the Commissioner of Social Security may, on that basis, determine that the applicant/recipient is ineligible for SSI benefits.

Endnotes

1. 694 N.Y.S.2d 88, 257 A.D.2d 256 (N.Y. App. Div. 2d Dep't, July 6, 1999).
2. 694 N.Y.S.2d 82, 257 A.D.2d 275 (N.Y. App. Div. 2d Dep't, July 6, 1999).
3. 2000 WL 730801, 2000 N.Y. Slip Op. 05628 (N.Y., June 8, 2000) (No. 83, 84).
4. *In re John "XX,"* 226 A.D.2d 79, 652 N.Y.S.2d 329 (3d Dep't 1996).
5. 94 N.Y.2d 110, 700 N.Y.S.2d 413 (N.Y. Nov. 18, 1999).
6. 258 A.D.2d 729, 686 N.Y.S.2d 875 (App. Div. 3rd Dep't, Feb. 4, 2000).
7. 96 ADM-8.

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Hold on to Your Hats, the New Federal Regulations on Medical Information, Transmission, Security and Privacy Are Coming

By Anne Maltz

Introduction

The purpose of this article is to bring to your attention the significant and imminent changes in the regulatory world with regard to electronically transmitted medical information. At the moment there is no coordinated federal or New York State system that addresses the security and privacy of medical information which is transmitted electronically. This is all about to change as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)¹ and the regulations which will be finalized over the course of this year and 2001. The purpose of this article is to highlight the main components of the proposed rules and explain their impact upon the health care system. The article will begin with a very brief overview of the law pre-HIPAA, and go on to discuss the two basic components of the proposed regulations; electronic transfer and security of data and privacy of medical information. The article will touch on federal preemption issues and close with a practical discussion of compliance.

Privacy and Confidentiality Pre-HIPAA

Currently, there are a number of laws which address in piecemeal fashion the confidentiality of medical information. Drug or alcohol abuse prevention and treatment records are protected.² Records that are created as part of treatment under the Medicare program are protected; the protective system varies with the type of entity which creates the record.³ Records created during research on human subjects are protected.⁴ Health care records of students created at school are protected.⁵ In addition, there are New York state laws which address privacy and transferability of medical records as well as special classifications of records like HIV/AIDS and mental health records. For a good overview of the New York privacy and confidentiality laws I'd recommend Frank Serbaroli's articles "Confidentiality of Medical Records, Parts I and II."⁶

Into this piecemeal world enters HIPAA's Administrative Simplification rules.⁷ The goal of this section of HIPAA is to improve the efficiency and effectiveness of the health care system and to encourage development of a health information system by establishing standards and requirements to facilitate electronic transmission. To accomplish these goals the Health & Human Services Department, (HHS) has created standards for the electronic transfer and security of data in order to enhance the ability of various parts of the health care system to com-

municate. It has also created standards to regulate and protect the individually identifiable medical information that belongs to each patient.

Who Are the Regulations Directed Towards?

The proposed regulations ("Regulations") are directed towards covered entities who are transmitting health care information electronically in the course of a transaction. The first step to grasping the significance of the Regulations is to understand the defined terms "covered entity," "health information," "electronic transmission" and "transaction."

The term *Covered Entity* is defined to include health plans, health care providers and health care clearinghouses. A health plan is an entity that provides or pays the cost of medical care. Examples of health plans are health insurance, the health maintenance organizations or group health plans administered pursuant to ERISA. A health care provider is any person or organization which furnishes, bills or is paid for health care services or supplies in the normal course of business. Providers include institutional providers (i.e., hospitals and nursing facilities), or individual providers such as physicians or nurses. A health care clearinghouse is a public or private entity that processes or facilitates the processing of non-standard data elements of health information into standards data elements. This is the type of entity that is hired, for example, by a physician practice, to reformat the practice's claims prior to submission for payment.

Health Information: Health information is defined as all recorded information that relates to the past, present or future physical or mental condition of an individual or the provision of or payment for care rendered to such individual. **Electronic Transmission** is the transmission of information via computer, disk or tape and does not include transmission through fax or telephone.

Sixty-two percent of *all claims* are processed electronically. Hospitals and pharmacies process 80 percent of their claims electronically. Once the claims are transmitted electronically, the information is protected and remains protected even after it is printed out of the computer, becomes paper and is put in the patient's chart.

Transaction: A transaction is defined as the exchange of information between two parties to carry out financial or administrative activities related to health care. There are nine specific transactions listed in the Regulations.

These are:

1. Health claims;
2. Health claim attachments;
3. Enrollment and disenrollment in a health plan;
4. Eligibility for a health plan;
5. Health care payment and remittance advice;
6. Health plan premium payments;
7. First report of injury;
8. Health claim status;
9. Referral certification authorization; plus other financial and administrative transactions as the Secretary of Health and Human Services determines. This would include coordination of benefits.

So, when any one of the covered entities is transmitting any type of health care information electronically, via a computer or a disk, in the course of a transaction, that information is protected under these Regulations and guided by the rules that we will now discuss.

Electronic Transfer of Data and Electronic Security

HHS is obligated, pursuant to HIPAA, to adopt standards in consultation with pertinent organizations. These standards, once adopted and finalized, will become the universal format for the data elements for all components of the nine plus transactions discussed above. Specifically, HIPAA requires standards to be set in five areas:

1. Unique health identifiers;
2. Code sets;
3. Electronic security of health information;
4. Electronic signature;
5. Transfer of information among health plans.

Unique Health Identifier: HHS must adopt standards for the creation of unique health identifiers and the purposes for which they may be used. A unique health identifier is a numeric code which, by itself, is sufficient to identify a member of the health care system. There are four kinds:

1. *Individual:* The individual code has been placed on hold until the privacy regulations have been finalized.
2. *Employers:* The code for employers was proposed in 1998 and was expected to be finalized in June of 2000.

3. *Health Plans:* The code for health plans was expected to be proposed in June of 2000.
4. *Health Care Providers:* The code for health care providers was proposed in May of 1998 and was expected to be finalized in June of 2000.

Standards for Electronic Transactions: HHS must adopt standards that select code sets for each data element for the nine plus transactions listed above. Once adopted, the code sets must be disseminated to all members of the health care system. HHS adopted and issued such standards for eight electronic transactions and the code sets used in those transactions on August 11, 2000.⁸

Electronic Security of Health Care Information: HHS must adopt standards that account for the technical capabilities of the recording system which will be implementing the standards. Further, HHS is required, based on such standards to create safeguards to protect the information from reasonably anticipated threats to security; unauthorized use and disclosure of information; and to monitor and assure compliance.

Electronic Signature: HHS is required to develop the standard for transmission and authentication of electronic signature for the nine plus transactions discussed above.

Transfer of Information Among the Health Plans: HHS must adopt uniform data standards so that health plans can share information among themselves regarding such important information as coordination of benefits and sequential claims processing. Once compliance is required, a health plan may not refuse to handle a properly formatted claim.

Privacy Regulations for Individually Identifiable Health Care Information

Who Are the Regulations Directed Towards?

These regulations are directed at Covered Entities plus business partners who are transmitting individually identifiable health information in the course of a transaction. The term "Business Partner" is a legal fiction created by HHS to cover all subcontractors who do business with a Covered Entity and receive protected information in the process; for example, third party administrators, claims processing companies, accounting firms, attorneys. If HHS had not created such fiction, the Regulations would not have the far-reaching effect Congress intended. Business partners and covered entities are required to enter into "chain of trust" agreements in which the business partner is held to the covered entity's obligations with regard to confidentiality and privacy. Under the proposed regulations, individuals who submit personally identifiable medical information are third-party beneficiaries of the chain of trust agreements. Some commentators have argued that individuals should not be made third-party

beneficiaries to such agreements because the Regulations do not create an independent right of action, and in effect the third-party beneficiary rule does create such a right of action. It will be interesting to see how the final rules come out on this issue.

Individually Identifiable Health Information is health information that contains personally identifying information such as name, address, social security number; items that make it clear who the patient is. Once such information is *electronically transmitted*, as discussed earlier, it becomes protected information if it is transmitted in the course of the nine plus transactions discussed above.

HHS has expanded the list of nine plus transactions to include uses and disclosures other than treatment payment and health care operation. Commentators, including the American Hospital Association, are concerned that creating an expanded list will ultimately limit the number of transactions that are covered under the Regulations.

When Is Individually Identifiable Information Not Protected?

1. If the information is not transmitted by a covered entity, i.e., an individual transmitting their own information to a Web site is not protected because an individual is not a covered entity. However, if a doctor or a pharmacist at the Web site sends information back which includes personally identifiable information as part of a transaction that information becomes regulated.
2. No-fault insurers, property and casualty insurers are not covered entities. Personal medical information created as a result of a car accident and submitted to a no-fault insurer is not protected.
3. Information not electronically sent is not protected under the Regulations.

So What Are These Privacy Protections?

The patient's right to information about the privacy protections and the patient's right to authorize access to their information. Patients, for the first time are entitled to specific rights and expectations with regard to the handling and release of their personally identifiable information. There are five patient rights to information.

Patient's Right to Information

1. Notice

The covered entity must provide plain English written notice of its policies and procedures regarding protection of individually identifiable health information. The notice must also include an explanation of the complaint process, including contact person, the fact that certain disclosures may only be made with specific authorization

which may be revoked. It must provide notice of a policy change before such implementation of such change.

2. Access

An individual is now entitled to inspect and copy their records unless such inspection would endanger the life of that individual or another. Any denial requires a written explanation of the basis of such denial as well a description of the complaint process.

3. Amendment and Correction of the Record

An individual is entitled to recommend corrections or amendments to their medical record. The entity must respond within 60 days of the request. If it agrees to make such correction it must indicate on the record that it was corrected and disseminate the correction to entities that would have relied on the information. If the covered entity refuses to make the correction it must provide a written explanation including notice that the patient has the right to file a complaint and add a statement of disagreement to their record.

4. Accounting for Disclosures

The covered entity is obligated to keep track of certain disclosures. That being said it has no obligation to account for disclosures which occur in the course of treatment, payment or health care operations or if such disclosure would impede law enforcement or oversight agency activities. The covered entity must respond to an individual's request within 30 days of such request. The response must include the date and to whom the information was sent, a description of the information sent, a copy of the disclosure request and notice to the business partners because they must cooperate as well.

5. Restriction of Use and Disclosure of Information

Individual may request that information released in the course of treatment, payment or health care operations be limited either in amount or to whom it is sent. However, the covered entity need not honor the request. That being said, it's hard to see procedurally which covered entity would be willing to tailor its release of information to individuals. In practice I suspect that this right will not be much of a right at all. In sum, there are five basic rights, maybe really four: notice, access, amendment and accounting for disclosures.

6. Minimum Necessary Standard

So far, the Regulations look very pro-consumer. Covered entities must track and provide information with the consequent administrative burden. In addition, in making any permissible disclosure, providers are required to send only the minimum amount of information necessary to get the point across. The decision of what's necessary is to be made case by case using an objective reasonableness standard.

Commentators have noted that it is dangerous for one person to determine how much information the next person should have. Especially if the information is medical and the people making decisions are clerks referring limited medical information.

Patient Authorizations

Patient authorizations are not required and accounting is not necessary for treatment, payment, and health care operations, i.e., the original nine transactions. There are a large number of additional transactions as mentioned earlier, that are disclosable without specific authorization but these must to be accounted for. For example: disclosures for health and oversight activities, judicial and administrative proceedings, coroner's and medical examiner's, law enforcement officials, government health data systems activities, the facility patient directory, financial institutions claims processing activities. . . . The list goes on and on and appears in the regulations.⁹

The common thread for the few cases where an authorization must be obtained is money. Any disclosure for marketing, renting or bartering the information or releasing the information to a non-health-related division of the same company requires authorization. For example, an insurance company that sells both a health product and a life insurance product cannot share the information it's gained on the health side with its life side without a specific authorization. A covered entity may not share the protected information with the individual's employer nor may it share with anybody for purposes of fund raising or with a health plan prior to an individuals' proposed enrollment.

Where specific authorization is required it must be executed. A model form appears in the Regulations.¹⁰ The elements that are important to include in such an authorization are:

- a description of the information to be disclosed;
- to whom it would be disclosed;
- who made the request;
- a date and expiration date;
- the purpose of the request;
- the fact that the individual may refuse to sign;
- the fact that agreeing to authorize may not be a condition of treatment.
- Finally, the covered entity must disclose the fact of monetary gain.

An issue which was not discussed, but will need to be addressed in the final regulations, is that Regulations refer purely to individual data and not group data. NCQA and others require health plans to collect and transmit group

outcome information. Nothing in the Regulations specifically permits this release. This issue should be clarified. In a related issue, there is no recognition of non-governmental research entities and their need for data. For example, while there is a methodology for transmitting de-identified data to these types of organizations, the de-identified data section is so extensive that the data that comes out is useless because it has no content. We don't believe that it was the intention of the regulators to hobble research activity and so we expect that there will be some change in the final regulations.

Complaints, Penalties for Noncompliance

The regulations take great trouble to outline HHS's philosophy with regard to compliance. Basically, HHS plans to take a cooperative approach to provide technical assistance and to encourage covered entities to comply. However, HHS makes it clear that it recognizes that there will always be entities that are not in compliance with regulations. For those entities, there are civil and criminal penalties.

How Does the Process Work?

The patient himself, his/her representative, or a whistle blower has the right to file a complaint with HHS formally or informally. The complainant must identify the entity's alleged violation and file the complaint within 180 days of such violation. There is no time frame in which HHS is required to complete investigation of the complaint. Covered entities, as you may have guessed, are required to maintain records of authorizations and all the policies and procedures that they've put into place. They must participate in compliance reviews and provide information to HHS upon demand. The regulations specifically state that an entity may not intimidate or discriminate or take retaliatory action against any employee who opposes a practice by an entity that is made unlawful by the Regulations. This prohibition is important because there is no private right of action and there is no built in statutory monitoring system.

Complaint Resolution: Initially HHS will attempt to reach an informal resolution. If unsuccessful, it may make a formal finding of noncompliance and either initiate civil penalties or refer the matter to the Department of Justice for criminal prosecution. The formal finding may also trigger a full-scale review by HHS. This alone could be enough of an impetus to settle.

Civil Penalties: HHS is obligated to initiate civil action within six years of initial claim presentation. The accused party is entitled to written notice and an opportunity for a hearing with counsel prior to a final adverse determination. Keep in mind that if HHS has six years within which to initiate the action, the issue may be stale by the time it is argued, in which case counsel will have a good argument to negotiate a reduced sanction.

The monetary penalties are set at a maximum of \$100 for each violation, with a maximum \$25,000 for all violations of identical requirements which occur in one year. Needless to say, it is very easy to imagine four or five repetitive violations maxing out until the covered entity owes more than \$100,000. Civil penalties are not available if the violation is otherwise punishable under the criminal penalty statute or if the noncompliance was not discovered and not discoverable. The determination of what was or was not discoverable is another area ripe for argument. Appeal of an HHS decision must be made within 60 days or such determination is final. The decision may be appealed to the Court of Appeals.

Criminal Penalties: Criminal penalties are available for wrongful and knowing disclosure of information which violates the Regulations. For example, misuse of a unique health identifier or the intentional improper use of individually identifiable health information, i.e., a claims processor gossips about an individual's medical record with another person.

The punishment for violations of this type is up to \$50,000 or imprisonment of up to one year or both. If information is obtained under false pretenses for example, a news reporter poses as an official of a health plan in order to get the medical record of a famous person, the punishment is a maximum of \$100,000 or imprisonment of up to four years or both. If the information is obtained with the intent to sell, transfer or use for commercial advantage or personal gain or malicious harm, as in the case of a health plan wanting to help its bottom line, by selling its data to a marketing company without obtaining authorization from all of the patients, the fine would be up to \$250,000 or imprisonment of up to ten years or both.

Federal Preemption

What About State Law?

The federal regulations provide for "floor preemption." This means that the federal regulations will supercede any contrary provision of state law, except in six cases: state laws that regulate (i) fraud and abuse; (ii) health and insurance plans; (iii) reporting on health care delivery or costs; (iv) controlled substances; (v) the privacy of individual medical records more stringently than do the federal laws; or (vi) other purposes determined by the HHS.

So How Can You Tell When Preemption Has Occurred?

Well, you can't conclusively. Only the state may request a determination on preemption. There are certain situations where no HHS determination is required, these are: public health, surveillance, licensing, auditing, or health plan regulatory functions of the state.

Areas Where Preemption Is Likely to Increase Privacy Protection

1. Patients are required to be notified of their rights.
2. Patients may not be refused treatment for a refusal to sign authorization if it is for any purpose other than treatment, payment or health care operations.
3. Patients have the right to receive an accounting of all disclosures.

Areas in Which New York Law May Be More Stringent Than Federal Law.

1. **Legal Proceedings:** New York requires a patient consent or a court order for the release of patient information during litigation. The federal regulations permit even a nonparty to receive medical records once an attorney certifies that such records concern a litigant.
2. **Access to Medical Records:** The federal regulations permit access within 30 days. New York State requires access within ten days.
3. **HIV Disclosure:** New York State has a specific formal patient consent for release of HIV information. The penalty is \$5,000 per violation. Federal law penalty for willful disclosure is jail time of up to a year or \$2,000 fine or both.
4. **Deceased Persons:** Federal law says covered entities must protect information for two years. The state has no similar limit for protection of such information.

Compliance

Large entities are required to comply within two years and smaller entities within three years from publication of the final regulations. Individual final regulations are projected to be published throughout 2000 and possibly 2001 so compliance phased in.

Now, What to Do?

Policy Manual

In order to be compliant with the Regulations, a covered entity, i.e., a hospital, health plan, health care provider, or a health care clearinghouse and its business partners, must create a compliance program which includes an information policy manual. The first step toward developing such a program is to determine the information flow, from the first contact when the patient steps into the office to the last contact when the information leaves the office, plus every step in between. Once this is determined, a policy manual can be developed that

is customized to the entity's needs. No specific guidelines are provided by HHS, thus the size and complexity of the manual to be developed is discretionary. It is obvious that stringent computer security procedures and clear information policies properly taught are the best methods of preventing unauthorized disclosure and ultimate liability. A noninclusive list of the areas ripe for technical policies are:

- authorized use of computer equipment, acquisition and use of software, prevention of computer viruses, avoidance of copyright infringement;
- use and protection of portable computing equipment and information contained on it;
- e-mail and voicemail protocols;
- policies regarding automated list serves;
- guidelines for use of the Internet and protecting entities from online risks; and
- policies governing development of sites for the World Wide Web.

A noninclusive list of the areas ripe for privacy policies are:

- policies regarding use, transfer and release of information by each "person" in the system;
- policies regarding notice, access, amendment/correction accounting and restriction of records;
- a policy regarding the "minimum necessary" application;
- a policy regarding releasing information not in the course of treatment; and
- a policy regarding obtaining specific authorizations.

Training

Once the policy manual is developed, the training program and documentation of such program must be implemented. All employees who have access to the information covered by the Regulations; that's health information, as well as personally identifiable health information, are required to be trained in the proper protection of such information. The training will vary with the type of information the individuals have access to. For example, once the software is upgraded to track internal and external complaints, the policy is put into place, staff will have to be trained and allocated to respond to patient's complaints in a timely fashion. Individuals who merely input claims data will not have to be trained on complaint protocols.

What Does the Future Hold? What Is the Impact of These Significant Regulations on the Health Care Delivery System?

Even though we do not have the final Regulations and there are controversial issues to be settled, there are certain things that we do know with certainty. First, a large amount of money and time will have to be allocated to the analysis of the organization and the creation and implementation of compliance protocols. This cost coupled with the potential penalties for noncompliance and third party litigation will add an additional burden to health care system participants. A cottage industry will develop that will assist covered entities to achieve and maintain compliance. The changes will enhance communication between the different members of the health care system. There may be consolidation in the claims processing industry. Entities that do their own processing may choose to outsource rather than bear the expense of compliance, smaller processing companies may close rather than bear the upgrade expense. There certainly should be less paper, whether that happens or not remains to be seen. Finally, patients, for the first time, will have privacy protections for their health information when it is electronically transmitted.

Endnotes

1. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (codified in scattered sections of 42 U.S.C. and 18 U.S.C.).
2. 42 U.S.C. 290ee-3 & 290dd-3, 42 CFR part 2.
3. Hospitals, 42 CFR § 482.13, Long Term Care Facilities 42 CFR § 483.10 Home Health Agencies, 42 CFR § 484.48.
4. 45 CFR part 46.
5. 20 U.S.C. § 12 329, 34 CFR part 99.
6. Francis J. Serbaroli, *Confidentiality of Medical Records, Parts I and II*, N.Y.L.J., June 1, 1994, at 3, and July 6, 1994 at 3.
7. 42 U.S.C. §§ 1320d *et. seq.* (1998).
8. 65 Fed. Reg. 50311 (2000) (to be codified at 45 CFR parts 160 and 162).
9. 64 Fed. Reg. 59955 (1999) (to be codified at 45 CFR part 164.510) (proposed Nov. 3, 1999).
10. 64 Fed. Reg. 60065 (1999) (to be codified at 45 CFR part 164.508) (proposed Nov. 3, 1999).

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Health Care Providers Should Be Wary of Referrals to Family Members

By Melissa M. Zambri

Most providers of health care know that there is an increased level of scrutiny surrounding their profession as of late and the importance of compliance with complex laws, rules and regulations. While much has been written directing providers on the ins and outs of laws regarding self-referrals, there has been little in the way of warning providers about the dangers of referring to those that are within his or her family. Having recently come across discussions regarding such situations and having dealt with physicians who were related but unknowing of the complex rules, this article seeks to warn providers and their counsel of the pitfalls that exist when referring to family members that are also health care providers.

Federal regulations, traditionally known as the Stark laws, prevent a physician from making certain referrals to family members where the referral is for certain health care services, the family member has a certain financial relationship with the referred-to entity, and Medicare or Medicaid is to pay for the services.¹ Referral is defined broadly and generally includes any ordering of an item or service, request for consultation, or establishment of a plan of care.² Family members that fall under the statute are: husbands; wives; natural or adoptive parents; children; siblings; stepparents and stepchildren; stepbrothers and stepsisters; fathers-, mothers-, sons-, daughters-, brothers-, and sisters-in-law; grandparents and grandchildren; and the spouse of grandparents and grandchildren.³ Prohibited services include: clinical laboratory services;⁴ physical therapy services; occupational therapy services; radiology services; radiation therapy services and supplies; durable medical equipment and supplies; nutrients and related equipment and supplies; prosthetics and orthotics and related devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.⁵

To be prohibited, the family member must have a certain financial relationship with the referred-to entity, namely an ownership or investment interest in the entity or a compensation relationship with the entity.⁶ The ownership or investment interest may be through equity, debt or other means.⁷ The compensation relationship may involve any type of payment, discount, forgiveness of debt, or other benefit, direct or indirect, between the member of the physician's family and an entity.⁸ There are certain exceptions to both the ownership and com-

pensation arrangement including, among others, those for group practices.⁹ There are also exceptions to only the ownership or investment prohibition, for example, ownership of investment securities that are publicly traded.¹⁰ There are also some exceptions to the prohibitions in regards to compensation arrangements including, among others, those for the leasing of office space and equipment, and bona fide employment relationships.¹¹ To benefit from falling into an exception the elements of the exception must be strictly met. Violations can lead to large monetary penalties and exclusion from the Medicare and Medicaid programs.¹²

When applying the "no referrals to family members" rule, one colleague has described a situation where the son of a prominent family practitioner went off to medical school to later return to his hometown and procure employment with the *only* radiology group in the town. The colleague reported that the Health Care Financing Administration (HCFA), the subset of the United States Department of Health Human Services that regulates the Medicare and Medicaid programs, advised that the father physician could not refer to his son's group.

Another example cited by colleagues involved three brothers who owned a nursing home and decided that they wanted to purchase a pharmacy company to supply their nursing home residents.¹³ One of the brothers was married to a physician who, as part of her private practice, provided clinical services to the nursing home residents. As such, she would be ordering pharmaceuticals, a designated health service, from a company that her husband had an ownership interest in. The attorney was able to make the arrangement fit under the exception for rural areas. Absent that, the arrangement would have violated Stark.

New York State laws have similar prohibitions, although the state laws sweep more broadly in some respects. For example, while the federal regulations use the term "physician" when discussing the referral laws, the state regulations use the term "practitioner." Practitioners include physicians, dentists, podiatrists, chiropractors, nurses, midwives, physician or specialist assistants, physical therapists, and optometrists.¹⁴ The outright ban is on the referral¹⁵ of clinical laboratory services, pharmacy services and x-ray imaging services where there is a financial relationship¹⁶ in the entity by the referring physician or a family member.¹⁷ There are

exceptions to the ban.¹⁸ There are also exceptions for certain ownership interests and investment interests¹⁹ and some for certain compensation arrangements.²⁰ Compensation arrangements that do not fall within the Department's enumerated exceptions between a health care provider of clinical laboratory services, pharmacy services or x-ray or imaging services and a family member may, upon application of the parties, qualify for an exception from the prohibitions on referrals to such provider by such practitioner based on such compensation arrangement.²¹ Practitioners should, in all circumstances, be certain to follow the statute and regulations closely to completely satisfy any exceptions to the prohibitions.

When considering services that are not of the clinical laboratory, pharmacy or x-ray imaging type, the referral may be made to the family member but disclosure to the patient may be required.²² Specifically, where the practitioner or family member has an ownership or investment interest in the referred-to provider or a compensation arrangement with the referred-to provider that is in excess of fair market value or which provides for compensation that varies directly or indirectly based upon the volume or value of any referrals of business between the parties, disclosure of the arrangement must take place. For example, if a physician that specialized in sports medicine were to refer a patient for physical therapy services where the physician's sister had an ownership interest or prescribe equipment sold by an entity with which her brother-in-law had a compensation arrangement that varied based upon the volume of referrals to the entity, there would be a violation of the law unless proper disclosure was made to the patient.²³ The disclosure must provide notice of the financial relationship and must also inform the patient of his or her right to utilize an alternative provider if any such provider is reasonably available.²⁴ The form must also be posted prominently in the practitioner's office.²⁵ In addition, each time disclosure is made to a patient, a record of the disclosure must be made in the patient's medical record.²⁶

Providers should consult their attorneys regarding such arrangements and should disclose all relationships that might come into play under the rules. Attorneys should probe into the family backgrounds of physician clients to guard against an illegal referral occurring. Specifically, the following information should be included when analyzing any referral relationship: the purpose of the arrangement; the nature of each party's contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (and any family members that are involved) and any entities that provide services, either

those designated under the federal laws or other services that might still qualify for the state prohibitions; the types of services that the physician wishes to refer; and whether the referrals will involve Medicare or Medicaid patients.²⁷ Most importantly, providers and attorneys should be aware that even facts that may seem irrelevant when analyzing a business transaction should be disclosed by providers and analyzed by attorneys to avoid the pitfalls of the very complex regulatory environment.

Endnotes

1. 42 U.S.C. § 1395nn(a).
2. 42 CFR § 411.351.
3. *Id.*
4. 42 CFR §§ 411.1, 411.350, 411.353(a).
5. 63 FR 1659 (1998).
6. 42 U.S.C. § 1395nn(a).
7. *Id.*
8. 42 CFR § 411.351.
9. 42 U.S.C. § 1395nn(b).
10. 42 U.S.C. § 1395nn(c); 42 CFR § 411.356.
11. 42 U.S.C. § 1395nn(e); 42 CFR § 411.357.
12. 42 U.S.C. § 1395nn(g).
13. *Compliance Strategies: Watch Out for Family Members' Relationships under Stark*, Healthcare Financial Ventures Report, Atlantic Information Services, Inc., April 19, 1995, available in LEXIS.
14. New York Public Health Law § 238(11).
15. Referral means the request by a practitioner for such enumerated services, including the request by a practitioner for consultation with another practitioner, and any test or procedure ordered by, or performed by or under the supervision of that other practitioner, and the establishment of a plan of care that includes the enumerated services with certain exceptions. New York Public Health Law § 238-a(6)(a-c).
16. Ownership interest, investment interest or compensation relationship. New York Public Health Law § 238(3).
17. New York Public Health Law § 238-a(1)(a). Family members include spouse; natural and adoptive parents; children and siblings; stepparents; stepchildren and stepsiblings; father-in-law; mother-in-law; brothers-in-law; sisters-in-law; sons-in-law, daughters-in-law; and grandparents and grandchildren. New York Public Health Law § 238(8).
18. Exceptions for group practices, in-office ancillary services, pre-paid health service plans, inpatient hospital services, outpatient emergency services, and general hospitals where the financial relationship is not related to the provision of the enumerated services. New York Public Health Law § 238-a(2)(a-f).
19. New York Public Health Law § 238-a(3) (no ownership or investment interest if in publicly traded corporation). Also exceptions for entities in rural areas, certain arrangements with general hospitals, and ambulatory surgical centers where disclosure is made to the patient. New York Public Health Law § 238-a(4)(a-d). See also 10 N.Y.C.R.R. § 34.7 (exceptions where the immediate family member of the practitioner has a compensation relationship with a large, publicly traded corporation and where the family member satisfies certain criteria; or the provider with whom the family member has a compensation

arrangement receives 20 percent or less of its referrals from financially interested practitioners).

20. Compensation arrangements include any arrangement involving any remuneration between a practitioner, or immediate family member, and a health care provider. The term remuneration includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind with exception for certain arrangements for (i) payments for the rental or lease of office space; (ii) administrative services for a general hospital; (iii) certain identifiable services where the remuneration is fair market value and the agreement is commercially reasonable; (iv) the relocation of a physician to work at a general hospital; (v) an isolated transaction; and (vi) a salaried member of a group practice. New York Public Health Law § 238-a(5)(a-b).
21. 10 N.Y.C.R.R. § 37.7(c)(1). The Department of Health reviews applications to determine the risk of payor or patient abuse in relation to patient benefits. The Department considers the following: (i) the nature of the relationship between the health care provider and the immediate family member of a practitioner; (ii) the nature of the family member's financial interest; (iii) the percentage of the provider's business attributable to the practitioner's referrals; (iv) the percentage of the provider's business attributable to referrals by all interested practitioners; (v) the gross value of the provider's business attributable to the practitioner's referrals; (vi) the gross value of the provider's business attributable to referrals by all interested practitioners; (vii) the fair market value of the immediate family member's services; (viii) certification that the compensation paid to the family member is consistent with fair market value and is not based upon the volume or value of any referrals by the practitioner; (ix) for Medicare providers of clinical laboratory services, documentation that the arrangement falls under a federal exception to such compensation arrangements, and (x) any statement setting forth the reasons why the parties believe that granting the exception would not be against the public interest. 10 N.Y.C.R.R. § 34.7(c)(1)(i-x). Note that this regulation was enacted in 1993, prior to Stark II which expanded the list of designated health services from clinical laboratory services to the designated health services discussed above. As such, (ix) from above is outdated and, if amended, would include the other designated health services.
22. The statute should be consulted for exceptions to the disclosure rule. New York Public Health Law § 238-d. The disclosure must be in the following form:

NOTICE TO PATIENTS

Because of concerns that there may be a conflict of interest when a physician refers a patient to a health care facility in which the physician has a

financial interest, New York State passed a law. The law prohibits me, with certain exceptions, from referring you for clinical laboratory services, pharmacy services or x-ray or imaging services to a facility in which I or any of my immediate family members have a financial interest. If any of the exceptions in the law apply, or if I am referring you for other than clinical laboratory, pharmacy, or x-ray or imaging services, I can make the referral under one condition. The condition is that I disclose this financial interest and tell you about alternative places where you may go to obtain these services. This disclosure is intended to help you make a fully informed decision about your health care.

I or my immediate family members have a financial relationship with the following providers:

For more information about alternative providers, please ask me or my staff. We will provide you with names and addresses of places best suited to your individual needs that are nearest to your home or place of work.

Name of Practitioner

10 N.Y.C.R.R. § 34.6.

23. John M. O'Connor and Donald M. Spector, *A Primer on New York State's Self-Referral Law and Regulations*, New York Health Law Update, March 1994.
24. 10 N.Y.C.R.R. § 34.5(b).
25. *Id.*
26. 10 N.Y.C.R.R. § 34.5(d).
27. 42 CFR § 411.372 (b)(4) (listing relevant information required by HCFA for a formal advisory opinion).

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Enforcing Restrictive Covenants Among Professionals

By Elliot Polland

New York traditionally has not favored restrictive covenants in employment agreements that prevent a person from pursuing his chosen vocation after termination of the employment relationship.¹ An exception to this rule was judicially recognized if the skills of the employee were considered to be extraordinary or unique. Thus restrictive covenants contained in an employment agreement amongst members of the “learned professions”² have been held to be enforceable if they are a) reasonable in geographic scope; b) reasonable in time; c) necessary to protect the legitimate interests of the employer; d) not harmful to the public; and e) not unduly burdensome. Where these criteria have been satisfied injunctive relief can be obtained barring the former employee from competing. This article will explore these five factors and demonstrate how New York Courts have interpreted them.

Geographic Scope

The first criteria to be examined is the size of the geographic exclusion. There are no hard and fast rules as to what constitutes a fair and necessary boundary for protection from competition. The protected area cannot be viewed in a vacuum. What is permissibly protected depends on the nature of the practice as well as the area from which the employer draws its patients. This necessitates a case-by-case determination with considerable judicial subjectivity determining if the restrictive covenant should be enforced. Restrictions have run the gamut from barring a former professional employee from competing in any one of five designated rural counties,³ barring employment in a single county,⁴ barring competition by mileage⁵ to refusing to enforce relatively small restrictions.⁶ Where a Court determines a need for protection but finds the contractual restriction too broad, it has the authority to pare down the restriction.⁷ However, caution dictates that imposing an overreaching, overly broad and coercive territorial restriction may result in the Court refusing to enforce any restriction rather than attempting to rewrite the restriction to reflect the legitimate needs of the employer from competition. In drafting the restrictive covenant consideration should be given to language authorizing the Court to pare down the geographic scope, or the time restriction, to conform to the Court’s view of what would be needed to protect the employer’s interests should the Court find the covenant too broad.

As an alternative to a specified geographic restriction, consideration should be given to barring the for-

mer employee from specified hospitals or other institutions.⁸

A common thread used by the courts for determining the propriety of the territorial restriction is consideration of the area from which the practice draws its patients.⁹ Setting a geographically protected zone cannot be determined without simultaneously considering the legitimate needs of the former employer to be protected from competition. This illustrates the need for the courts to juxtapose all five factors in determining whether, and to what extent, a restrictive covenant should be enforced.

Time

Not only must the restriction be geographically reasonable but it must be reasonable in time as well. Here again, the enforceability of a time restraint is dependent on the nature and location of the employer’s practice. Enforced restrictions have run the range from as little as one year,¹⁰ to three years,¹¹ five years¹² and in one instance for perpetual duration.¹³

Need to Protect the Employer’s Legitimate Interests

The underlying purpose of a restrictive covenant is to protect an employer from competition by a former employee and thus a prerequisite to enforceability is the employer’s need for protection. If the employer closes the office and doesn’t rechannel the patients to a nearby office, a restrictive covenant will not be enforced as it is not needed to protect the employer from competition.¹⁴ Similarly, where the employer sells its practice it may no longer have standing to claim that the former employee’s competition interferes with its legitimate business interests.¹⁵

Recently the author successfully represented a health care practitioner in challenging a restrictive covenant based on the fact that the party seeking enforcement was not licensed to practice health care in New York and thus had no legitimate business interest to protect.¹⁶

Protection of the employer’s business warrants including a clause barring contacting and solicitation of the patients by the employee. Such clauses are enforced but often an exception will be carved out for patients brought by the employee to the employer’s practice.¹⁷ Another variation is to have the employment agreement

contain an agreed monetary sum for breaching the covenant. Recently New York's Court of Appeals held enforceable a contract which provided a departing employee, who served the employer's former clients within 18 months of termination, was liable for damages based on a percentage of the employer's fees previously charged to that client.¹⁸

Harm to the Public

Consideration must be given to the impact exclusion of the former employee will have upon the public. Where there are other practitioners available in the same professional discipline, the courts will find no harm will accrue to the public by enforcing the restrictive covenant.¹⁹ Where competitive protection is warranted, consideration of the availability of other practitioners is not limited to the immediate vicinity but cases have even considered such availability in somewhat distant areas.²⁰

In considering the public's needs, judicial flexibility is often required. In one instance where a physician was excluded from practicing at hospitals located in a designated city, an exception was created to permit him to see patients who reside outside of that city but who were hospitalized at facilities within that city.²¹

Unduly Burdensome

The burden of enforcement of the restrictive covenant on the former employee seems to be the least significant of the factors. If the other four factors warrant injunctive relief, inevitably courts will determine the burden on the former employee to be minimal as it doesn't preclude the employee from practicing outside of the barred area.²²

Conclusion

In drafting a restrictive covenant due consideration must be given to the five factors in order to assure that it will be upheld when needed. The key is to avoid the appearance of an overly broad, punitive restriction, which risks being unenforceable. Instead, the draftsman should focus on the legitimate needs of protection from a former employee.

Endnotes

1. *Columbia Ribbon & Carbon Mfg. Co. v. A-1-A Mfg. Co.*, 42 N.Y.2d 496, 398 N.Y.S.2d 1004, 369 N.E.2d 4.
2. The phrase "learned professions" is not precisely defined. However, case law has interpreted that phrase to mean those professions for which state licensure is required, and it encompasses health care professionals, accountants, engineers, landscape architects, and other licensed professionals.
3. *Karpinski v. Ingrasci*, 28 N.Y.2d 45, 320 N.Y.S.2d 1, 268 N.E.2d 751.
4. *Foster v. White*, 248 A.D. 451, 290 N.Y.S. 294, *aff'd*, 273 N.Y. 596.
5. *Gelder Medical Group v. Webber*, 41 N.Y.2d 680, 394 N.Y.S.2d 867, 363 N.E.2d 573 (30 miles); *Penny W. Budoff, P.C. v. Jenkins*, 143 A.D.2d 250, 532 N.Y.S.2d 149 (10 miles).
6. *Michael I. Weintraub, M.D., P.C. v. Schwartz*, 131 A.D.2d 663, 516 N.Y.S.2d 946 (Court would not enforce five-mile restriction from hospital where former employee had worked during his employment but found a five-mile restriction from the former office was reasonable).
7. *Karpinski v. Ingrasci*, *supra* at 28 N.Y.2d 51-52.
8. *Arnold R. Leiboff, M.D., P.C. v. Pelaez*, 249 A.D.2d 497, 671 N.Y.S.2d 336 (former employee directed to resign from two hospitals).
9. *Karpinski v. Ingrasci*, *supra* at 28 N.Y.2d 49-50.
10. *Rifkinson-Mann v. Kasoff*, 226 A.D.2d 517, 641 N.Y.S.2d 102.
11. *Novendstern v. Mount Kisco Medical Group*, 177 A.D.2d 623, 576 N.Y.S.2d 329, *lv. dism.* 80 N.Y.2d 826, 587 N.Y.S.2d 908, 600 N.E.2d 655.
12. *Gelder Medical Group v. Webber*, *supra*.
13. *Karpinski v. Ingrasci*, *supra*.
14. *Last v. New York Institute of Technology*, 219 A.D.2d 620, 631 N.Y.S.2d 397.
15. *Pascal v. Beigel*, 202 A.D.2d 483, 609 N.Y.S.2d 72.
16. *Martone v. Healthsouth Holdings, Inc.*, S. Ct., N.Y. Co., Wilk, J., Index # 601546/99.
17. *Jerry Kindman & Co., P.C. v. Stollar*, 151 A.D.2d 393, 543 N.Y.S.2d 81.
18. 4 No. 67 BDO *Seidman v. Hirshberg*, QDS: 10107640.
19. *Bollengier v. Gulati*, 233 A.D.2d 721, 650 N.Y.S.2d 56.
20. *Gelder Medical Group v. Webber*, *supra*.
21. *Muller v. N.Y. Heart Center Cardiovascular Specialists, P.C.*, 238 A.D.2d 776, 656 N.Y.S.2d 464.
22. *Rifkinson-Mann v. Kasoff*, *supra* (exclusion from one Westchester County hospital did not prevent practice at other hospitals in the county nor in the nearby metropolitan New York region).

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Discounts and Scholarships: New York State Bar Association members may apply for a discount or scholarship to attend this program, based on financial hardship. This discount applies to the educational portion of the program only. Under that policy, any member of our Association who has a genuine basis of his/her hardship, and if approved, can receive a discount or scholarship, depending on the circumstances. To apply for a discount or scholarship, please send your request in writing to Kimberly S. Bruhns at: New York State Bar Association, One Elk Street, Albany, New York 12207.

SCHEDULE OF EVENTS

WEDNESDAY, OCTOBER 11

8:30 a.m. to Registration

9:00 a.m.

9:00 a.m. to Welcome and Introduction

9:10 a.m.

9:10 a.m. to Federal Fraud and Abuse Law and Regulation

10:00 a.m. Discussion of the federal anti-kickback, Stark II and False Claims statutes and regulations, with particular emphasis on physician sole and group practice enforcement issues. The speaker will emphasize the practical application of each of these relevant fraud and abuse laws to physician practice issues by providing and discussing case examples, such as the Kansas City anti-kickback case and other relevant cases.

Peter Millock, Esq.

Nixon Peabody, LLP

Albany, New York

**10:00 a.m. to
10:10 a.m.** **Break**

**10:10 a.m. to
11:00 a.m.** **State Fraud and Abuse Law Regulation**

Discussion of the state anti-kickback, mini-Stark and False Claims statutes and regulations, with particular emphasis on physician sole and group practice enforcement issues. The speaker will emphasize the practical application of each of these relevant fraud and abuse laws to physician practice issues by providing and discussing case examples.

Jose Maldonado, Esq.
Deputy Attorney General
Director, Medicaid Fraud Control Unit
Office of the New York State Attorney General
New York, New York

**11:00 a.m. to
11:50 a.m.** **Anatomy of an Investigation**

Discussion of the investigation process and what to expect as well as how to respond to investigators.

Robert G. Trusiak, Esq.
Assistant US Attorney
Western District - New York

**11:50 a.m. to
1:00 p.m.** **Lunch - Legal and Regulatory Enforcement Update - Keynote**

Lunch as well as a keynote speaker who is the attorney who was the principle drafter of the OIG physician compliance guidance. She will discuss recent health care fraud issues with respect to physician practice issues and OIG perspectives on physician compliance initiatives.

Kimberly Brandt, Esq.
Office of the Inspector General, USDHHS
Washington, D.C.

**1:00 p.m. to
1:50 p.m.** **Real Life Physician Qui Tam and Investigation Cases**

Discussion of the recent qui tam suit against sole practitioner physician in New York and the subsequent settlement and Corporate Integrity Agreement.

Robert W. Biddle, Esq.
Bennett & Nathan, LLP
Baltimore, Maryland

**1:50 p.m. to
2:20 p.m.** **Compliance Program Basics**

Discussion of compliance program elements and issues relating to implementation in solo and small practice settings.

Patrick Formato, Esq. and Ann Corrozza, Esq.
Abrams, Fensterman, Fensterman & Flowers, LLP
Lake Success, New York

**2:20 p.m. to
2:30 p.m.** **Break**

**2:30 p.m. to
3:20 p.m.** **Auditing and Monitoring Billing Practices**

Introduction and explanation of the resources and methods available to physicians and group practices to ensure claims for reimbursement are submitted appropriately. The speaker will provide examples of cost-efficient policies and procedures for the sole practitioner and small group practice setting.

Mike Lewensohn



**NEW YORK STATE BAR ASSOCIATION
Health Law Section with the
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Fall Meeting
October 11, 2000
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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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Medical Malpractice in New York

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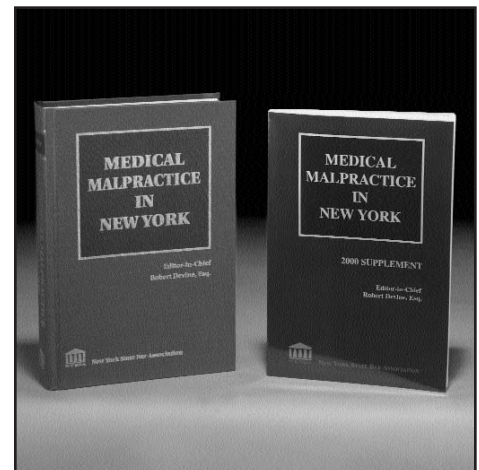
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