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Health Law Journal

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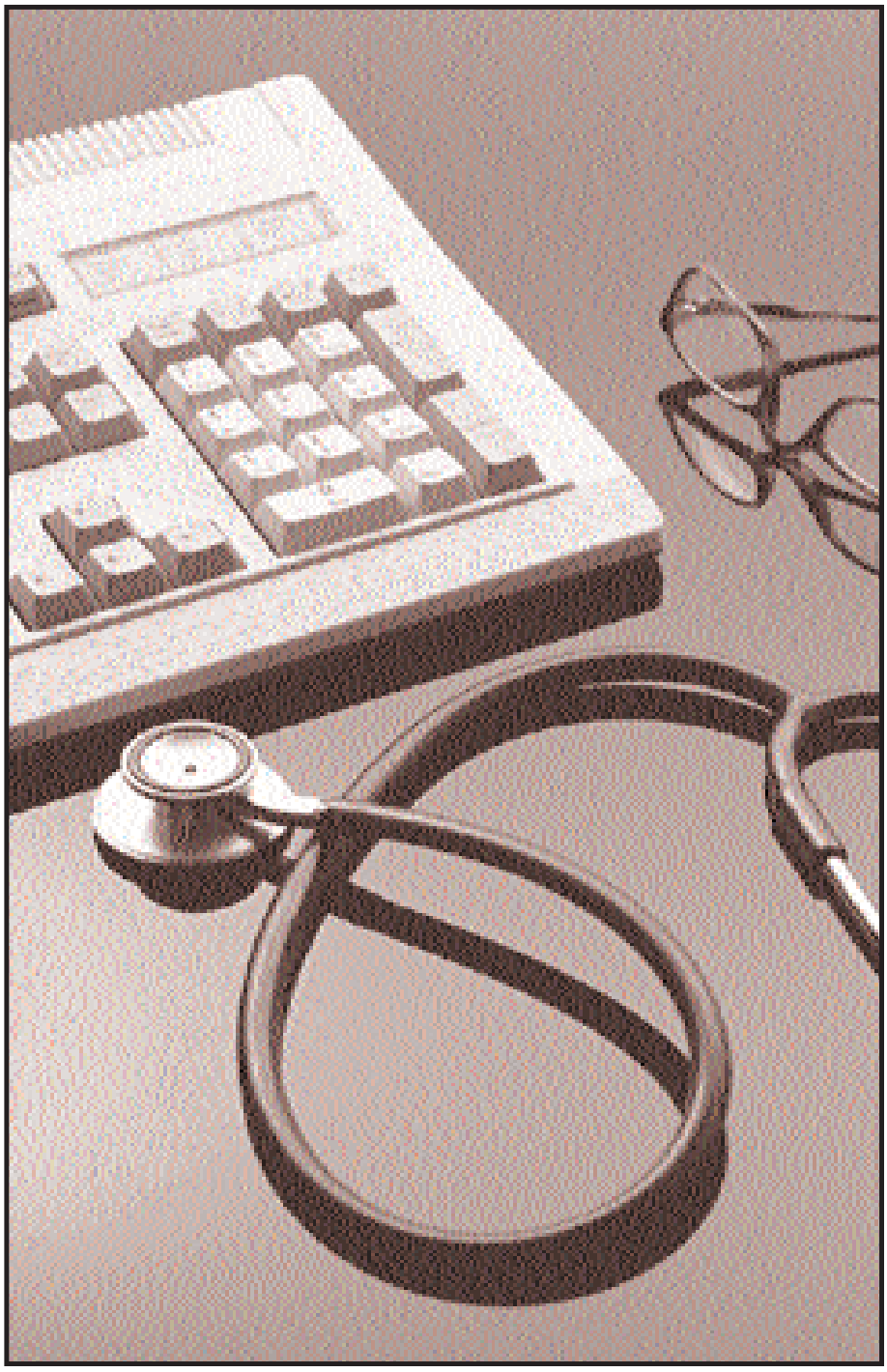

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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ALBANY LAW SCHOOL

A Message from the Section Chair

The Chair's message typically updates Section members on our activities and upcoming events. For this issue, however, I am exercising my prerogative as Chair to take this opportunity to reflect on the last few months. Indeed, for many of us the past few months have been like no other period we have ever experienced.

On a personal note, beginning with my friend Mark Shulman, who was murdered on September 11, 2001, I have attended three memorials in the past few months. The second memorial was for Lynn Terrelonge, a colleague and friend I have known for over a decade, who died suddenly from cancer. She died during her term as President of the Brooklyn Bar Association. Today, I attended the memorial service for David Glaser, my friend, colleague, client and fellow delegate to the White House Conference on Aging, who recently retired as Chief Executive Officer and President of the Parker Jewish Institute for Health Care and Rehabilitation.

Unlike Mark, Lynn and David died of natural causes. Like Mark, Lynn and David died at relatively young ages. The loss of all three has had a profound effect on those who knew them. Their deaths are also a loss for those who did not know them. We all suffer when we lose our silent heroes.

Each of them possessed unique qualities that made them very special. Mark had the ability to make others feel incredibly special. When you were Mark's friend, you had a cheerleader for life. On a personal level, I knew Mark believed I could do anything I wanted—I wish I had the faith in me that he did. I wish I could have told him how he helped me in his own subtle way.

Lynn and I shared a bond in that we both became lawyers as second careers and we shared a love for Brooklyn, New York. Lynn was often recognized for her service to our profession and community. She was recently elected as the first African-American woman of the Brooklyn Bar Association. Her greatest attribute was that she was able to unite people of all different backgrounds.

At her memorial service, a judge eulogized her with the following anecdote: "Lynn was as comfortable spending time with friends in Bedford Stuyvesant as she was at a bar association function at the Waldorf Astoria." As one who will always be—first and foremost—a kid from the Linden projects in East New York, Brooklyn, I appreciate the model Lynn set by always being true to herself and those she cared about, regardless of where she was or who she was with.

David Glaser was a man of vision. A man of many accomplishments, David will be remembered by many for redefining the mission of nursing homes from being a place where people went to die to that of a sophisticated health care facility that treated and cared for elderly and disabled citizens so that they reached their full potential and were able to return home to lead productive lives.

I will personally remember him for hiring my young law firm to provide legal services to his facility. Other health care facilities began to use our firm because they reasoned if David Glaser uses them, they must know what they're doing. His professional accomplishments notwithstanding, David Glaser will be remembered by all who knew him as "a humble, generous and compassionate man, and will remain forever in our hearts as a shining example of the best of humanity."

As I reflect on these three very special people, I recognized one common trait they all possessed—a deep love and devotion to their families. It is true, indeed, that when we die we are most remembered not for our professional titles, we are remembered most for our family titles: husband, wife, mother, father, sister, brother, son, daughter, aunt, uncle, cousin, friend.

In closing, I am grateful for the help and support that I have received from so many members of the Section. In honor of Mark, Lynn and David and in my appreciation of your support, I urge you to take time from your hectic schedules to celebrate your family and close friends.

Robert Abrams

Lettter to the Editor

Dear Associate Dean Moore:

The Nursing Home Community Coalition of New York State (NHCC), a statewide coalition of consumer, civic and professional organizations, working for over 20 years for better nursing home care, would like to comment on the Winter 2002 Edition: "Penalizing Health Care Providers: Enforcement or Exploitation?"

We believe that government has not become "unduly harsh and unfair or exploitative in its enforcement efforts." We believe that the state is finally beginning to do its job.

In the 1970's and 80's there were major nursing home scandals in New York State and around the nation. The Institute of Medicine (IOM) conducted a national study of the appalling situation of nursing home care in our country. This study led to the Omnibus Budget Reconciliation Act of 1987 ("Nursing Home Reform Act of 1987"). Although passed in 1987, care standards and regulations, derived from the Act, did not go into effect until the early 1990's. Providers then fought "tooth and nail" not to allow the enforcement provisions of the Act go into effect. Finally, after much fighting, the enforcement sections went into effect in 1995, ten years after the IOM study began. From the very beginning, providers complained about this enforcement system, whittling away pieces of it, never really allowing it to be fully implemented without constant bickering.

We were very worried that just as the enforcement system was finally beginning to work, it would be weakened and destroyed. In fact, even though the enforcement provisions of the Nursing Home Reform Law went into effect in 1995, we saw little of the new system in New York State. It wasn't until 1999 that we began to have some hope. Finally, after years of not holding providers accountable (e.g., in 1997, only one of our 680 facilities was fined even though 405 deficiencies were found in 159 facilities), our state began to identify serious problems and hold facilities responsible by fining them, directing how they should correct these problems, requiring in-service training and instituting state monitoring, if appropriate.

You know, fining works. In 1995, we conducted a study with Charles Phillips of the Research Triangle Institute and found that facilities that were fined tended to have many fewer violations on surveys conducted after being fined than they had prior to the fining. Facilities that were not fined tended to have about the same number of violations (actually slightly more).

NYAHSA's report states that surveyors should work in a *consultative* manner with facilities. Do we really want to go back to the 1970's and 1980's when good surveillance and enforcement were rare? One of the conclusions of the IOM's groundbreaking national study of those years was that regulators were making a mistake by not swiftly enforcing standards and that when surveyors *consulted* with providers, rather than discipline them, facilities went in and out of compliance, never remaining in full correction for very long. Shouldn't we learn from history? Do we want to go back to the scandal days?

Providers in our state are angry. They are angry because they are used to not being answerable for their actions or inactions. Rather than be angry at an earlier Department of Health that ignored problems they might have been able to solve, they are angry at the present Department that is finding many of the problems that have always been there. Surveyors are not "out to get them." Surveyors are trying to detect serious problems in order to do their job—protect vulnerable residents. Finally they are being allowed to do so.

While we agree with NYAHSA that the surveyor process can be more uniform and consistent, we do not believe that the problems now being identified are trivial. For years we have had to listen to residents and families complain about serious problems either never identified by the state, or, if identified, never sanctioned. Now we are beginning to see these problems detected and, yes, written about in the press. The state is now letting consumers know about identified problems and consumers are asking questions.

Whenever I am asked "What is a good nursing home?" I say, "A good home is one which knows it has problems and is willing to work with residents, families and anyone else to solve them." Instead of spending their energy on how to solve identified problems, NYAHSA is complaining about the regulators and even blaming the media for the bad press they get. Correct the problems and the media stories will change.

Sincerely,

Cynthia Rudder, Ph.D.
Director

In the New York State Courts

Court Overturns Office-Based Surgery Guidelines

New York State Ass'n of Nurse Anesthetists v. Novello, 189 Misc. 2d 564, 734 N.Y.S.2d 420 (Sup. Ct. Albany County 2001). In December 2000, the New York State Department of Health published on its Web site "Clinical Guidelines for Office-Based Surgery." The guidelines were designed to provide a comprehensive roadmap for physicians and certified registered nurse anesthetists (CRNAs) to follow when performing office-based surgical procedures.

The Health Department styled this roadmap as guidelines rather than regulations because the state Legislature has specifically withheld from the Health Department the authority to regulate the conduct of physicians in non-hospital-based settings. The Health Department's General Counsel, in a memorandum written two months before the issuance of the guidelines, stated that "[a]bsent any statutory authority, regulations governing the establishment and operation of physician office-based surgical practices cannot be promulgated. Guidelines, however, could be issued. Although such guidelines would not have the force of law, they could be useful as community standards of care in disciplinary proceedings."

After the Health Department issued the guidelines, the state CRNA association brought a declaratory judgment lawsuit challenging them as outside the Health Department's jurisdiction to promulgate. Last November, the Supreme Court, Albany County, agreed, invalidating the regulations. In reaching its decision, the court pointed to the fact that, although styled as guidelines, the Health Department clearly expected that physicians and CRNAs treat the guidelines as mandatory regulations. Since the Legislature had specifically prohibited the Health Department from issuing regulations governing office-based surgery procedures, the court concluded that the guidelines exceeded the Health Department's statutory authority and, accordingly, had to be invalidated.

Professional Organizations' Recommendation to Use Female Observers During Medical Procedure Does Not Constitute an "Industry Standard"

Diaz v. New York Downtown Hospital, 287 A.D.2d 357, 731 N.Y.S.2d 694 (1st Dep't 2001). Plaintiff alleged that a hospital's failure to have a female observer present for vaginal sonograms was negligent, and the hospital was therefore liable to plaintiff for a sexual assault against her by the employee of the hospital's independent contractor.

The Appellate Division ruled that it was not reasonably foreseeable that the employee of the independent contractor would sexually assault the plaintiff. The Appellate Division found that the independent contractor had sufficiently screened the background of its employee and found "nothing as to the employee's background that would have placed defendant on notice of or alerted it to a potential propensity for violence or sexual abuse." In addition, the Appellate Division rejected the plaintiff's contention that the hospital was negligent by reason of its failure to follow "recommendations" and "guidelines" of two professional organizations, the American College of Radiology (ACR) and the American Institute of Ultrasound in Medicine (AIUM), both of which suggested that it was advisable to have a female observer present during the exam. The court found that such "guidelines" and "recommendations" were merely advisory, and did not establish customary practice or industry standard. Further, testimony by plaintiff's expert concerning the industry standard provided no additional dispositive information, because he cited only to the ACR and AIUM recommendations, rather than providing any information concerning actual radiological practice and the standard use of female observers during exams.

Court Lacks Authority Under Public Health Law to Modify a Living Will; Court Improvidently Exercised Discretion in Establishing Guardianship for Person and Property of Terminally Ill Person Where Living Will, Durable Power of Attorney and Trust Were Already Established

In re Albert S. (Anonymous), 730 N.Y.S.2d 128 (2d Dep't 2001). In a proceeding pursuant to Article 81 of the New York Mental Hygiene Law and the New York Public Health Law, the healthcare agents of a terminally ill person appealed from a judgment of the Queens County Supreme Court that established a guardianship for the person and property of the terminally ill person, and imposed upon the healthcare agents the condition that they forgo any steps to hasten his death. The Appellate Division, Second Department reversed, and remitted the matter to the trial court for further proceedings.

The Appellate Division found that the living will of Albert S. demonstrated that he held a firm commitment to the termination of life-supporting medicine that would only serve to artificially prolong his life. Since his intention was to withhold certain medications and his current condition was terminal, the Appellate Division held that Albert S. would want his medical care to cease. Accordingly, the motion court improperly concluded that the healthcare agents of Albert S. failed to establish by clear and convincing

evidence that his living will directed the same.

Moreover, the Appellate Division held that the trial court had improperly imposed upon the healthcare agents the condition that they forgo steps to hasten the death of Albert S. until his death was imminent and inevitable. The Appellate Division held that there was no authority in the New York Public Health Law that enables a court to modify a living will.

Finally, the Appellate Division held that the trial court improperly exercised its discretion in establishing a guardianship for the person, and for the property, of Albert S. The court noted that a guardian is to be appointed solely as a last resort, where there is no other available alternative that will adequately protect the person. In this case, however, a living will and durable power of attorney had both been prepared. Thus, a guardianship for the person was unnecessary. Furthermore, since a trust containing sufficient funds had been set up to pay for the care of Albert S., the establishment of a guardianship for his property was also unnecessary.

Employee's Subjective Belief About Poor Air Quality in Hospital Lab Is Insufficient to Support Claim Under New York Labor Law § 740, the Whistleblower Statute

Khan v. State University New York Health Science Center at Brooklyn, 734 N.Y.S.2d 92, 288 A.D.2d 350 (2d Dep't 2001). The Appellate Division held that to sustain a cause of action under Labor Law § 740, an employee must prove that the employer engaged in an activity, policy or practice that constituted an actual violation of a law, rule or regulation. The court further held that an employee's good-faith reasonable belief that an actual violation of a law, rule or regulation occurred is insufficient—there must be an actual violation.

In this matter, the defendant Health Science Center came forward with proof to establish that during the period relevant to the plaintiff's complaints of unsafe conditions in the workplace, the defendant's laboratories were not found to be in violation of any safety or health standards promulgated under the United States Occupational Safety and Health Act of 1970 (OSHA) or any of the regulations promulgated by the Department of Labor. The plaintiff failed to submit any admissible evidence that the conditions at the laboratories were unsafe due to poor air quality, such as test results showing that during the relevant period of time the air quality fell below the permissible standards set forth by OSHA.

Given the plaintiff's failure to make the requisite factual showing of an actual violation of a law, the plaintiff could not defeat defendant's motion for summary judgment. The court stated that the plaintiff's own uncorroborated and unsubstantiated opinion that the defendant's laboratories were unsafe amounted to no more than a "reasonable belief of a possible violation" which, without any evidence or proof to support it, did not support a cause of action to recover damages under Labor Law § 740. Reversing the motion court, the Appellate Division granted summary judgment for defendant Health Science Center.

Commissioner of Health Improperly Denied County Hospital's Request for a Hearing to Challenge Reimbursement Rates

In re Monroe Community Hospital 734 N.Y.S.2d 776 (4th Dep't. 2001). The petitioner, County of Monroe, commenced an Article 78 proceeding challenging the Medicaid reimbursement rates established by the State Commissioner of Health for Monroe Community Hospital (the "Hospital"). Prior to commencing the proceeding, the petitioner had requested a hearing on several issues that, according to petitioner, resulted in an improper reduction in reimbursement rates applicable to the Hospital. The issues were whether financial loss from an employee cafeteria resulted from an employee benefit; whether errors on reporting square footage caused allocation of overhead costs to non-allowable cost centers; and whether errors in reporting nursing hours resulted in artificially low base year costs.

The Commissioner denied the request for a hearing on the basis that petitioner failed to provide a collective bargaining agreement or employee-employer contract providing for reduced meal prices for employees, which the Commissioner determined to be necessary to establish that the employee cafeteria was a fringe benefit that could be factored into the Hospital's reimbursement rate. However, in response to the petitioner's Article 78, the Commissioner gave a different reason for denying petitioner's request that related to lack of additional information being provided by petitioner. The lower court relied on this new assertion and dismissed the Article 78 petition.

Petitioner appealed the dismissal. The Appellate Division reversed the lower court's decision because the court had improperly relied on a ground that was not invoked by the Commissioner when it originally denied the petitioner's request for a hearing. Moreover, the Appellate Division held that the fact that there is no collective bargaining agreement or contract for employee reduced-priced meals is not a rational basis for the Commissioner to deny a hearing, since that fact is not dispositive on the issue of whether the employee cafeteria is a fringe benefit.

Similarly, the Appellate Division held that it was improper to deny, as a matter of law, petitioner's request

for a hearing to the extent that it sought to correct a reporting error that resulted in an erroneous reductions in the Hospital's amount of reimbursement. Such issues were questions of fact that required a hearing. Accordingly, the Appellate Division remitted the matter to the Commissioner for a hearing on the disputed issues.

Allegedly Negative Job Reference by an Employee's Former Supervisor at Hospital to Employee's Future Supervisor Did Not Support Claim for Tortious Interference with Prospective Contractual Relations

Miller v. Mount Sinai Medical Center, 733 N.Y.S.2d 26, 288 A.D.2d 72 (1st Dep't 2001). Plaintiff alleged that her employment contract with a prospective employer hospital was rescinded after a supervisor from her former hospital employer met with the plaintiff's future supervisor. Since the employment contract with plaintiff's new employer was undisputably terminable at will, the court held that it only contemplated prospective contractual relations and, as such, a claim for tortious interference with an existing contract could not be made.

The court further held that the plaintiff failed to state any claim for tortious interference with prospective contractual relations, since there was no showing that plaintiff's purported prospective contractual relations were interfered with by "wrongful means" as required by case law. The court held that it was reasonable for the plaintiff's future supervisor to speak with her former supervisor about plaintiff's work performance at her former job. The mere fact that plaintiff's former supervisor may have given plaintiff a negative job reference, or did not believe plaintiff to be a qualified candidate for the position, did not constitute interference by "wrongful means."

Even if plaintiff has stated a claim for tortious interference with prospective contractual relations, the plaintiff failed to demonstrate that the sole purpose of her former supervisor's alleged "interference" was to harm the plaintiff—a necessary prerequisite for a claim for tortious interference with prospective contractual relations. Accordingly, the Appellate Division affirmed dismissal of the complaint.

Hospital Did Not Waive Its Right to Assert Privilege Not to Disclose Peer Review Report

Nga Le v. Stea, M.D., 730 N.Y.S.2d 620 (4th Dep't 2001). A discovery dispute arose in this medical malpractice action, in which plaintiff sought damages for injuries allegedly sustained while undergoing spinal fusion surgery at the defendant hospital. The two defendant doctors who performed the surgery, and the defendant anesthesiologist for the surgery, underwent peer reviews after the plaintiff's surgery. One of the defendant surgeons moved to compel the discovery of the peer review report of the Department of Anesthesiology which contained the minutes from that department's morbidity and mortality conference regarding plaintiff's case. The defendant hospital cross-moved for a protective order with respect to the report.

The surgeon asserted that because the former Chief of the Department of Anesthesiology had previously handed the report to him, the hospital had waived any claim of privilege with respect to the report. The motion court held that the hospital waived its statutory privilege with respect to the report and ordered its disclosure, noting that the issue of its admissibility would be determined at trial. The Appellate Division reversed, and granted the hospital's cross-motion for a protective order.

The parties did not dispute that the peer report fell within the statutory protection against disclosure afforded by New York Education Law § 6527, and New York Public Health Law §§ 2805-j, k and m. The issue before the Court, therefore, was whether the hospital had waived its right to assert the privilege, because the Chief of the Department of Anesthesiology had previously shared the peer review document with one of the two defendant surgeons.

The court found that there was no intentional waiver of the privilege by the hospital. The court also ruled that because the surgeon who saw the report was under peer review for the same surgery, he was not a disinterested third party. Accordingly, sharing the report with the surgeon did not waive the peer review privilege.

Administrative Review Board Has Right to Overturn Decision of Hearing Committee in Physician Disciplinary Proceeding

Wilkins v. New York State Department of Health, 733 N.Y.S.2d 788 (3d Dep't 2001). A physician brought an Article 78 proceeding following revocation of his medical license by the Board of Professional Medical Conduct (BPMC). Although the physician was charged with practicing medicine with gross negligence, gross incompetence, negligence on more than one occasion and incompetence on more than one occasion, a Hearing Committee of the BPMC found the physician guilty only of ordinary negligence on more than one occasion, and placed him on three years' probation. However, the Administrative Review Board (ARB), convened to review the Hearing Committee's decision at the request of the parties, determined that the physician was guilty of gross negligence, as well as the charges sustained by the Hearing Committee, and revoked the physician's license.

The court, in reviewing the ARB's conduct, found that "the ARB is empowered to substitute its judgment for that of the Hearing Committee in resolving issues of credibility and determining guilt." The court further found that it was proper for the ARB to base its penalty on the physician's demonstrated lack of insight into his deficiencies and tendency to blame others, and that doing so did not constitute an adjudication of guilt for uncharged conduct (i.e., failure to admit mistakes).

Because the ARB's decision could not be held to be arbitrary or capricious, the determination of the ARB was confirmed.

Registered Physician Assistant Cannot Serve as "Lay Member" of Professional Medical Conduct Hearing Committee

Mayer v. Novello, 288 A.D.2d 780, 733 N.Y.S.2d 305 (3d Dep't 2001). A physician brought an Article 78 Proceeding to contest the composition of the Hearing Committee convened by the Board of Professional Medical Conduct (BPMC). The doctor objected at the outset of his hearing to a registered physician assistant serving as the "lay member" of the Committee. The objection was overruled by the Committee, which subsequently found the physician guilty of several of the BPMC charges against him.

The court found that it was improper for three medical practitioners whose professions are subject to the Public Health Law § 230 disciplinary process to serve on a Hearing Committee whose members, under the same law, must consist of "two physicians and one lay member."

The court further found that the physician's objection, made the day of the hearing, was not untimely because he only discovered the composition of the Committee at a prehearing conference held eight days earlier.

The court remitted the Committee's determination for a new hearing.

Article 78 Proceeding Found to Be the Only Proper Vehicle for Review of Physician's License Revocation

Horne v. New York State Department of Health, 287 A.D.2d 940, 731 N.Y.S.2d 781 (3d Dep't 2001). A plastic surgeon, who lost his medical license following a full hearing and appeal by the Board of Professional Medical Conduct (BPMC), initiated a discrimination lawsuit based on the revocation of his license. He claimed that the BPMC discriminated against him because of a disability stemming from adult attention deficit disorder (ADD).

The court found that his discrimination claim sounded in the nature of wrongful revocation of his medical license. Because he was, in actuality, seeking a review of the BPMC's determination, an Article 78 proceeding was the only appropriate action. As the time period for the bringing of an Article 78 proceeding had expired, the court upheld the Supreme Court's order dismissing the case.

The court noted that its actions toward the physician were necessary, because to rule otherwise would "circumvent the body of law which defines the extent of judicial review of administrative proceedings and could lead to wholly inconsistent ultimate determinations."

Barring One of Physician's Four Attorneys From Medical Discipline Hearing Did Not Deprive Physician of Fair Hearing

Alexander v. State Board for Professional Medical Conduct, 287 A.D.2d 918, 731 N.Y.S.2d 797 (3d Dep't 2001). A physician charged with sexual misconduct, failure to obtain and document a complete medical history and failure to maintain adequate medical records brought an Article 78 Proceeding to contest the revocation of his medical license by the Board of Professional Medical Conduct (BPMC). The physician sought review of the court because the Hearing Committee barred one of his four lawyers from the room, and allegedly restricted cross-examination of the patients. Additionally, the physician claimed that the Committee and later the Appellate Review Board (ARB) made several procedural errors.

The court held that the Committee's decision to bar one of the physician's four lawyers from the hearing room was not unfair, especially in light of the fact that the attorney was not licensed to practice in New York. It additionally noted that, "the constitutional right to effective assistance of counsel does not extend to administrative hearings of this type."

The court also rejected the assertion of procedural errors, noting that "it is well established that an administrative determination may only be annulled where prejudice so permeates the underlying hearing as to render it unfair."

As to the physician's penalty, the court noted that it had consistently upheld the revocation of a medical license where a physician was found to have engaged in misconduct of a sexual nature with patients.

SID-DOH Rule That Limited Provider Participation in External Appeals Is Invalid

HANYS, et al. v. Serio, et al. (3d Dep't 2002). Department of Health and the State Insurance Department regulations governing the external appeals of claims denials allow providers to appeal "retrospective" denials but not "concurrent" denials. HANYS, Citizen Action of New York and several regional hospital associations challenged the validity of two provisions of those external appeals regulations. The first provision defined "concurrent" denial to include any denial that results from a utilization review process that was

initiated during the course of treatment—even if it was not issued until long after the completion of treatment. The court upheld that provision as rational.

The second provision prohibited a patient's designee, e.g., a provider, from appealing a concurrent denial once services have been completed. This effectively prevented providers from acting on behalf of patients in a broad range of appeals. The court struck down this provision as not supported by the external appeals statute.

The state has filed an appeal, and the ruling is stayed pending that appeal.

State Supreme Court Approval Not Required for Hospitals to Affiliate Under a Common Member-Parent

Nathan Littauer Hosp. Assn. v. Spitzer, 734 N.Y.S.2d 671 (3d Dep't 2001). Two not-for-profit hospitals, Nathan Littauer Hospital Association in Gloversville, NY and St. Mary's Hospital in Amsterdam, NY, sought to affiliate by creating a new corporation, Tri-County Health System (TCHS), and making it the sole member of each hospital. The hospitals also planned to amend and restate their certificates of incorporation to give certain reserve powers to the new parent.

The Attorney General took the position that plaintiffs were required to seek State Supreme Court approval of their restated certificates of incorporation in accordance with N-PCL 804 and 805, on the ground that the amendment to Nathan Littauer Hospital's certificate "seeks to change or eliminate a purpose or power enumerated in the corporation's certificate of incorporation, or to add a power or purpose not enumerated therein." The Attorney General further contended that the transactions constituted a "disposition of assets" that required Supreme Court approval pursuant to N-PCL 510 and 511.

The hospitals disagreed, commenced a declaratory judgment action and prevailed in the Supreme Court. On appeal, the Appellate Division affirmed, finding that the restated certificates of incorporation show no change to Littauer's underlying corporate purpose. It specifically rejected an argument by *amicus* Planned Parenthood that the amendment would change the corporate purpose by affecting the ability of Littauer to provide abortion and other reproduction-related services. As the court stated, "the decision to delineate in a restated certificate of incorporation a specific or potential restriction upon the services to be provided by the corporation is not the functional equivalent of altering the corporation's underlying purpose or curtailing its power to achieve its overall objectives."

Finally, the court rejected as "without authority" the Attorney General's contention that the change in membership of Littauer and the corresponding reservation of powers to TCHS constitutes an "other disposition" of assets under N-PCL 510 and 511.

NOTE: This decision is reprinted in full on page 70 of this edition. The Attorney General has filed an appeal with the N.Y. State Court of Appeals.

Case Update

Sithian v. Staten Island University Hospital (New York court awards attorneys' fees to hospital under Health Care Quality Improvement Act), described in the previous issue of this column, has been reported at 734 N.Y.S.2d 812 (Richmond Co. Sup. Ct. 2001).

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

In the New York State Legislature

2002/2003 Health Care Package

On January 15th, after significant behind-the-scenes negotiations notable even by Albany standards, the legislature passed a major health care package (Senate 6084/Assembly 9610) that included funding for worker recruitment and retention, authorized the conversion of Empire Blue Cross Blue Shield into a for-profit entity, streamlined Medicaid and Child Health Plus and otherwise significantly altered the health care landscape in New York State. The Governor, shortly thereafter, signed the legislation into law as Chapter 1 of the Laws of 2002. A summary of key provisions follows.

Worker Recruitment and Retention

Hospitals. $650 million will be distributed over three years for workforce recruitment and retention. The funds will generally be paid as a Medicaid rate increase, but will be allocated based on each hospital's reported 1999 gross salary and fringe-benefit costs. HHC hospitals will receive their allocated monies as a grant. Hospitals will be required to use these funds solely for the purpose of recruitment and retention of "non-supervisory" workers, . . . or any worker with direct patient-care responsibility."

In addition, $45 million will be distributed through an RFP for innovative workforce recruitment and retention programs, and $237 million in NYPHRM funds will be distributed to hospitals previously owed this money.

Community Health Centers and Other Diagnostic and Treatment Centers. $39 million will be distributed over three years for workforce recruitment and retention to not-for-profit D&TCs eligible to receive Medicaid managed care transition funding and to those serving individuals with developmental disabilities. These D&TCs include community health centers, family-planning clinics, PCAP providers and clinics serving the homeless. Like the funding for hospitals, these funds will be paid as a Medicaid rate increase, but will be allocated based on each center's reported 1999 salary and fringe-benefit costs.

Nursing Homes. $475 million will be distributed over three years for workforce recruitment and retention to nursing homes. A portion of these funds will be distributed as grants for quality improvement. An additional $30 million over three years will be distributed to financially distressed nursing homes.

Personal Care. $597 million will be distributed over three years to raise Medicaid reimbursement for personal care for purposes of improving workforce recruitment and retention. Of these funds, $555 million will be allocated to the New York City home attendant program. The remaining $42 million will be added to personal care rates in the rest of the state.

Streamlining Enrollment and Recertification in Medicaid and Child Health Plus

Personal Interviews. The bill eliminates the face-to-face interview upon recertification of eligibility for both children and adults on Medicaid.

Attestation of Income Information for CHP Recertification. In lieu of the documentation traditionally required to recertify financial eligibility for CHP, a family may simply attest to its income and provide the social security numbers of each parent and legally responsible adult who is a member of the child's household.

Attestation of Resource Information. Individuals applying for or recertifying for community Medicaid will be able to self-attest to their resources.

Grace Period for CHP Recertification. Children who appear to remain eligible for CHP coverage at recertification, but who have not fully documented their eligibility, will continue to be covered for a period of two months from the date on which their eligibility would otherwise terminate.

Expand Facilitated Enrollment. Organizations and health care providers will be permitted to engage in facilitated enrollment upon application to DOH, regardless of the availability of funding.

Notification of Insurance Options. Any time an action is taken with respect to applicants' or recipients' Medicaid coverage, the individuals must be informed in writing as to: their right to Medicaid coverage without cash assistance; transitional Medicaid, Family Health Plus and Child Health Plus; and Medicaid for aged, blind and disabled.

Administrative Changes. In addition to the legislative provisions, DOH has indicated that it will eliminate the requirement that individuals applying or recertifying for Medicaid document their social security number. Further, it will eliminate the requirement that children recertifying for CHP document their residence.

Expansions of Medicaid Eligibility

Medicaid Buy-In. Disabled workers with net income up to 250% of the federal poverty level and assets of up to $10,000 will be eligible for Medicaid. Workers with income above 150% of the federal poverty level will pay a premium for

coverage based on a sliding fee scale. This provision will not take effect until April 2003.

Breast and Cervical Cancer Coverage. In accordance with authorizing federal legislation, uninsured or underinsured individuals with income up to 250% of the federal poverty level diagnosed with breast or cervical cancer by the CDC's early detection program will be eligible for Medicaid for the period in which they are undergoing treatment for breast or cervical cancer.

Other Medicaid Issues

The package included several measures to reduce Medicaid spending and raise revenue, including the revival of the nursing home assessment.

Medicaid Cuts. The Legislature *rejected* the Governor's proposals to reduce Medicaid reimbursement for part-time clinics by 35% and limit reimbursement for Medicare Part B services received by Medicaid/Medicare dual eligibles to the Medicaid rate of payment (known as crossover payments). The Legislature *accepted* the Governor's proposal to mandate generic substitution of brand-name pharmaceuticals, unless the physician obtains prior approval from DOH. The Commissioner has discretion to exempt certain brand-name drugs from the prior approval requirement.

Implementation of Federal Prospective Payment System for Federally Qualified Health Centers. The legislation includes provisions lifting the freeze on Medicaid reimbursement for FQHCs and implementing the federally mandated prospective payment reimbursement methodology for those facilities, effective January 1, 2001.

Nursing Home Assessment. The legislation reinstates the 6% assessment on gross receipts for 3 years, with Medicaid reimbursing for its share.

Covered Lives Assessment

The legislation eliminates a reduction that was previously scheduled to take place in 2002 in the professional education pool funding raised through the covered lives assessment paid by health insurers. Accordingly, the covered lives assessment is likely to remain at the 1996 level.

EPIC

Rebates. The legislation conforms the methodology for determining rebates owed by pharmaceutical manufacturers to the methodology in place for Medicaid.

Coordination of Benefits. Commencing April 2002, a data match will be conducted with health insurance beneficiary records to facilitate the use of insurance benefits, where available, to cover prescription drug costs.

Early Intervention

The legislation strengthens existing law requiring health insurers that cover early intervention services to provide reimbursement for those services.

Empire Conversion

The legislation authorizes Empire Blue Cross Blue Shield (but, under the statute, no other non-profit health insurer) to convert to a for-profit entity. The proceeds of the Empire conversion will be allocated largely to the workforce and other initiatives set forth above. Five percent of the proceeds will be distributed to a foundation with trustees appointed by the Governor and legislative leaders.

This last provision may be among the more controversial: After years of debate over how and whether non-profit plans might convert to for-profit status, it was only the necessity created by a post-September 11th state fiscal crisis and a desire to provide the additional resources to the health care system that led to the Empire conversion authorization. Unlike those conversions in other states that resulted in the funding of large charitable entities to carry on the non-profit missions of the converting plans, New York State has effectively captured the lion's share of the assets to support its own initiatives. Given some of the uncertainties surrounding the sources of funding for this health care initiative—including an increase in the federal Medicaid matching share—the legislature may be looking to utilize the charitable assets of any future conversions in a way to bolster the fiscal foundation of these spending commitments.

Compiled by James W. Lytle, managing partner of the Albany offices of Kalkines Arky Zall and Bernstein, LLP. The firm, which is based in Manhattan, represents a wide array of health care and other regulated entities and devotes a substantial part of its practice to the representation of health care clients before the Legislature and state regulatory bodies.

In the New York State Agencies

Department of Health Regulations

Personal Care Services

Notice of Adoption. The Department of Health amended section 505.14(b) of title 18 N.Y.C.R.R. in response to a court order to amend the regulations. The purpose of the regulations is to establish general parameters for the administration, provision and reimbursement of Medicaid reimbursable personal care services. Personal care services must be denied or discontinued when such services are no longer medically necessary or when such services cannot maintain a patient's health and safety in his home. Filing Date: October 16, 2001. Effective Date: October 31, 2001. *See* N.Y. Register, October 31, 2001.

Change in Ownership Language in Medicaid Rate Calculation

Notice of proposed rule making. The Department of Health gave notice of its intent to amend Subdivision k of section 86-2.10 of title 10 N.Y.C.R.R. to allow for a recalculation of the nursing facility Medicaid rate utilizing a new base period cost report when there is a change in ownership between a parent and child. Recalculation of rates will only be allowed if the change in ownership occurs only once every ten years. *See* N.Y. Register November 28, 2001.

Health Care Practitioner Referrals and Laboratory Business Practices

Notice of Adoption. The Department of Health amended part 34 of title 10 N.Y.C.R.R. to bring state regulation into compliance with federal rules and clarify State direct billing and anti-kickback laws. Filing Date: December 5, 2001. Effective Date: December 26, 2001. *See* N.Y. Register, December 26, 2001.

Physician Profiling

Emergency rule making. The Department of Health added a new part 1000 to title 10 N.Y.C.R.R. in order to implement the Patient Health Information and Quality Improvement Act of 2000. The Act requires the Department of Health to collect information and create individual profiles on physicians that shall be available for dissemination to the public to improve the quality of health care in the state. The Department must also provide each physician with a copy of his/her profile prior to dissemination to the public. Filing date: December 19, 2001. Effective date: December 19, 2001. *See* N.Y. Register, January 9, 2002.

Adult Day Health Care Regulations

Emergency rule making. The Department of Health repealed parts 425, 426 and 427 of title 10 N.Y.C.R.R. and added a new part 425 to title 10 N.Y.C.R.R. in order to ensure that individuals receive adult day health care when appropriate and that providers are accountable for providing necessary and appropriate care. The proposed regulations provide for general requirements for the operation of an adult day health care, as well as specified minimum program and service components that must be available. Filing date: January 2, 2002. Effective date: January 2, 2002. *See* N.Y. Register, January 23, 2002.

State Insurance Department Regulations

Privacy of Consumer Financial Information

Emergency rule making. The Department of Insurance added a new part 420 to title 11 N.Y.C.R.R. to provide rules and regulations on the privacy of consumer financial and medical information complementing the rules established by various federal regulatory agencies pursuant to title V of the Gramm-Leach-Biley Act, 15 U.S.C. §§ 6801 *et seq.*, and preserving the ability of New York State to promulgate rules concerning insurance consumer protections. Filing date: September 21, 2001. Effective date: September 21, 2001. *See* N.Y. Register, October 10, 2001.

Standards for Safeguarding Consumer Information

Notice of proposed rule making. The Department of Insurance gave notice of its intent to add a new part 421 to title 11 N.Y.C.R.R. to establish standards for developing and implementing administrative, technical and physical safeguards to protect the security, confidentiality and integrity of customer information. *See* N.Y. Register, November 21, 2001.

Healthy New York Standardized Application

Emergency rule making. The Department of Insurance amended sections 362-2.3 and 362-4.3 of title 11 N.Y.C.R.R. in order to require health maintenance organizations and participating insurers to accept a simplified, standardized application for the

Healthy New York program provided by the Insurance Department that will facilitate the appropriate enrollment and ease administrative processes. The requirements for demonstrating income eligibility have also been modified in order to eliminate some of the complexity from the application process. Filing date: November 19, 2001. Effective date: November 19, 2001. *See* N.Y. Register, December 5, 2001.

Fraud Prevention

Notice of proposed rule making. The Department of Insurance gave notice of its intent to amend sections 86.4 and 86.6 of title 11 N.Y.C.R.R. in order to make applicable to certain health care providers and exempt certain others from the requirement to submit fraud prevention plans and revise the qualifications for individuals to serve as insurance fraud investigators. *See* N.Y. Register, December 26, 2001.

Financial Risk Transfer Agreements

Notice of adoption. The Department of Insurance amended part 101 of title 11 N.Y.C.R.R. in order to assess the financial responsibility and capability of health care providers to perform their obligations under certain financial risk-sharing agreements and set forth standards pursuant to which providers may adequately demonstrate such responsibility and capability to insurers. Filing date: January 15, 2002. Effective date: January 15, 2002. *See* N.Y. Register, January 30, 2002.

Complied 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 has served 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 Ms. Vimala Varghese, an associate at Cadwalader, Wickersham & Taft, in compiling this summary is gratefully acknowledged.

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***American Journal of Law & Medicine*, volume 27, numbers 2 and 3 (2001):**

- Lucian L. Leape, *Foreword: Preventing Medical Accidents: Is "Systems Analysis" the Answer?*
- Jerome P. Kassirer, *Financial Conflict of Interest: An Unresolved Ethical Frontier.*
- Stephen R. Latham, *System and Responsibility: Three Readings of the IOM Report on Medical Error.*
- Joan H. Krause, *Medical Error as False Claim.*
- Sidney D. Watson, *Race, Ethnicity and Quality of Care: Inequalities and Incentives.*
- David M. Studdert and Troyen A. Brennan, *Toward a Workable Model of "No-Fault" Compensation for Medical Injury in the United States.*
- Michael Baram, *Making Clinical Trials Safer for Human Subjects.*
- Fritz H Bach, Adrian J. Ivinson and H.E. Judge Christopher Weeramantry: *Ethical and Legal Issues in Technology: Xenotransplantation.*
- Tony R. Maida, *How Judicial Myopia is Jeopardizing the Protection of People with HIV/AIDS Under the ADA.*
- Peter J. Van Hemel, *A Way Out of the Maze: Federal Agency Preemption of State Licensing and Regulation of Complementary and Alternative Medicine Practitioners.*

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- Peter R. Roest, *Recovery of Medicare and Medicaid Overpayments in Bankruptcy.*
- David B. Brushwood, *Responsive Regulation of Internet Pharmacy Practice.*
- Sara E. Zeman, *Regulation of Online Pharmacies: A Case for Cooperative Federalism.*
- Kara M. Friedman, *Internet Prescribing Limitations and Alternatives.*
- Jannet M. Carmichael and Janice A. Cichowlas, *The Changing Role of Pharmacy Practice—A Clinical Perspective.*
- Raegan A. McClain, *The Government, the Legislature and the Judiciary—Working Towards Remedying the Problems with the Civil False Claims Act: Where Do We Go From Here?*
- Amy Baum Goodwin, *Striving for a Secure Environment: A Closer Look at Hospital Security Issues Following the Infant Abduction at Loyola University Medical Center.*

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- Norman L. Cantor, Glucksberg, *The Putative Right to Adequate Pain Relief, and Death with Dignity.*
- Scott M. Himes, *The Collision of Healthcare and Corporate Law in a Hospital Closure Case.*
- David Villar Patton, Dawn R. Landers and Indu T. Agarwal, *Legal Considerations of Sleep Deprivation Among Resident Physicians.*
- Andres Rueda, *Rethinking Blood Shield Statutes in View of the Hepatitis C Pandemic and Other Emerging Threats to the Blood Supply.*
- Elizabeth K. Schneider and Joseph J. Simeone, *Pain and Disability Under Social Security: Time for a New Standard.*
- Elisabeth H. Sperow, *Section 525(a) of the Bankruptcy Code Plainly Does Not Apply to Medicare Provider Agreements.*
- Brian Gradle, *Sample Patient Medical Information Use and Disclosure Notice.*

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- John D. Columbo, *Private Benefit, Joint Ventures, and the Death of Healthcare as an Exempt Purpose.*
- Thomas K. Hyatt, *One for You and Two for Me: Revenue Sharing Arrangements in Charitable Healthcare Organizations.*
- Gerald M. Griffith, *TBOR2 Compliance Plans: From Rebuttable Presumption to Enforcement.*
- Douglas M. Mancino, *A Contemporary Reexamination of Revenue Ruling 69-545 and the Promotion of Health Rationale for Exemption.*
- Thomas B. Leary, A*ntitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II.*
- *Health Care Compliance Table of Acronyms.*

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- Erica Rose, *Financial Conflicts of Interest: How Are We Managing?*
- Timothy Caulfield, *Globalization, Conflicts of Interest and Clinical Research: An Overview of Trends and Issues.*
- Michael J. Malinowski, *Institutional Conflicts and Responsibilities in an Age of Academic-Industry Alliances.*

- Pilar N. Ossorio, *Pills, Bills and Shills: Physician-Researcher's Conflicts of Interest.*
- Janet Fleetwood, *Conflicts of Interest in Clinical Research: Advocating for Patient-Subjects.*
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- *Symposium: Patient Injury, Medical Errors, Liability, and Reform 9.*

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- Melissa Cole, *Beyond Sex Discrimination: Why Employers Discriminate Against Women with Disabilities When Their Employee Health Plans Exclude Contraceptives from Prescription Coverage*, 43 Ariz. L. Rev. 501 (2001).
- Phyllis C. Borzi, *Distinguishing Between Coverage and Treatment Decisions Under ERISA Health Plans: What's Left of ERISA Preemption?* 49 Buffalo L. Rev. 1219 (2001).
- Rhonda Gay Hartman, *Adolescent Decisional Autonomy for Medical Care: Physician Perceptions and Practices*, 8 U. Chi. L. Sch. Roundtable 87 (2001).
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- Judith C. Appelbaum and Jill C. Morrison, *Hospital Mergers and the Threat to Women's Reproductive Health Services: Applying the Antitrust Laws*, 26 N.Y.U. Rev. L. & Soc. Change 1 (2000-2001).
- Jon Bauer, *The Character of the Questions and the Fitness of the Process: Mental Health, Bar Admissions and the Americans with Disabilities Act*, 49 UCLA L. Rev. 93 (2001).
- Geoffrey C. Marczyk and Ellen Wertheimer, *The Bitter Pill of Empiricism: Health Maintenance Organizations, Informed Consent and the Reasonable Psychotherapist Standard of Care*, 46 Vill. L. Rev. 33 (2001).

Compiled by Dale L. Moore, Associate Dean of Academic Affairs and Professor of Law, Albany Law School.

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

For Your Information

By Claudia O. Torrey

The following bullets highlight information of interest:

- Effective March 4, 2002, a new rule requires *all* attorneys practicing in New York State to provide clients with a written letter of engagement. The new rule is a joint order of the appellate divisions, and is found in part 1215 to title 22 of the New York Codes, Rules and Regulations (N.Y.C.R.R.). Although the rule is mandatory and not advisory, a joint order, as opposed to a disciplinary rule, should send the message that the rule is not an attorney disciplinary matter.

  The letter of engagement applies to corporate clients, as well as individuals; and a retainer agreement can be substituted for a letter of engagement. Also, the rule shall not apply to: representation of a client wherein the fee to be charged is less than $3,000; representation wherein the attorney's services are of the same general kind as previously rendered to and paid for by the client; or representation in domestic relations matters subject to part 1400 of the Joint Rules of the Appellate Division.

- On January 31, 2002, Department of Health and Human Services (DHHS) Secretary Tommy Thompson announced that DHHS will release the first 20 percent of $1.1 billion in bioterrorism preparedness funds for states. The funds are to be utilized by the states for such items as: the enhancement of hospital readiness systems for handling large numbers of casualties; the expansion of public health capabilities; the development of comprehensive bioterrorism plans; and the improvement of connectivity between hospitals and local and state health departments regarding disease reporting.

- On December 19, 2001, in the quest to keep the delivery of healthcare within New York State a positive experience, the New York State Department of Health (DOH) implemented emergency regulations regarding a public physician profile law. The regulations implement parts of the Patient Health Information and Quality Act of 2000, which requires the state to publish information about physicians, hospitals and health plans, as well as create individual professional profiles of physicians for dissemination to the public.

  On January 9th, the DOH clarified in the state Register what information must be provided by physicians, and how frequently the information needs to be updated. Besides information on graduate medical education and board certification, the physician profiles must include such items as settlements, criminal convictions, judgments and medical malpractice awards.

  The physician profile law can be found in part 1000 of title 10 of the N.Y.C.R.R. As this issue was going to press, the physician profile law had not yet been adopted in final form by DOH.

- The Association for the Accreditation of Human Research Protection Programs (A^2HRP^2) has released interim standards for the accreditation of human research protection programs. The standards embody nine principles that A^2HRP^2 believes will keep ethical behavior and ethical expectations consistent, regarding the protection of individual research participants. Some of the principles are: that the standards should promote the development and implementation of outcomes that can provide a basis for demonstrating quality improvement over time; that regulatory compliance is a minimum expectation for a research protection program; and that the accrediting process should create an educational atmosphere involving discussion and constructive feedback.

  A^2HRP^2 is a private, nonprofit entity developed by Public Responsibility in Medicine and Research of Boston. The model for A^2HRP^2 is the Association for the Assessment and Accreditation of Laboratory Animal Care, an entity that keeps up with animal research care in approximately 800 institutions around the world.

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

Bounty Amid Scarcity: The Health Care Workforce Legislation

By Eugene M. Laks

Omnibus health care legislation was proposed by the Governor and passed by the legislature in January, as Chapter 1 of the Laws of 2002. A central focus of the legislation is to provide over the next three years approximately $1.8 billion in additional funds, principally through the Medicaid program, for health care workforce recruitment and retention, and to address potential shortages of health care workers. In structuring a program through increases in Medicaid reimbursement, 50% of the cost will be borne by the federal government. Funding is provided for hospitals, nursing homes, personal care services providers and freestanding clinics. Workforce components of the Governor's proposal were developed with support of health care providers and health workers' labor union Local 1199 of the Service Employees International Union.

The segments of the health care service delivery system that are not included as beneficiaries of this program have been exhorting the legislature and the Governor in fashioning the 2002-2003 state budget to provide additional funding to help meet their workforce needs. These include certified home health agencies, long-term home health programs, hospice programs and mental health care program providers.

The legislation also reinstituted the state's 6% assessment on nursing home gross receipts. While this tax will be reimbursable by Medicaid, nursing homes will not be able to recover this additional cost from other payors, such as Medicare. Some nursing homes may lose more than they gain under this bill.

A major uncertainty surrounds one of the funding sources for this bill, the state's proposal for an increase in federal funding of the state's Medicaid program, the federal medical assistance percentage (FMAP), from 50% to 53%. The state's share of any such increase is dedicated as a funding source for the initiatives under this legislation. However, the President has not included such an increase in the proposed federal 2002-2003 budget. New York has been working with Congress to obtain these funds, but the outcome is uncertain. An alternate source of funding would have to be identified in the 2003 state legislative session if these additional funds are not forthcoming from the federal government.

This omnibus bill also made numerous changes to other aspects of the state's financial support for the health care delivery system. This article provides a brief summary of this complex legislation.

Workforce Recruitment and Retention

The major initiative of the legislation is directed at improving conditions for the health care workforce. Funds are provided to eligible health care providers, targeted for annual increases in provider expenditures for workforce recruitment and retention, e.g., increases in workers' salary and fringe benefits. The funding is contingent on federal approval under the Medicaid program.

Aggregate dollar amounts will be allocated for categories of providers over a 3-year period, April 1, 2002 through December 31, 2004. The health care provider categories are: non-public general hospitals,[1] $544 million; public general hospitals,[2] $107 million; non-public residential health care facilities,[3] $253 million; public residential health care facilities,[4] $35 million; personal care services providers in New York City,[5] $555 million; personal care services providers outside New York City,[6] $42 million; and specified types of diagnostic and treatment centers,[7] $39 million.

Within each of the general hospital, residential health care facility (nursing home) and diagnostic treatment center provider categories, funds are to be allocated by the Department of Health from the aggregate dollar allocation for each year to individual health care providers, proportionally based on each provider's relative share of reported 1999 gross salary and fringe benefit costs for all providers within the category. The allocation methodology considers the gross amounts, not related to a provider's payor mix.

For personal care services providers, allocations in New York City will be made, and Medicaid rates will be adjusted in accordance with a memorandum of understanding between the state and the city to be developed for the purpose of supporting the recruitment and retention of personal care services workers. Outside of New York City, funds will be allocated, and Medicaid rates adjusted, among providers based on the 1999 relative number of hours of care provided. The additional Medicaid funding provided for personal care services workers will not affect the calculation of medical assistance savings targets for the social services districts.[8]

The amount allocated to each non-public general hospital and non-public residential health care facility will be treated in total as a Medicaid reimbursable cost add-on. Medicaid rates of payment for each provider

will be adjusted based on the provider's Medicaid utilization data for the period two years prior to the applicable rate period. Thus, there will be a unique adjustment for each provider. For non-public general hospitals, Medicaid inpatient rates of payment will be adjusted and discrete Medicaid additional rates of payment established for Medicaid and Family Health Plus patients participating in managed-care programs. This approach is modeled after the Medicaid payment system for graduate medical education in which a teaching hospital submits a separate bill to the state for each Medicaid managed-care patient upon discharge. For non-public residential health care facilities, Medicaid inpatient per diem rates of payment will be adjusted. It is expected that rate adjustments for the first year will be made in the July 2002 Medicaid rates.

The financial benefit any provider will actually realize in a rate period from the adjustments will be dependent on that provider's actual rate period Medicaid utilization. There will not be any volume adjustments for differences between the base year and rate year Medicaid utilization.

For public general hospitals, New York has maximized amounts that can be claimed under the federal disproportionate share hospital program for uncompensated care, additional Medicaid payments for care of the uninsured and Medicaid patients.[9] Medicaid hospital and nursing home reimbursement rates also are subject to federal ceilings on the amount that a state may pay, related to calculations under Medicare reimbursement principles.[10] For public hospitals and public nursing homes, further increasing Medicaid reimbursement for workforce recruitment and retention efforts would not be effective. The legislation provides that for public facilities, the amounts allocated to each provider will be distributed as grants for workforce recruitment and retention.

An additional $10 million over three years is provided for grants to non-public general hospitals that experience reductions in bad debt and charity care pool funding, because increased Medicaid payments under the workforce program result in the hospital exceeding its federal disproportionate share hospital limits.[11] Supplemental funds, $15 million per year, are provided for non-public general hospital Medicaid rate adjustments for extraordinary costs related to workforce recruitment and retention.[12] Funds will be provided through a competitive process.

Providers are prohibited from using the funds for any purpose other than recruitment and retention of non-supervisory workers or workers with direct patient care responsibility. Providers will be required to submit a written certification to the Department of Health attesting that the funds have been so applied, and will be subject to audit and recoupment for non-compliance.

Nursing Home Quality Improvement Demonstration Program

Annual funding of $62 million is provided for nursing homes for such projects as increasing direct care staff, increasing training and education of direct care staff, efforts to decrease staff turnover and other quality of care initiatives.[13] Funds will be awarded on a competitive basis and reflected in Medicaid rate increases or for public providers awarded as grants.

Nursing Home Assessment

The state's 6% assessment on nursing home gross receipts received on a cash basis is reinstituted effective April 1, 2002.[14] This provider tax had previously been phased-out. The assessment will be considered a reimbursable provider cost and will be reflected in Medicaid reimbursement rate increases.[15] The state will pay the non-federal share of the Medicaid rate increase without local contribution.[16] This will mitigate the impact of the assessment on a nursing home to the extent that the home's patient mix is composed of Medicaid patients. The assessment is paid by nursing homes to the Commissioner of Health and deposited by the Commissioner to the State General Fund.

Empire Blue Cross and Blue Shield Conversion

Statutory authority is provided for the Empire Blue Cross and Blue Shield conversion from a not-for-profit company to a business corporation based on a plan of conversion, public hearings and approval by the Superintendent of Insurance.[17] Adequate protection of the current contract holders must be provided. A public asset fund is established from 95% of the fair market value of assets to be converted. Funds are dedicated for support of the health care initiatives instituted or supported through this bill. A charitable corporation is established to receive and manage a charitable asset, the remaining 5% from the conversion, with an estimated value of $50 million, which will be devoted to such charitable initiatives as expansion of access to health care through insurance and delivery of services to the uninsured and public education about health care issues.

Medicaid Upper Payment Limits

Under recent changes in federal regulations, for a limited period of time increased Medicaid reimbursement is authorized for the class of providers that are

non-state operated public general hospitals (i.e., county and public benefit corporation operated hospitals).[18] The Medicaid reimbursement ceiling for the class is established at 150% of a reasonable estimate by the state of the amount that would be paid for the services calculated under Medicare reimbursement principles, rather than 100%. Provisions are enacted to provide increased Medicaid reimbursement for non-state operated public general hospitals, including targeting funding within the New York City Health and Hospitals Corporation to increase funding to 100% and for such period as is permissible to 150% of the ceiling.[19] Local governments are responsible for the non-federal share of the adjustments.[20] Funds under this program must first be offset by any reductions in eligibility for Medicaid disproportionate-share hospital funding before any benefit would be realized by a hospital. Such Medicaid reimbursement is exempt from the 1% provider-tax assessment on hospital inpatient revenue.[21]

Funding Sources for Medicaid Rate Adjustments and Grants

The state share of the Medicaid rate adjustments and grants under the workforce programs and other initiatives under this legislation is derived through the "public goods" pool mechanism, the Tobacco Control and Insurance Initiatives Pool, established under the Health Care Reform Act. The increased funding for the annual Tobacco Control and Insurance Initiatives Pool to provide the state share of the increased Medicaid program expenditures is derived from several sources, including:

- funds made available from the conversion of Empire Blue Cross and Blue Shield from a not-for-profit company to a business corporation; [22]
- any funds derived by the state from an increase in the FMAP for New York (the local share would flow to New York City and the counties to offset local Medicaid costs of implementing this legislation);[23]
- increase in the annual target amounts for calculation of the third-party payor hospital inpatient covered lives assessments (payor tax);[24]
- increase in the cigarette tax by 39¢ per pack, from $1.11 to $1.50;[25]
- funds available from New York City or a county in which a public general hospital receives a benefit from increased public hospital Medicaid reimbursement related to increased upper payment limits;[26] and
- proceeds from the final dissolution of the MMIA.[27]

The 6% assessment on nursing home gross receipts is not a source of funding for the pool. That revenue goes to the State General Fund.

Medical Malpractice Insurance

The state program under which funds are provided to purchase an additional $1 million per claimant and $3 million in aggregate in excess medical malpractice insurance for physicians and dentists is continued, with the initial level that each participating physician or dentist must purchase increased to $1.3 million per claim and $3.9 million in aggregate from the current requirement of $1.0 million per claim and $3.0 million in the aggregate.[28] Financial support for the program is provided from the Tobacco Control and Insurance Initiatives Pool.[29] The authority of the Superintendent of Insurance to establish premium rates for medical malpractice insurance also is continued. All participating physicians and dentists must participate in a proactive risk management program.[30]

Other Pool Funding Initiatives

Grant funds of $30 million over 3 years are provided for financially disadvantaged nursing homes to promote financial stability and quality improvement initiatives.[31]

Additional funding is provided for the state's Elderly Pharmaceutical Insurance Coverage program (EPIC), which provides subsidized coverage for prescription drugs for low-income seniors from the pool rather than from the State General Fund.[32]

Increased pool funding is provided to subsidize Roswell Park Cancer Institute.[33]

Increased pool funding is provided for public health programs.[34]

Funding is provided for the state share of Medicaid expenditures for patients eligible for Medicaid based upon expanded eligibility criteria, up to 250% of the federal poverty level, for persons under treatment for breast or cervical cancer[35] and for disabled persons eligible under an increased income eligibility ceiling.[36]

Up to $11 million may be transferred from the pool to the State General Fund.

Hospital Cash Flow Improvements

Pool reserves in NYPHRM and HCRA pools would only be maintained by the Department of Health for 36 months after the close of a pool year.[37] Over $200 million in accumulated NYPHRM and HCRA pool reserves will be distributed. Any adjustments to pool allocations after a 36-month period would be applied against cur-

rent pool allocations. Also, the basis for initial distributions of Medicaid disproportionate-share hospital funds for public general hospitals under the state's maximization program is updated from 1995 data to 2000 data.[38]

Child Health Plus

Acceptable types of documentation to establish income eligibility are specified;[39] limited presumptive eligibility is provided upon recertification of eligibility;[40] additional community-based organizations and health care providers may provide community outreach, education and facilitated enrollment;[41] the Commissioner of Health is directed to develop a simplified recertification form;[42] and the program is extended to July 1, 2003.[43]

Medicaid Eligibility

The eligibility process for verification of financial information is specified;[44] a simplified recertification of eligibility form will be developed;[45] applicants with dependent children must be informed of the availability of Medicaid coverage under various programs and Child Health Plus;[46] additional community-based organizations and health care providers may provide community outreach, education and facilitated enrollment;[47] and expanded eligibility criteria, up to 250% of the federal poverty level, are provided for persons under treatment for breast or cervical cancer,[48] which persons are not eligible to participate in Medicaid managed-care programs.[49]

The Medicaid income eligibility ceiling is raised for disabled persons who are in the workforce.[50] An opportunity to buy-in to the Medicaid program through payment of a premium, related to income of the low-income disabled person, is provided.[51] Such disabled persons are not required to participate in Medicaid managed-care programs,[52] although an eligible person who is not required to pay a premium to participate in Medicaid may voluntarily opt to join a managed-care plan.[53]

Medicaid Prescription Drug Benefit

A brand name prescription drug for which there is a multi-source therapeutically and generically equivalent drug will not be covered under Medicaid unless the drug is exempted by the Commissioner of Health from the restriction.[54]

Health Care Services for State and Local Prison Inmates

Provision is made for reimbursement to correctional services, subject to federal approval, of federal funds expended for health care services provided for state and local correctional services inmates who are Medicaid eligible. Eligible services are inpatient services provided in general hospitals, residential health care facilities, psychiatric hospitals and intermediate care facilities.[55]

Federally Qualified Health Centers

State law is revised retroactive to January 1, 2001, to meet federal statutory requirements which establish a methodology for calculating Medicaid reimbursement rates for federally qualified health centers and rural health centers.[56]

Early Intervention Services

Insurers are prohibited from excluding coverage of services based upon the availability of the state's early intervention program benefits, and state early intervention program reimbursement is secondary to coverage under insurance policies and secondary to coverage under the Medicaid program.[57]

EPIC

Limitations are provided on state reimbursement to pharmacies for prescription drugs provided under the EPIC program for eligible elderly persons,[58] and the manufacturer's drug rebate program is revised.[59] EPIC coverage is made secondary to private insurance coverage, and provision is made for recovery by the EPIC program of amounts expended when EPIC should have been the secondary payor.[60]

Miscellaneous Provisions

Statutory time frames for notice of and promulgation of Medicaid reimbursement rates are waived for purposes of implementing this act.[61]

The sunset dates for various programs related to Medicaid managed care are extended for another year to June 30, 2003.[62] The sunset date applicable to the statutory provisions governing capital cost reimbursement for residential health care facilities is extended to December 31, 2003.[63]

The Medicaid program for buy-in to the Medicare Part B program for certain low-income elderly categories by paying or subsidizing the premium is continued.[64]

Flexibility is provided for counties to operate regional Medicaid transportation programs.[65]

The amount that a health care practitioner or provider may charge an attorney for making a copy of a medical record is increased, effective April 1, 2002, to $1 per page from 75¢ per page.[66]

Certificate of need fees charged by the Department of Health are increased.[67]

Conclusion

Next year marks the expiration of the current HCRA legislation which establishes the hospital inpatient Medicaid reimbursement methodology and establishes pools for funding hospital bad debt and charity care, graduate medical education and numerous health care initiatives. The enactment of the workforce recruitment and retention legislation this year with its multi-year funding commitment paves the way for resolution of HCRA reauthorization issues next year. However, if the anticipated funds from an increase in the FMAP are not forthcoming, an alternative funding source will have to be identified. The health care workforce initiative may drain funds from competing health care priority funding requests.

Endnotes

1. *See* N.Y. Public Health Law § 2807-c(30)(a) (PHL).
2. *See* PHL § 2807-c(30)(b).
3. *See* PHL § 2808(18)(a).
4. *See* PHL § 2808(18)(b).
5. *See* PHL § 2807-v(bb).
6. *See* Social Services Law § 367-q (SSL).
7. *See* PHL § 2807(17).
8. *See* Act, Part A, § 4.
9. *See* 1996 N.Y. Laws ch. 474, § 211, *as amended by* Act, Part B, § 6; 1996 N.Y. Laws ch. 474, § 212.
10. *See* 42 C.F.R. §§ 447.272 and 447.321.
11. *See* PHL § 2807-c(30)(c).
12. *See* PHL § 2807-c(31).
13. *See* PHL § 2808-d.
14. *See* PHL § 2807-d(2)(b)(vi).
15. *See* PHL § 2807-d(10)(c).
16. *See* SSL § 368-a(1)(v).
17. *See* Insurance Law §§ 4301(j), 7317.
18. *See* 67 Fed. Reg. 2602 (2002) (to be codified at 42 C.F.R. §§ 447.272 and 447.321).
19. *See* Act, Part A, §§ 11-14, Part B, §§ 13, 14.
20. *See* Act, Part A, § 22, Part B, § 18.
21. *See* Act, Part A, § 17, Part B, § 15.
22. *See* Insurance Law §§ 4301(j), 7317(e).
23. *See* Act, Part A, § 27.
24. *See* PHL § 2807-s(6)(a).
25. *See* Tax Law §§ 471(1), 471-a, 482.
26. *See* Act, Part A, § 20.
27. *See id.* § 43.
28. *See* 1986 N.Y. Laws ch. 266, § 18 as amended by Act, Part A, §§ 36-40.
29. *See* PHL § 2807-v(1)(v).
30. *See* Act, Part A, § 42.
31. *See* PHL § 2808(19).
32. *See* PHL § 2807(v)(1)(n)(iii), (iv).
33. *See* PHL § 2807-v(1)(o)(iii), (iv).
34. *See* PHL § 2807-v(1)(k)(ii), (iii).
35. *See* PHL § 2807-v(1)(w).
36. *See* PHL § 2807-v(1)(ff).
37. *See* Act, Part A, § 24.
38. *See* 1996 N.Y. Laws ch. 474, §§ 211(1)(b), 212(1) as amended by Act, Part B, §§ 7, 8 respectively.
39. *See* PHL § 2511(2)(f).
40. *See* PHL § 2511(2)(j).
41. *See* PHL § 2511(9)(h).
42. *See* PHL § 2511(16-a).
43. *See* 1998 N.Y. Laws ch. 2, § 47 as amended by Act, Part A, § 55.
44. *See* SSL § 366-a(2).
45. *See* SSL § 366-a(15).
46. *See* SSL § 366-a(9).
47. *See* SSL § 369-ee(4).
48. *See* SSL § 366(4).
49. *See* SSL § 364-j(3)(d)(xiii).
50. *See* SSL § 366(1)(a)(12), (13).
51. *See* SSL § 367-a(12).
52. *See* SSL § 364-j(3)(d)(xiv).
53. *See* SSL § 364-j(3)(c)(vi).
54. *See* SSL § 365-a(4)(a-1).
55. *See* Act, Part B, §§ 9-12.
56. *See* PHL § 2807(8).
57. *See* Insurance Law § 3235-a; PHL § 2557(1).
58. *See* Executive Law § 547-j(1).
59. *See* Executive Law § 547-j(3)(a), (b).
60. *See* Executive Law § 547-j(4).
61. *See* Act Part A, § 73, Part B, § 29.
62. *See* Act, Part B, §§ 22, § 23.
63. *See* Act, Part B, § 24.
64. *See* SSL § 367-a(3)(d)(1), (2).
65. *See* SSL §§ 365-a(2)(j), 365-h(3).
66. *See* PHL § 18(2)(e), Mental Hygiene Law § 33.16(b)(6).
67. *See* PHL § 2802(7).

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Recent Developments Under Kendra's Law

By Keith J. Brennan

Introduction

On January 3, 1999, an event occurred that galvanized the mental health community, and served as a catalyst for an effort to identify and address the needs of the small population of persons who respond well to treatment when hospitalized, but who have trouble maintaining their recovery once back in the community. On that date, Andrew Goldstein, a man with a history of mental illness and hospitalizations, pushed Kendra Webdale onto the subway tracks in a tunnel beneath the streets of Manhattan. Ms. Webdale lost her life as a result. Through the leadership of Governor Pataki, a bipartisan effort was forged with the New York State Legislature to create a resource delivery system for this population, which, in view of their treatment history and present circumstances, are likely to have difficulty living safely in the community.[1]

On August 29, 1999, Governor George Pataki signed Kendra's Law, creating a statutory framework for court-ordered assisted outpatient treatment (AOT), to ensure that individuals with mental illness, and a history of hospitalizations or violence, participate in community-based services appropriate to their needs.[2] The law became effective in November of 1999. Since that time, 1,823 court orders have been issued for AOT statewide, together with 612 renewal orders.[3] The majority of orders and renewals have been issued in New York City.

The statute creates a petition process, found in Mental Hygiene Law § 9.60 (MHL), designed to identify those persons who may not be able to survive safely in the community without greater supervision and assistance than historically has been available. A description of many aspects of the petition process follows, and is in turn followed by a review of some of the more important court decisions concerning Kendra's Law.

Filing the Petition

Kendra's Law establishes a procedure for obtaining court orders for certain patients to receive and accept outpatient treatment.[4] The prescribed treatment is set forth in a written treatment plan prepared by a physician who has examined the individual.[5] The procedure involves a hearing in which all the evidence, including testimony from the examining physician, and, if desired, from the person alleged to need treatment, is presented to the court.[6] If the court determines that the individual meets the criteria for AOT, an order is issued to either the director of a hospital licensed or operated by the Office of Mental Health (OMH), or a director of community services who oversees the mental health program of a locality (i.e., the County or the City of New York mental health director). The initial order is effective for up to six months[7] and can be extended for successive periods of up to one year.[8] Kendra's Law also provides a procedure for the removal of a patient subject to a court order to a hospital for evaluation and observation, in cases where the patient fails to comply with the ordered treatment and poses a risk of harm.[9]

"On August 29, 1999, Governor George Pataki signed Kendra's Law, creating a statutory framework for court-ordered assisted outpatient treatment to ensure that individuals with mental illness, and a history of hospitalizations or violence, participate in community-based services appropriate to their needs."

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

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

7. a parole officer or probation officer assigned to supervise the person.[10]

The petition must include the sworn statement of a physician who has examined the person within ten days of filing of the petition, attesting to the need for AOT.[11] In the alternative, the affidavit may state that unsuccessful attempts were made in the past ten days to obtain the consent of the person for an examination, and that the physician believes AOT is warranted. In the latter case, if the court finds reasonable cause to believe the allegations in the petition are true, the court may request that the patient submit to an examination by a physician appointed by the court, and ultimately may order peace officers or police officers to take the person into custody for transport to a hospital for examination by a physician. Any such retention shall not exceed twenty-four hours.[12]

The petitioner must establish by clear and convincing evidence that the subject of the petition meets all of the following criteria:

1. He or she is at least 18 years old; and
2. is suffering from a mental illness; and
3. is unlikely to survive safely in the community without supervision; and
4. has a history of lack of compliance with treatment for mental illness that has:
    a. at least twice within the last 36 months been a significant factor in necessitating hospitalization or receipt of services in a forensic or other mental health unit in a correctional facility or local correctional facility (not including any period during which the person was hospitalized or incarcerated immediately preceding the filing of the petition), or
    b. resulted in one or more acts of serious violent behavior toward self or others, or threats of or attempts at serious physical harm to self or others within the last 48 months (not including any period in which the person was hospitalized or incarcerated immediately preceding the filing of the petition); and
5. is, as a result of his or her mental illness, unlikely to voluntarily participate in the recommended treatment pursuant to the treatment plan; and
6. in view of his or her treatment history and current behavior, the person is in need of assisted outpatient treatment in order to prevent a relapse or deterioration which would be likely to result in serious harm to self or others; and
7. it is likely that the person will benefit from assisted outpatient treatment; and
8. if the person has executed a health care proxy, any directions included in such proxy shall be taken into account by the court in determining the written treatment plan.[13]

In addition, a court may not issue an AOT order unless it finds that assisted outpatient treatment is the least restrictive alternative available for the person.[14]

Notice of the petition must be served on a number of people or entities, including the person, his or her nearest relative and the Mental Hygiene Legal Service (MHLS), among others.[15] The court is required to set a hearing date that is no more than three days after receipt of the petition, although adjournments can be granted for good cause.[16]

If the court finds by clear and convincing evidence that the subject of the petition meets each of the criteria and a written treatment plan has been filed, the court may order the subject to receive assisted outpatient treatment. The order must specifically state findings that the proposed treatment is the least restrictive treatment that is appropriate and feasible, must include case management or Assertive Community Team services and must state the other categories of treatment required. The court may not order treatment which is not recommended by the examining physician and included in the treatment plan.[17] Appeals of AOT orders are taken in the same manner as specified in MHL § 9.35 relating to retention orders.[18]

If in the clinical judgment of a physician, the assisted outpatient has failed or refused to comply with the treatment ordered by the court, efforts must be made to achieve compliance. If these efforts fail, and the patient may be in need of involuntary admission to a hospital, the physician may request the director of community services, his designee, or other physician designated under § 9.37 of the MHL to arrange for the transport of the patient to a hospital. If requested, peace officers, police officers or members of an approved mobile crisis outreach team must take the patient into custody for transport to the hospital. An ambulance service may also be used to transport the patient. The patient may be held up to 72 hours for care, observation and treatment and to permit a physician to determine whether involuntary admission under the standards set forth in Article 9 of the MHL is warranted.[19]

The legislation also provides for the exchange of clinical information pertaining to AOT patients. Kendra's Law amends MHL § 33.13, the confidentiality provision, to clarify that OMH licensed or operated facilities may share confidential patient information, when such sharing is necessary to facilitate AOT.[20]

Legal Developments

Since the legislation became effective, New York courts have addressed a number of issues related to the statute, and have rendered decisions regarding the constitutionality of the statute, as well as decisions construing statutory provisions concerning the criteria for AOT orders, and the evidentiary standard under the statute.

Constitutional Challenges

In *In re Urcuyo*,[21] the first court challenge to the constitutionality of Kendra's Law, the MHLS moved for dismissals on behalf of two respondents to Kendra's Law petitions in Supreme Court, Kings County. Respondents argued that Kendra's Law violated the due process and equal protection guarantees of the New York State and the United States Constitutions because the statute did not require a judicial finding of incapacity prior to the issuance of an order requiring the respondent to comply with the AOT treatment plan. The court rejected all of respondents' arguments, and held that the statute was in each respect constitutional.

The challenge was based largely upon the Court of Appeals decision in *Rivers v. Katz*.[22] The *Rivers* court acknowledged that all patients have a fundamental right to determine the course of their own treatment, but also that there may be circumstances where it is necessary to administer treatment to a psychiatric inpatient over the patient's objections, pursuant to either the state's police power or *parens patriae* power. *Rivers* established a procedural standard for such medication over objection, requiring a judicial finding that the patient lacks the capacity to make competent decisions concerning treatment. This is a judicial determination, not a clinical determination, and recognizes that there is a cognizable deprivation of liberty resulting from a decision to forcibly medicate a person who has been involuntarily committed.

Respondents in *Urcuyo* urged the court to equate the infringement of a patient's liberty interest as a consequence of an AOT order with the *Rivers* situation, where a psychiatric inpatient is forcibly medicated against his or her will. Respondents pointed to the compulsive nature of court orders, and reasoned that the threat of removal for observation as a result of non-compliance is so akin to the forcible medication situation in *Rivers*, that identical due process safeguards are constitutionally required.[23]

The court answered by stating that AOT patients are not involuntary inpatients, and therefore are not even subject to medication over objection. There is no threat of medication over objection because there is no authorization in the statute for such measures, and that "[e]ven if a patient is eventually retained in a hospital after the seventy-two hour evaluation period [pursuant to 9.60(n)], he or she still cannot be forcibly medicated absent a judicial determination of incapacity or under emergency circumstances."[24]

With respect to respondents' attempts to draw analogies between forcible administration of medication over objection, and the more remote possibility of clinical intervention in the event of non-compliance, the response was equally succinct:

> This court rejects respondents' argument that an assisted outpatient order, while not providing for the forcible administration of medication, unreasonably violates the patient's right to refuse medication by threatening arrest upon non-compliance with the plan. . . . the court does not agree with respondents' argument that a failure to take medication results in the summary arrest of the patient. Rather, the patient's failure to comply with the treatment plan, whose formulation the patient had the opportunity to participate in, leads to the heightened scrutiny of physicians for a 72-hour evaluation period, but only after a physician has determined that the patient may be in need of involuntary admission to a hospital.[25]

Ultimately, the 72-hour observation period was held to be "a reasonable response to a patient's failure to comply with treatment when it is balanced against the compelling state interests which are involved."[26] Furthermore, the removal and 72-hour observation provisions of the statute were held to be in accord with earlier judicial constructions of the dangerousness standard embodied in the MHL provisions concerning involuntary commitment.

One such precedent was *Project Release v. Prevost*,[27] which held that MHL provisions authorizing involuntary observation periods of up to 72 hours satisfy constitutional due-process standards. Reference was also made to prior decisions permitting clinicians, and courts, to consider a patient's history of relapse or deterioration in the community, when weighing the appropriateness of an exercise of the police power or the *parens patriae* power. For example, *Seltzer v. Hogue*[28] involved a civilly committed patient whose behavior improved in the hospital, but who would not comply with treatment, and whose condition would deteriorate in the community. The *Hogue* court considered evidence of the patient's behavior in the community, and pattern of treatment failures, and ordered his continued retention under MHL section 9.33. Relying on *Hogue*, the

Urcuyo court held that it was appropriate to consider the patient's behavior in the community, and any history of treatment failures, when making a determination regarding dangerousness in a proceeding pursuant to Kendra's Law.[29]

Reviewing the specific criteria that must be shown by a petitioner, the high evidentiary standard requiring that those criteria be shown by clear and convincing evidence, and the prior judicial acceptance of other MHL provisions which are analogous to the 72-hour observation provision of Kendra's Law, the court found respondents' constitutional due-process rights are sufficiently protected.

In the wake of the decision in *In re Urcuyo*, the Supreme Court, Queens County, was presented with another constitutional challenge to Kendra's Law. In *In re K.L.*,[30] the MHLS moved for dismissal of a petition on behalf of respondent, arguing that the statute was unconstitutional on two grounds—that the statute unconstitutionally deprived patients of the fundamental right to determine their own course of treatment, and that the statutory provisions concerning removal for observation following non-compliance with the AOT order are facially unconstitutional.

The first challenge brought by the respondent in *K.L.* echoed the constitutional challenge in *Urcuyo*, and asked the court to equate AOT with the type and degree of deprivation of liberty implicated in *Rivers*, which involved the forcible medication of a psychiatric inpatient over the patient's objection.[31] Respondent argued that in those cases where the treatment plan included a medication component, the court could avoid finding the statute unconstitutional by construing it to require a judicial finding that the patient lacked the capacity to make reasoned decisions concerning his medical treatment. Respondent reasoned that the procedural safeguards developed in *Rivers* could be imported into the AOT procedure, and preserve the patient's right to control his course of treatment.

Respondent's characterization of Kendra's Law orders as tantamount to medication over objection was rejected, and the *Rivers* facts distinguished from the AOT situation. Notably, while *Rivers* reaffirmed the right of every individual to determine his or her own course of treatment, it is likewise true that "this right is not absolute, and must perforce yield to compelling state interests when the state exercises its police power (as when it seeks to protect society), or its *parens patriae* power (to provide care for its citizens who are unable to care for themselves because of mental illness)."[32] The court then rejected the *Rivers* analogy:

> However, there is a fundamental flaw in respondent's position in this regard. Under Kendra's Law, the patient is not required to take any drugs, or submit to any treatment against his will. To the contrary, the patient is invited to participate in the formation of the treatment plan. When released pursuant to an assisted outpatient treatment order, no drugs will be forced upon him if he fails to comply with the treatment plan.[33]

After the *Rivers* analogy was deemed inappropriate, the court went on to analyze whether the deprivation of a patient's liberty interests occasioned by a Kendra's Law order represented a constitutional exercise of the state's police or *parens patriae* powers. In light of exhaustive legislative findings, and "elaborate procedural safeguards to insure the protection of the patient's rights,"[34] the court concluded:

> Given that the purpose of Kendra's Law is to protect both the mentally disabled individual and the greater interests of society, the statute is narrowly tailored to meet its objective. In view of the significant and compelling state interests involved, the statute is not overly broad, or in any way unrelated to, or excessive in light of those interests.[35]

Respondent's contention that, in order for the removal provision (MHL § 9.60(n)) to pass constitutional muster, the patient must be afforded notice and an opportunity to be heard prior to any removal for observation, was also rejected. Contrary to respondent's position that the statute permits summary arrest without any due process, for an AOT order to issue in the first instance there must have been a judicial finding, based on clear and convincing evidence, that in the event of a failure to comply with treatment, the patient will likely present a danger to himself or others. In addition to this prior judicial finding, failure to comply does not automatically result in the immediate confinement of the patient. In fact, the court went to great lengths to articulate the significant procedural requirements which must be met prior to any effort to remove the patient who has failed to comply with his treatment plan:

> Before a physician may order [removal] of a patient to a hospital for examination, the following must take place:
>
> 1. The physician must be satisfied that, efforts were made to solicit the patients compliance; and
>
> 2. In the clinical judgment of the physician, the patient (a) "may be in need of

involuntary admission to a hospital pursuant to section 9.27 of the Mental Hygiene Law;" or (b) "immediate observation, care and treatment of the patient may be necessary pursuant to Mental Hygiene Law sections 9.39 or 9.40." Then,

3. The physician may request "the director," or certain other specific person, to direct the removal of the patient to an appropriate hospital for examination, pursuant to specific standards.

4. The patient may be retained only for a maximum of 72 hours.

5. If at any time during the 72-hour period the patient is found not to meet the involuntary admission and retention provision of the Mental Hygiene Law, he must be released.[36]

With reference to other provisions of the MHL which permit the involuntary removal of a person to a hospital, and which have all been constitutionally upheld,[37] the court noted that the removal provisions in Kendra's Law contemplate even greater procedural protections. For example, removal under Kendra's Law requires a prior judicial finding that removal may be appropriate in the event of failure to comply.

Although Kendra's Law was declared "constitutional in all respects," by the court in *In re K.L.*,[38] the decision has generated an appeal to the Second Department by respondent. The outcome of that appeal will determine the extent to which the constitutionality of the statute remains an issue.

Decisions Construing the Statutory Criteria

In addition to the decisions concerning constitutional issues in *In re K.L.* and *In re Urcuyo*, there is now some guidance from the courts concerning the statutory criteria for Kendra's Law orders, MHL § 9.60(c).

Soon after the statute became effective, a debate emerged with respect to the proper construction of the alternative criteria concerning a respondent's prior need for hospitalization, or prior violent acts. Among other criteria, a Kendra's Law petitioner must demonstrate under MHL § 9.60(c)(4):

> [that] the patient has a history of lack of compliance with treatment for mental illness that has:
>
> (i) at least twice within the last thirty-six months been a significant factor in necessitating hospitalization in a hospital, or receipt of services in a forensic or other mental health unit of a correctional facility or a local correctional facility, not including any period during which the person was hospitalized or incarcerated immediately preceding the filing of the petition or:
>
> (ii) resulted in one or more acts of serious violent behavior toward self or others or threats of, or attempts at, serious physical harm to self or others within the last forty-eight months, not including any period in which the person was hospitalized or incarcerated immediately preceding the filing of the petition . . .

The Two-Hospitalization Criteria

The first prong of MHL § 9.60(c)(4) is satisfied when a petitioner demonstrates that a patient has been hospitalized twice, as a result of treatment failures, within the past 36 months (referred to as the "two-hospitalizations" criterion). The 36 month look-back period excludes the duration of any current hospitalization.

In June of 2000, a Kendra's Law petition was brought in Supreme Court, Richmond County, alleging that the respondent had been hospitalized on two occasions within the statutory look-back period—within the time period of the current hospitalization plus 36 months.

In *In re Sarkis*,[39] the respondent moved to dismiss the petition, arguing, among other grounds, that the petition was deficient because it counted the current hospitalization as one of the two hospitalizations required to satisfy MHL § 9.60(c)(4)(i). Respondent reasoned that the statutory language, which excluded the duration of the current hospitalization from the look-back period, must also be construed to exclude the current hospitalization from being counted as one of the two hospitalizations required.

The court relied on the specific language of the statute, and rejected respondent's argument:

> [R]espondent's position is based on a flawed interpretation of the statutory provision, which reads [9.60(c)(4)(i)] as modifying the single word "hospitalization" appearing in the first clause of Mental Hygiene Law 9.60(c)(4), rather than the grammatically more consistent

> "thirty-six months" period during which the noncompliance resulting in such hospitalizations must occur.[40]

It is the duration of the current hospitalization which is excluded from the look-back period. In any event, it is the need for hospitalization as a result of noncompliance which is at the bottom of the two-hospitalization requirement. "The triggering event for purposes of Mental Hygiene Law 9.60(c)(4)(i) is not the hospital admission but rather the noncompliance with treatment necessitating the hospitalization, and is complete before the hospitalization begins."[41]

Respondent appealed the denial of his motion to dismiss, and the Appellate Division, Second Department affirmed, writing:

> [W]e agree with the Supreme Court's interpretation of Mental Hygiene Law § 9.60(c)(4)(i) . . . The appellant interprets this provision as precluding the consideration of his hospitalization immediately preceding the filing of the petition as one of the two required hospitalizations due to noncompliance with treatment within the last 36 months . . . we reject the appellant's interpretation . . . which would inexplicably require courts to disregard the most recent incident of hospitalization due to noncompliance with treatment in favor of incidents more remote in time.[42]

The decision in *In re Dailey*[43] is in accord with *In re Sarkis*. In *Dailey*, the court rejected an argument identical to that offered by respondent in *Sarkis*, holding that reading the statutory language, together with the legislative history, "leads to the conclusion that the section seeks only to expand the number of months which a petitioner can look back to thirty-six months prior to the current hospitalization and *does not exclude* the acts of non-compliance with treatment and the current hospitalization itself from consideration for an AOT order"[44]

The Violent Act Criteria

The second prong of MHL § 9.60(c)(4) is satisfied when a petitioner establishes that a patient has committed one or more acts of serious violent behavior toward self or others or threats of, or attempts at, serious physical harm to self or others within the last 48 months (referred to as the "violent act" criterion). However, in language which is similar to the two-hospitalizations requirement discussed above, the 48 month look-back period excludes the duration of any current hospitalization or incarceration.

This provision of the statute was the subject of an appeal to the Second Department. In *In Weinstock (Hector A.)*,[45] the trial court had dismissed the petition because the violent act relied upon to satisfy the statutory criteria occurred while the patient was hospitalized. The respondent stabbed a hospital worker during his current hospitalization, and the outcome of the case hinged on whether the stabbing could be used to satisfy the violent act criterion of MHL § 9.60(c)(4). On appeal, petitioner argued that the 48 month exclusion applies only to the duration of the look-back period, and should not be read to exclude violent acts occurring during the current hospitalization. The respondent argued that the language excluding the duration of the current hospitalization from the 48 month look-back period also required the court to exclude evidence of any violent acts or threats during the current hospitalization. The Second Department reversed the trial court's dismissal, and held that the evidence related to the stabbing was admissible to satisfy the violent act requirement:

> There is no merit to the patient's argument that the violent act he committed against a hospital employee must be disregarded under Mental Hygiene Law § 9.60(c)(4)(ii). This provision simply extends the 48 month period for considering the patient's violent behavior by the duration of his hospitalization or incarceration "immediately preceding the filing of this petition." This provision in no way eliminates from consideration violent acts occurring during the hospitalization or incarceration.[46]

Hector A. cited with approval the rationale articulated in *In re Weinstock (Julio H.)*,[47] where respondent sought dismissal of an AOT petition, and argued for a construction of MHL § 9.60(c)(4)(ii) which would exclude violent acts which occur while a person is hospitalized from being used to satisfy the requirements of that section in an AOT petition.

The respondent in *Julio H.* moved for dismissal of the AOT petition on two grounds: First, he argued that the exclusion of the current hospitalization from the 48 month look-back period also excludes any violent acts during the current hospitalization. Second, he urged the court to accept the premise that a person who is currently hospitalized is receiving treatment, is therefore deemed compliant, and thus violent acts occurring during hospitalization could never be the result of noncompliance with treatment.

Both arguments were rejected, with the result that respondent's violent act occurring during his current hospitalization could be used to satisfy the violent act criterion of MHL § 9.60(c)(4)(ii). Further, there is no irrebuttable presumption of compliance during hospitalization, and the issue of whether a patient has been noncompliant with treatment while in a psychiatric hospital "is a fact to be determined at the AOT hearing."[48] This is significant, because the petitioner must establish a nexus between the patient's violent behavior and his failure to comply with treatment. By denying respondent's argument that compliance in the hospital is presumed, the court created an opportunity for petitioners to demonstrate a nexus between non-compliance, and violence, based on the patient's behavior while hospitalized.[49]

Decisions on the Applicability of the Physician-Patient Privilege

In addition to challenges to the constitutionality of Kendra's Law, and clashes over the appropriate construction of the two-hospitalizations and violent act criteria, there have been challenges involving the type of evidence which may, or must be offered in support of an AOT petition.

One significant evidentiary challenge involved the practice of having a patient's treating physician testify at the mandatory hearing on the petition. The practice prompted objections based on the physician-patient privilege, which is codified in N.Y. Civil Practice Law & Rules 4504 (CPLR).

Supreme Court, Queens County, was faced with such a challenge in the Spring of 2000, in *In re Sullivan (Nathan R.)*,[50] and ultimately ruled that the statutory privilege did not operate to prevent a treating physician from also fulfilling the role of examining physician in a Kendra's Law proceeding.

To meet the statutory requirements for AOT, a petition must be accompanied by an affidavit by an "examining physician," who must state that he or she has personally examined respondent no more than 10 days prior to the submission of the petition, that such physician recommends AOT and that the physician is willing and able to testify at the hearing on the petition.[51] The examining physician is also required to testify at the hearing on the petition concerning the facts underlying the allegation that the respondent meets each of the AOT criteria, including testimony that a court order is the least restrictive alternative, and concerning the recommended treatment plan.[52]

In *Nathan R.*, the examining physician was also respondent's treating physician. Respondent moved to dismiss the petition, on the basis that "the physician-patient evidentiary privilege codified in CPLR 4504 absolutely prohibits a treating psychiatrist from submitting an affidavit or giving testimony in support of [an AOT] petition."[53] The motion to dismiss was denied:

> CPLR 4504 does not prevent a treating physician from disclosing information about the patient under all circumstances. . . . The protection of the physician-patient privilege extends only to communications and not to facts. A fact is one thing and a communication concerning that fact is an entirely different thing.[54]

The decision allowed that there may in fact be specific communications which are entitled to protection, but the burden is on the movant to demonstrate the existence of circumstances justifying the recognition of the privilege. Even in such cases, the privilege will only be held to attach to specific communications, and broad, conclusory claims of privilege, such as those made by respondent's counsel in *Nathan R.*, will not suffice.[55]

Respondent also suggested that because a treating physician is among those enumerated who may bring a petition, and a petitioner cannot also act as the examining physician, a treating physician is statutorily prohibited from fulfilling the role of examining physician. This argument was also rejected:

> It is unclear whether the [respondent] is also claiming that Mental Hygiene Law § 9.60 prohibits a treating psychiatrist from being the examining physician. It does not. It only prevents a treating psychiatrist from being the petitioner if the treating psychiatrist is the examining physician.[56]

Supreme Court, Queens County, was faced with an identical argument, in a motion to dismiss a Kendra's Law petition shortly after *Nathan R.* was decided. In *Amin v. Rose F.*,[57] respondent urged the court to dismiss the petition as insufficient, because the respondent's treating physician was also the examining physician, and therefore his testimony in support of the petition would be prohibited by the physician-patient privilege. In denying the motion, the court looked at, among other things, the legislative history of Kendra's Law, and held:

> [I]t is clear that the legislature intended and desired for the subject's treating physician to be intimately involved with the various aspects of assisted outpatient treatment, and thereby implicitly waived the physician-patient privi-

> lege for the purposes of assisted outpatient treatment. . . . Indeed, it would serve no useful purpose to insist on the physician-patient privilege under M.H.L. 9.60, and, in fact, would frustrate the clear intention of the legislature to keep mentally ill persons in the community and out of inpatient psychiatric hospitalization. Furthermore, once the privilege is waived, it is waived for all purposes . . . This clearly includes allowing the treating psychiatrist to examine the subject of the AOT proceeding, and to testify as to his findings at that hearing.[58]

Therefore, although the statute prohibits a treating physician from being both the petitioner and the examining physician with respect to a particular patient, the statute does not prohibit the treating physician from also being either the examining physician or the petitioner.

The respondent in *Amin* appealed the decision denying her motion to dismiss. However, because the respondent ultimately entered into a voluntary agreement for treatment, the appeal was dismissed as moot.[59]

Other Decisions

In *In re Longo*,[60] a case before the Supreme Court, Monroe County, a dispute evolved concerning whether a respondent has the right to a hearing before an order can issue for his removal to a hospital for the purposes of an examination. Even after the court formally requested that respondent submit to such an examination, he refused. Instead, respondent objected to the request, demanding that he be provided with a hearing prior to any court-ordered examination, and that to do otherwise would violate his constitutional due-process rights. Relying on MHL § 9.60(h)(3), which governs situations where a patient refuses to permit an examination by a physician, the court ordered the removal for examination:

> The court rejects respondent's contention that the statute implies the requirement of such a hearing, although in some cases it may be appropriate to do so. [The petition] sufficiently sets out grounds establishing reasonable cause to belief that the petition is true. The respondent was given ample opportunity to be heard at oral argument with respect to the petition and, indeed, plans to submit written opposition to the petition itself. However, this court feels that the statute authorizes the court to make a finding on the papers submitted when appropriate and empowers the court to authorize the police to take respondent into custody for purposes of the physician examination.[61]

Longo provides guidance on the issue of the procedure for pre-hearing examinations, but leaves open the possibility that judges may find it appropriate in certain circumstances to conduct a hearing prior to ordering the removal of a patient for examination. The governing standard remains whether the affidavits and other clinical evidence offered by the petitioner establish reasonable grounds to believe that the petition is true. This is a standard which is decidedly lower than that applicable to a decision on the merits of the petition, and the court in *Longo* was prudent in not allowing the hearing on the examination issue to expand into a hearing on the petition itself.

Questions regarding the evidentiary standard applicable to AOT hearings have also found their way into the courts. For example, in *In re Jesus A.*,[62] respondent moved to dismiss the petition, arguing that petitioner failed to offer facts sufficient to establish that an AOT order was appropriate. The court was critical of the affidavit of the examining physician, which merely paraphrased the criteria, concluding:

> Clearly, these allegations, which are nothing more than conclusions, not facts, are insufficient. It thus is the holding of this court that, as in all other cases, allegations which are nothing more than broad, simple conclusory statements are insufficient to state a claim under section 9.60 of the Mental Hygiene Law.[63]

The petitioner submitted a supplemental affidavit in an attempt to cure the deficiencies found in the original. This effort also failed, because it was not based upon "personal knowledge or upon information and belief in which event the source of the information and the grounds for the belief must be provided."[64]

If it was not clear prior to *Jesus A.*, the fog has now lifted—the petition must contain specific evidence, whether in the form of documents, affidavits or testimony, that all of the criteria are met. This burden must be carried by reference to facts, and the mere paraphrasing of the statutory language will not suffice.

In *Jesus A.*, although there was a dispute over whether petitioner had met its evidentiary burden, it was without dispute the petitioner's burden. In *Cohen v.*

Anne C.,[65] the court was asked to construe MHL § 9.60(m), and determine the allocation of the burden of proof in a jury appeal of a Kendra's Law order.

Respondent was the subject of an AOT order, and as the expiration of the initial six-month order approached, an application was filed for an extension of the original order for an additional twelve months. Respondent failed to move in opposition to the extension, but after the extension was granted, demanded a jury trial to "review" the extension order.

Kendra's Law contains an appeal provision, which incorporates by reference the procedures found in MHL § 9.35, which permits jury review of retention orders. The court construed that provision, as incorporated into Kendra's Law, to guarantee Kendra's Law respondents the right to the type of review contemplated by Article 55 of the CPLR.[66]

By characterizing a request for review under MHL § 9.60(m) as an appeal, the court identified the respondent as the appellant. This is significant, because respondent had argued that MHL § 9.60(m) guaranteed the right to a rehearing. In a rehearing, the petitioner would be forced to carry the burden of demonstrating by clear and convincing evidence that all of the statutory criteria had been met. By denominating the respondent the appellant, the tables are turned, and now the respondent must carry the burden of demonstrating that the criteria had *not* been met.[67] Further, the court held that the respondent/appellant was bound by the same standard of proof in its appeal as the petitioner had been at the hearing itself—she must prove that the criteria had not been met by clear and convincing evidence.[68]

Finally, respondent asked the court to consider the changes in her condition and circumstances since the order was issued. The court rejected respondent's request, and instead held: first, the proper mechanism for staying, modifying or vacating an existing order is provided by MHL § 9.60(1), not the jury appeal permitted by MHL § 9.60(m); and second, because it is an appeal, and not a motion to modify, the jury may not consider any new evidence.[69]

One last issue worthy of discussion is the amount of discretion a court may exercise in fashioning relief when deciding a Kendra's Law petition. In *In re Application of Manhattan Psychiatric Center*,[70] the Appellate Division, Second Department held it is within the authority of a trial court to grant or deny a Kendra's Law petition, but is beyond its authority to order retention pursuant to other sections of the MHL, or order treatment other than what is included in the treatment plan.

The case involved an AOT petition for a patient who, as well as having a history of mental illness and treatment failures, had a criminal history resulting from violent behavior. After the required hearing, and upon consent of the parties, the petition was granted. However, the court held the order in abeyance, pending an independent psychiatric evaluation of respondent. Although an AOT order ultimately was issued for the patient, the trial court at one point denied the petition, based on its own determination that the patient met the criteria for continued inpatient retention (the "dangerousness standard"), and should not be returned to the community, with or without AOT.

The Second Department accepted the case for review, and decided a number of issues raised by the lower court concerning the scope of that court's authority under the statute.[71] The first issue was whether the court may make its own determination of whether the patient meets the dangerousness standard, and was therefore beyond the reach of AOT. The Second Department responded in the negative, and limited the authority of the trial court to deciding whether the statutory criteria had been met, and then either granting or denying the petition. The decision whether to release the patient is a clinical determination left, in this case, to the director of the hospital. Kendra's Law does not provide an avenue for the subordination of that clinical judgment to a judicial determination that the patient should remain hospitalized.[72]

The second issue was whether MHL § 9.60(e)(2)(ii), which permits the court to consider evidence beyond what is contained in the petition, also implicitly provides the authority for the court to make a judicial determination with respect to the dangerousness standard. The Second Department answered again in the negative, and held that § 9.60(e)(2)(ii) only permits the consideration of additional facts in deciding whether the statutory criteria have been met, "[i]t is not an invitation to the court to consider the issue of dangerousness in respect of a decision to release the patient."[73]

An issue was also raised concerning whether a court has discretion to deny a petition, where the statutory criteria have been met. Noting that a court must deny the petition if the criteria have not been met, the Second Department concluded:

> Thus, the court's discretion runs only to the least restrictive outcome. In other words, a court may decide not to order AOT for a person who meets the criteria, but it may not decide to order AOT for a patient who does not meet the criteria. . . . In any event, no measure of discretion would be sufficient to permit a court to bar the release of a hospitalized patient (or, by extrapolation, to order the involuntary admission of an

unhospitalized patient) as an alternative to ordering AOT, because Kendra's Law does not place that decision before the court.[74]

Accordingly, it is now the case that clinical decisions, such as determinations of dangerousness, are not before the court during Kendra's Law proceedings. Judicial discretion is limited to deciding whether a petitioner has carried its burden of demonstrating that the statutory criteria are met by clear and convincing evidence, and then either granting or denying the petition.[75]

Conclusion

While there are still many issues that may want for the clarity provided by judicial review, a number of threshold issues have been resolved since Kendra's Law became effective. Most importantly, the statute survived constitutional challenges concerning the right to control one's treatment. Court-ordered AOT has been distinguished from forcible medication over objection, and any fears that such forced treatment would proliferate under Kendra's Law should be allayed by judicial recognition of the fact that forced medication over objection is never appropriate in an AOT treatment plan, and in any event cannot occur absent sufficient due process pursuant to *Rivers v Katz*.

It is currently the law that in meeting the two-hospitalizations criteria, although the duration of the current hospitalization is excluded from the respective look-back period, the current hospitalization itself can be used to meet the criteria. Similarly, in meeting the violent act criteria, although the duration of the current hospitalization is excluded from the respective look-back period, the violent acts occurring during the current hospitalization can be used to meet the criteria.

The petitioner must marshal facts and evidence, such as testimony from those with actual knowledge, in support of the petition. Mere recitations of the criteria, in affidavit form, will not suffice. In addition, while a patient's treating physician cannot be both the petitioner and the examining physician in an AOT proceeding, the treating physician can be one or the other.

If a patient refuses to submit to an examination, the court can order the removal of the patient to a hospital for the purposes of an examination. In such a circumstance, the petitioner must meet specific criteria justifying the removal, but the patient does not have an absolute right to a pre-removal hearing.

Kendra's Law provides for the review of an order granting a petition before a jury, but such a proceeding has the character of an appeal pursuant to Article 55 of the CPLR, and the burden of proof shifts to the appellant.

Finally, Kendra's Law does not authorize courts to make independent determinations concerning the issue of whether a patient meets involuntary inpatient criteria during a Kendra's Law proceeding. Statutory authority extends only to the judicial determination of whether the petitioner has met its burden of proving by clear and convincing evidence that the statutory criteria have been met, and then the court may either grant or deny the petition.

Endnotes

1. Prior to the enactment of Kendra's Law, and prior to the tragic event involving Ms. Webdale, a pilot program for assisted outpatient treatment was operated out of Bellevue Hospital in New York City. The pilot program was enacted in 1994 and codified as N.Y. Mental Hygiene Law § 9.61 (MHL). The pilot program expired in 2000. Although the pilot and the current law differ in many details, the basic framework for the current statute was based upon the pilot.
2. 1999 N.Y. Laws ch. 408.
3. Office of Mental Health Statewide AOT Report as of April 1, 2002.
4. Much of the information concerning the petition process in this article can be found at the New York State Office of Mental Health official web page, <http://www.omh.state.ny.us>, which contains a great deal of useful information about Kendra's Law.
5. MHL § 9.60(i)(1).
6. MHL § 9.60(h).
7. MHL § 9.60(j)(2).
8. MHL § 9.60(k).
9. MHL § 9.60(n).
10. MHL § 9.60(e)(1).
11. MHL § 9.60(e)(3)(i).
12. MHL § 9.60(h)(3).
13. MHL § 9.60(c).
14. MHL § 9.60(j)(2).
15. MHL § 9.60(f).
16. MHL § 9.60(h).
17. MHL § 9.60(j)(2).
18. MHL § 9.60(m).
19. MHL § 9.60(n).
20. In December of 2000, the federal Department of Health and Human Services promulgated regulations pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) establishing standards for the privacy of individually identifiable health information (45 C.F.R. Parts 160 and 164). The general rule established in these regulations is that individually identifiable health information cannot be used or disclosed by covered entities (e.g., providers who engage in electronic transactions) without patient consent or authorization. However, several of the listed exceptions to this requirement would permit covered entities to continue to exchange clinical information without patient consent or authorization as required by Kendra's Law and Kendra's Law court orders.
21. 714 N.Y.S.2d 862 (Sup. Ct., Kings Co. 2000).

22. 67 N.Y.2d 485 (1986).
23. *In re Urcuyo*, 714 N.Y.S.2d at 868.
24. *Id.* at 872, n. 3 (citations omitted).
25. *Id.* at 869–70.
26. *Id.* at 870.
27. 772 F.2d 960 (2d Cir., 1983).
28. 187 A.D.2d 230 (2d Dep't 1993).
29. *See In re Urcuyo*, 714 N.Y.S.2d, 862; *see also In re Francis S.*, 206 A.D.2d 4 (1st Dep't 1995), *aff'd*, 87 N.Y.2d 554 (1995). Francis S., like the patient in *Hogue*, was not dangerous in the structured environment of a hospital, but in the community failed to comply with treatment and decompensated to the point of dangerousness.
30. *In re Application of Glenn Martin, For an Order Pursuant to Section 9.60 of the Mental Hygiene Law (Kendra's Law) Authorizing Assisted Outpatient Treatment for K.L.*, 500748/00 (Sup. Ct., Queens Co. 2000) (Order Granting Kendra's Law Petition).
31. *Id.*, slip op. at 7.
32. *Id.*
33. *Id.*
34. *Id.*, slip op. at 8.
35. *Id.*, slip op. at 9.
36. *Id.*, slip op. at 11.
37. For example, MHL § 9.37, which provides for removal for a 72-hour observation period upon certification by a Director of Community Services, was upheld in *Woe by Woe v. Cuomo*, 729 F.2d 96 (2nd Cir. 1984), *cert. denied*, 469 U.S. 936. The court also cited *Thomas v. Culberg*, 741 F. Supp. 77 (S.D.N.Y. 1990), upholding § 9.41 of the MHL, which permits police officers to take into custody a person who appears to be mentally ill. The court in *In re K.L.* noted that these warrantless detention provisions were upheld, even though, unlike detentions pursuant to Kendra's Law, they do not follow from earlier judicial findings.
38. *In re Application of Glenn Martin*, 500748/00, slip op. at 14.
39. N.Y.L.J., Aug. 18, 2000, p. 29, col. 6.
40. *Id.*
41. *Id.*
42. *In re South Beach Psychiatric Center*, 727 N.Y.S.2d 149, 150 (2d Dep't 2001) (citations omitted).
43. 713 N.Y.S.2d 660 (Sup. Ct., Queens Co. 2000).
44. *Id.* at 663 (emphasis in original).
45. 733 N.Y.S.2d 243 (2d Dep't 2001).
46. *Id.* at 245.
47. 723 N.Y.S.2d 617 (Sup. Ct., Kings Co. 2001).
48. *Id.* at 619.
49. *See In re Weinstock (Shali K.)*, 300140-01 (Sup.Ct., Kings Co.) (Order denying Kendra's Law Petition), where the court accepted the argument that a violent act in the hospital may count under the statute, but denied the petition because petitioner failed to establish a nexus between the violent act and respondent's treatment failures.
50. 710 N.Y.S.2d 804 (Sup. Ct., Queens Co. 2000).
51. MHL § 9.60(e)(3)(i).
52. MHL § 9.60(h)(4).
53. *In re Sullivan (Nathan R.)*, 710 N.Y.S.2d at 805 (quoting respondent's counsel).
54. *Id.*
55. *Id.* at 806.
56. *Id.*
57. N.Y.L.J., Dec. 7, 2000, p. 31, col. 1.
58. *Id.*
59. *In re Rose F.*, __ N.Y.S.2d __ (2d Dep't 2002).
60. 186 Misc. 2d 188, 715 N.Y.S.2d 833 (Sup. Ct., Monroe Co. 2000).
61. *Id.* at 189.
62. 185 Misc. 2d 39, 710 N.Y.S.2d 853 (Sup. Ct., Queens Co. 2000).
63. *Id.* at 43 (citations omitted).
64. *Id.* (citations omitted).
65. 732 N.Y.S.2d 534 (Sup. Ct., N.Y. Co. 2001).
66. *Id.* at 541.
67. *Id.* at 542-43.
68. *Id.*
69. *Id.*
70. 728 N.Y.S.2d 37 (2d Dep't 2001).
71. Because the court did eventually sign an AOT order for the patient, the matter would appear to be beyond appellate review, based on the mootness doctrine. The Second Department accepted the case as an exception to the mootness doctrine, because it is "likely to be repeated, it involves a phenomenon which typically evades review, and it implicates substantial and novel issues." *Id.* at 39.
72. *Id.* at 42.
73. *Id.* at 43.
74. *Id.* at 43, 44 (citations omitted).
75. *See also In re Endress*, 732 N.Y.S.2d 549 (Sup. Ct., Onieda Co. 2001). The court in *Endress* believed that the patient should not be released into the community at all, but citing *In re Manhattan Psychiatric Center*, reluctantly granted the AOT petition, as the most appropriate outcome, given its limited alternatives.

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Sanctioning Substance-Abusing Home Relief Clients with the Loss of Medical Benefits—Legal and Policy Concerns

By Georganne Chapin

New York State's Social Services law allows local districts (i.e., county Departments of Social Service, or DSS, and, in New York City, the Human Resources Administration, or HRA) to discontinue Medicaid benefits for single adults who have been identified as substance abusers and who refuse or fail to comply with the type of treatment mandated by the state.[1] The law has been implemented through a series of administrative policies that require various actors within the system to pre-screen and report individuals with possible substance abuse to the local districts which, in turn, conduct formal assessments, mandate treatment services, track compliance and, if compliance is not forthcoming, cancel the Medicaid benefits of non-compliant recipients. Individuals required to pre-screen recipients include local district eligibility caseworkers and—most recently—enrollment and outreach staff from Medicaid managed care organizations (MCOs) and other organizations under "facilitated enroller" contracts with the districts. Additionally, managed care plans are required to report to the districts their Home Relief enrollees who may have been missed by the screening and assessment process, but who avail themselves of treatment for substance abuse. Reporting requirements placed upon MCOs are reinforced through financial incentives that permit the plans to escape payment for substance abuse services rendered to such enrollees.

In this article, I will review both legal and policy concerns related to New York's approach to Home Relief clients who are substance abusers. Particular examples will be given from the program as implemented in Westchester County—a mandatory Medicaid managed care setting. After providing a brief history of Medicaid managed care in the state and in Westchester—with an emphasis on the non-commercial nature of the health plans that dominate the industry—I will describe Westchester's policies regarding single adult substance abusers and will show how this approach, which evolved as a result of the emphasis on "personal responsibility" in the Welfare Reform Act of 1997[2], co-opts the MCOs' fiduciary duties to their enrollees; violates the confidentiality of substance abusers by sharing their medical information among numerous, untrained, unauthorized individuals; and channels them into a system that—because of the way it is organized—fails to adequately assess or address their medical and psychiatric needs. I will also comment on how these measures, despite their ostensible goal of encouraging substance abuse treatment and freeing the state from spending money on individuals who fail to engage in healthy behaviors, serve mainly as political window-dressing, and address neither individuals' health care needs nor the overall system's financial health.

I. Identification and Reporting of Substance Abuse Among Home Relief Clients in New York State and Westchester County

New York State's "Welfare Reform Act"[3] imposes mandatory identification and tracking of welfare and Medicaid recipients who have been identified as having substance abuse (including alcoholism) disorders. Additionally, compliance with substance abuse and alcohol treatment is a required condition for receiving both public assistance and medical assistance (i.e., Medicaid) for individuals in certain eligibility categories, namely the non-federally supported "Home Relief" or "Safety Net" categories. In Westchester County, which mandates that most Medicaid recipients enroll in one of five managed care organizations operating under contract with the County, the MCOs are required to notify the local Department of Social Services when an enrollee in a rate category subject to mandatory treatment either presents at a treatment program or is referred into treatment by his or her MCO physician. The enrollee then begins to be monitored by the County and—if she is a "Home Relief" client and she fails to comply with the type of substance abuse treatment specified by state law[4]—could be subject to loss of all public assistance benefits, including Medicaid. In addition to the contractual language obligating MCOs to "participate in the local planning process for serving persons with alcohol and substance addictions, to the extent required by the LDSS,"[5] the fact that substance abuse treatment for such enrollees can be paid for by the state on a fee-for-service basis (i.e., the MCO can escape financial risk for such services) encourages MCO compliance with the reporting process. This clearly creates a peculiar conflict in the fiduciary duty an MCO owes to its enrollees (see below).

MCOs operating as "facilitated enrollers" under the state's "Access[6] New York" program are involved even earlier in the process of identifying substance abusers

for potential tracking and sanctioning within the Medicaid system. Under facilitated enrollment, MCOs and other community-based organizations are literally deputized to take applications from individuals applying for Medicaid or the new "Family Health Plus"[7] program. As part of the application process, for each single or (married but) childless adult applicant who appears likely to fall into one of the Home Relief rate categories, facilitated enrollers are required to complete a prescreening form that is designed to identify substance abuse disorders. This form asks the enroller (an employee of an MCO or another agency under contract with the state) to ask the applicant ten questions including: "Have you lost a job or gotten into trouble at work within the last two (2) years?" and "Have you ever attempted to cut down on your alcohol or drug use?" and "Would you like information about alcoholism and/or substance abuse treatment?" In addition, and even more alarming given that enrollers need possess no particular clinical, social work or even general educational credentials, enrollers are asked to indicate—among other things—their observations regarding the applicant's appearance (e.g., "intoxicated," "drowsy," "glassy-eyes"), demeanor ("jittery," "argumentative," "hyperactive") and even to assess whether the applicant has a "runny nose (not a cold)."

MCOs are required to forward this form, along with the completed application, to the Department of Social Service which will, in turn, deliver it to a Certified Alcohol and Substance Abuse Counselor for follow-up, which includes a formal assessment of the client's possible substance abuse disorder. Thus begins the process of mandating an individual into service, tracking her compliance with the program and, potentially, in the event she fails to comply, sanctioning her by withdrawing her public assistance and Medicaid benefits.

While the ostensible reason for this process is to ensure that people are not unfairly placed into welfare-to-work programs if they are unable to function because of substance abuse, the likely effect is to discourage individuals from applying for assistance, and to punish them for behaviors that are socially undesirable but largely out of their control. Further, by enlisting facilitated enrollers—individuals and organizations who have undertaken to assist needy individuals in qualifying for assistance—in a process that can quickly go from friendly and helpful to demeaning and, ultimately, punitive, the state has co-opted MCOs for its anti-enrollee enforcement purposes. This is particularly ironic, given that these same MCOs have been historically required—in practice and by contract—to acquiesce unquestioningly to the needs and demands of enrollees.

II. Conflicting Fiduciary Duties of Health Plans Participating in New York's Medicaid Managed Care Program

The history of New York State's Medicaid managed care program is dominated by not-for-profit Prepaid Health Services Plans[8]—special-purpose managed care organizations (MCOs) "sponsored"[9] by facilities, such as community health centers and hospitals, that have traditionally cared for the poor. The original impetus behind the formation of special-purpose MCOs in New York, as in the nation at large, came from the recognition that Medicaid costs were continuing to increase, with no appreciable gains in quality of or access to care by the poor.[10] Reasoning that managed care had been proven to contain costs in commercial health insurance, officials in the Departments of Health and Social Services, backed by then-Governor Mario Cuomo, began devising a program by which the risk for medical expenditures for at least some portion of the Medicaid population could be shifted from the state to private entities. The state's Department of Health and Department of Social Services made funding available to a number of Safety Net providers, for the purposes of forming insurance companies that would agree to accept the risk of all covered health care services for certain categories of Medicaid patients, in exchange for a fixed monthly capitation payment. Seeing the opportunity to control a larger share of Medicaid funds and experiment with managed care, while retaining their "share" of funded Medicaid, several not-for-profit community health centers (CHCs)—either individually or as consortia—applied for and received state funding for the purpose of incorporating separate not-for-profit PHSPs.[11] In November 1986, HCFA's Regional Administrator confirmed to New York's Commissioner of Social Services that, as corporations owned and controlled by a migrant or community health center or groups of such health centers (grantees under §§ 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act), and which provide primary medical services essentially through such health centers," four applicant entities met "the requirements of §§ 1903(m)(2)(F) and (G) of the Social Security Act and can, therefore, contract for the delivery of prepaid health services to Medicaid recipients."[12]

Over the next several years, additional provider-sponsored PHSPs were licensed in New York State, as were a handful of for-profit independent (i.e., not provider-sponsored) PHSPs.[13] In addition, in response to both threatened financial sanctions for non-participation and a proactive effort during the mid-1990s to court their participation, a number of commercial HMOs began participating in Medicaid managed care throughout the state. Most subsequently withdrew,

leaving PHSPs – both not-for-profit and their for-profit counterparts—as dominant players in the state-sponsored managed care programs for low-income populations.[14]

While the full financial and policy-related implications of this fact are beyond the scope of this article, it is sufficient to say that the not-for-profit orientation of these organizations and their community-based philosophy, reinforced by New York's ongoing responsiveness to patient advocates and accommodation to the provider sponsors (especially hospitals), have combined to make Medicaid managed care an extremely client-centered enterprise. In this enterprise, most MCO personnel view themselves as advocates, ombudsmen and facilitators of services—rather than the stereotypic HMO employee whose job is to maximize profit by denying benefits to enrollees.

Black's Law Dictionary[15] defines a fiduciary relationship as one "in which one person is under the duty to act for the benefit of the other on matters within the scope of the relationship [and which] requires the highest duty of care." The definition goes on to give examples of typical situations in which a fiduciary relationship arises:

> [first], when one person places trust in the faithful integrity of another, who as a result gains superiority or influence over the first, [second] when one person assumes control and responsibility over another, [third] when one person has a duty to act for or give advice to another on matters falling within the scope of the relationship, or [fourth] when there is a specific relationship that has traditionally been recognized as involving fiduciary duties. . . .[16]

The traditional doctor / patient relationship, with its paternalistic overtones and emphasis on privacy, squared nicely with the fiduciary paradigm, which arose from the common law of trusts.[17] The fabric of this paradigm began to fray, however, as medicine became more complex and costly, and as patients began increasingly to rely on institutions rather than on individual physicians for their care—and on third parties to pay for that care.

The federal law that has unquestionably had the largest impact on the concept of fiduciary duty in health care is the Employee Retirement Income Security Act of 1974.[18] Known as ERISA, this law was enacted originally to address the problem of fraud and mismanagement in employee pension funds and, in an effort to impose nationwide uniformity, preempts state laws relating to employee benefit plans. Although Medicaid managed care is not subject to ERISA laws, the Act's importance in expanding the concept of the fiduciary to include functions, rather than only individuals, within a health care organization, is relevant. ERISA provides that fiduciaries shall discharge their duties "solely in the interest of the participants and beneficiaries,"[19] that is, "for the exclusive purpose of (i) providing benefits to participants and their beneficiaries; and (ii) defraying reasonable expenses of administering the plan."[20]

Most significant about this application of "fiduciary" under ERISA is that it vastly broadens the number and type of persons deemed to have a fiduciary duty to the beneficiary of a "plan." When applied to managed care, the financing and service delivery model that governs health care in the U.S. today, virtually any health care professional can be held accountable as a fiduciary as a result of exercising his employment function within a care plan that takes money from enrollees, employers or another payer (including the state) and allocates benefits to those who seek care. It appears, in fact, that the mere presence of a financial element in the relationship between insured and insurer exposes the insurer and his agents to the risk that their actions will be held to constitute a breach of fiduciary duty.[21]

Therefore, managed care plans are conceived to hold fiduciary duties to their enrollees. Furthermore, New York State's provider-sponsored PHSPs—because of their not-for-profit, community-based model, view themselves more as social service organizations than as insurance companies, and therefore—given increasing state-imposed disincentives on MCOs for denying services[22] and evident commitment to pay adequate premiums[23]—do very little to restrict benefits to their enrollees. Finally, the state itself perpetuates the premise that Medicaid managed care plans operate for the benefit of their enrollees, albeit via a contractual relationship with the government.[24] This concept is reinforced through state managed care regulations, policies and contracts, and through the oversight of marketing, member services and utilization review, and clinical case management functions. Furthermore, with the advent of Child Health Plus (CHP)[25]—a program for low-income children begun in 1991 and which now serves approximately 400,000 non-Medicaid eligible New York residents under the age of 19,[26] the role of provider-sponsored Medicaid managed care plans expanded, as they became a major force in identifying and recruiting potential enrollees. Given that CHP—unlike Medicaid—is available even to children who are undocumented immigrants, plans participating in CHP have made a concerted effort to present themselves as non-governmental, as respecting the confidentiality of applicants, and as advocates and indeed protectors for families that might otherwise be reluctant to interact with a public program for fear of sanctions or—worse—

deportation. Under CHP, although MCOs were neither required to ask nor to report on the immigration status of applicants, it took months, even years, to gain the confidence and trust of the target communities.

An MCO's extensive obligations to its enrollees result from various sources, including the state's and counties' administrative policies, a plan's own mission[27] and actual contractual obligations. Under the state's model Medicaid Managed Care contract (followed with only slight variation by all counties), for example, an MCO is contractually required to "make all reasonable efforts" to contact each new enrollee within thirty days in order to do *at least* the following: provide information about obtaining medical services; conduct a health screening to assess the enrollee's need for any special health care; offer assistance in arranging an initial visit to the enrollee's primary care physician (in Westchester County, the plan is also obligated to arrange transportation, including taxi service, if necessary); provide the enrollee with the plan's seven-day-a-week, 24-hours-a-day toll-free telephone number; and provide "appropriate mechanisms" to accommodate enrollees who do not have a telephone.[28] The MCO must provide a member handbook written at a sixth-grade reading level,[29] and make written marketing and other informational material available in a language other than English if at least five percent of the MCO's potential enrollees in any county speak that language as a first language.[30] If an MCO denies a service as not covered (e.g., on the basis of lack of medical necessity), the MCO must provide the enrollee with various written notices and forms explaining the enrollee's rights to appeal the decision, both internally and externally.[31]

A Medicaid managed care plan is responsible for discovering what services an enrollee may need, and then for coordinating the delivery of such services. For example, an MCO is required to identify adult enrollees who have (or who are at risk of having) chronic illnesses and physical or developmental disabilities, and determining such an enrollee's specific needs for specialist referrals, durable medical equipment and home health services.[32] For children with special health care needs, the MCO must also interact with school districts, child protective services, early-intervention officials and behavioral health and developmental disabilities service organizations in order to coordinate appropriate services.[33] The plan is also responsible for providing information about family planning services[34] and ensuring that its health care providers educate enrollees about the risk and prevention of sexually transmitted diseases.[35]

Clearly, a Medicaid managed care plan's obligations to its enrollees extend far beyond simply arranging for a network of health care providers and paying the bills for services. The plan is responsible for coordinating a wide range of services and ensuring that each enrollee receives the care that she needs. Taking any action that may result in an enrollee's being cut off from health care services violates a plan's primary goal of assisting its enrollees.

The facilitated enrollment process—which has now effectively deputized plans to take Medicaid, CHP and Family Health Plus applications[36]—grew out of the successes of MCOs in recruiting and enrolling children for Child Health Plus. However, in a cruel twist, these same MCOs that exercised their duty of care and confidentiality with applicants and enrollees are being asked to work as agents of the state in implementing a policy designed to identify, report and ultimately sanction individuals who might be substance abusers. It is impossible to reconcile these conflicting duties.

III. Other Legal Issues: The Right to Benefits and Confidentiality

Right to Benefits

Because Home Relief is a discretionary program funded exclusively with New York State dollars, recipients of benefits under this program are not entitled to federal remedies with regard to either the scope or administration of such benefits.[37] In recent years, several cases have been brought in New York courts by Home Relief recipients challenging termination of benefits by the Department of Social Services under the state-financed program.[38] Generally speaking, the courts have been unsympathetic with regard to claimants who are protesting the loss of cash assistance and medical benefits after failing to comply with work program requirements.[39] Because the Department's approach to substance abuse is tailored toward employability and actually builds in many of the same procedures imposed in the various "welfare-to-work" programs—e.g., formal assessment, determination of ability to work, referrals to treatment, clearly defined sanctions, opportunities to cure—it is highly unlikely that an individual identified as a non-compliant substance abuser could obtain judicial redress for loss of benefits.

Confidentiality

The importance of protecting an individual's health information has been highlighted by recent state regulation[40] and major federal legislation.[41] Particularly sensitive information, including information about substance abuse services, is afforded extra protection.[42] Federal law imposes strict confidentiality requirements on the record of any person who participates in a federally assisted alcohol or substance abuse program.[43] Specific patient consent is required for the release of records

regarding treatment in such a program, except under certain limited and specific circumstances.[44]

While pre-screening and referral may fall short of qualifying as confidential medical records, the fact that individuals and organizations, employed neither by the state nor the local districts, have access to private information about substance abuse is arguably a serious privacy violation. The notification requirements clearly violate the spirit, if not the letter, of the law. New York State's approach to requiring individuals who work for managed care organizations and facilitated enrollment agencies to ferret out and report substance abusers, and to subsequently mandate these individuals into assessment and treatment under a threatened loss of benefits, clearly conflicts with laws and policies intended to protect individual health information of a sensitive nature.

IV. Why Withholding Benefits Is Ineffective from Clinical and Policy Perspectives; Recommendations for Change

The denial of Medicaid benefits to substance abusers who fail to comply with DSS-ordered or -approved treatment serves no practical purpose. First, the screening requirements clearly function as a disincentive to someone who might otherwise *voluntarily* seek treatment. Upon learning that an enrollee has received substance abuse services, the plan is required to send the information to the county. The enrollee then risks losing benefits if she is unsuccessful in treatment. Second, there is no evidence that for an individual with a substance abuse disorder, the threatened loss of Medicaid is a meaningful incentive to enter and remain compliant with treatment. The high rate of failure to recertify in a timely manner for benefits among the general Medicaid and Child Health Plus population[45] demonstrates that, for individuals with multiple socioeconomic problems, possible loss of insurance is not a compelling reason to interface with a bureaucracy that often demands more than it gives in the short term. It is only logical that substance abusers—persons who are engaged in unhealthy, addictive behaviors—are even less likely to see medical coverage as an adequate incentive to comply with treatment that is, as yet, not compelling enough to outweigh other countervailing factors.

Further, the system's approach to serious, chronic substance abuse as a purely *voluntary, behavioral* disorder—embodying what one researcher refers to as a "moral deficit" or "learning/behavioral" philosophies of the disorder[46]—flies in face of evidence that the disorder is actually often a symptom of organic mental illness.[47] One official from Westchester County's Department of Community Mental Health estimates that from 25 to 40 percent of substance abusers identified by the County suffer from serious, undiagnosed, psychotic or affective disorders, specifically schizophrenia, bipolar disorder or severe clinical depression.[48] Although individuals identified through the facilitated enrollment process, or through the regular Medicaid eligibility intake process, are referred to a Certified Alcohol and Substance Abuse Counselor (CASAC) for further screening and evaluation—a process that theoretically could identify underlying mental illness—the CASACs themselves are limited by time and bureaucracy, as well as by their own backgrounds (CASAC certification does not require even a bachelor's degree, let alone clinical training in mental illness). Most importantly, both Medicaid clients and the Social Services workers charged with helping them are hamstrung by a treatment system polarized into "separate administrative divisions and funding pools which foster . . . political and administrative organization at the expense of creative and innovative care."[49] To wit, in Westchester County, there is only one program—located at Phelps Memorial Hospital—for mentally ill, chemically dependent (MICA) individuals. All other programs are classified as being designed for either "substance abuse" or "mental health"—never for both.[50] Because substance abuse treatment (with the important exception of methadone maintenance programs) is based on the behavioral model, and generally eschews the use of any type of drug treatment, while mental health programs increasingly employ psychiatric drugs to help their patients cope with brain disorders, it is no wonder that compliance with treatment is a serious problem.

The nature of New York's health care system is such that the lack of Medicaid eligibility at a given moment does not impede access to care if it is urgently required.[51] Federal law specifically protects substance abusers from discrimination "by any private or public general hospital, or outpatient facility . . . which receives support from any program supported in whole or in part by [federal] funds . . . ."[52]; in other words, any health care facility that bills Medicaid or Medicare must treat a substance abuser who requires services. In addition, hospitals and community health centers often provide care on a sliding fee scale to "self-pay" (i.e., uninsured) patients. Furthermore, if an individual becomes acutely ill and requires inpatient care, hospitals are able to access emergency Medicaid coverage—regardless of an individual's prior benefit record.[53] Thus, the cancellation of Medicaid benefits fails both as a behavioral incentive to get individuals off drugs, and as a way for the health care system to save money.

One final point remains, namely, that despite the state's and the counties' legal right to enforce compliance with substance abuse treatment and withhold benefits if such compliance is not forthcoming, the government lacks the personnel and systems to identify substance-abusing clients and track compliance, and thus to apply the sanctioning policies with any unifor-

mity.[54] It was doubtless in an effort to improve in these areas that the government enlisted managed care entities and facilitated enrollers in pre-screening applicants for assistance and turning in those who present for services. However, in addition to the problems connected to involvement of these organizations and individuals, there is no evidence that the local Departments of Social Services have actually implemented uniform processes for tracking and enforcing compliance or sanctions.

In sum, policies permitting New York State and the various counties to withhold Medicaid benefits from substance abusers on Home Relief who fail to comply with treatment infringe on the fiduciary duties of managed care organizations to their enrollees, violate confidentiality with regard to clients' health information, systematically fail to identify and address other compelling medical (especially psychiatric) needs, do nothing to reduce public expenditures on medical care, and are impracticable and unable to be implemented within the current social services system. These facts support the conclusion that the policies exist primarily as window-dressing: to show that the government will not tolerate "voluntary" illegal behavior among individuals in receipt of government benefits. If substance abuse is to be addressed in a meaningful way, federal and local governments should focus efforts on developing programs that incorporate an integrated medical and behavioral model into both diagnosis and treatment, and should provide such treatment to Home Relief clients on the same basis as other types of needed medical care.

Endnotes

1. New York Comp. Codes R. & Regs. tit. 18, § 351.2(i)(2)(iii) (N.Y.C.R.R.).
2. S. 5788, 220th Leg., pt. B (N.Y. 1997), Ch. 436 of Laws of 1997, subsequently codified throughout N.Y. Social Services Law (SSL).
3. *Id.*
4. N.Y.C.R.R. tit. 18, §§ 351.2(i), 370.2(8) (2001).
5. Medicaid Managed Care Model Contract, 1999, § 10.24.
6. "Access NY" is actually a marketing name that refers to the combined application and eligibility determination process for Medicaid, Child Health Plus, Family Health Plus and WIC.
7. SSL § 369-ee.
8. N.Y. Public Health Law § 4403-a.
9. The term "sponsorship" is somewhat misleading here, as the original PHSPs in New York were subsidized by NYS grant funding. *See* letter from Gary Riviello, New York State Department of Health, Bureau of Alternative Delivery Systems, to Eva Turbiner, Project Director, Westchester Prepaid Health Services Plan (September 11, 1986) and attached Amendment to New York State Department of Health Contract No. C-000938 (on file with WPHSP, Inc.).
10. Stephen Zukerman, Alison Evans and John Holahan, *Questions for States As They Turn to Medicaid Managed Care,* Urban Institute, number A-11 in Series, "Issues and Options for States" (Aug. 1997). <http://newfederalism.urban.org/html/anf_a11.htm>
11. Letter from William L. Roper, M.D., Administrator of the Health Care Financing Administration, D.H.H.S. to Robert Osborne, Deputy Commissioner, NYS Dept. of Social Services (undated, attached to Oct. 14, 1986 letter cited *supra* note 8, (on file with Westchester Prepaid Health Services Plan, Inc.).
12. Letter from William Toby, Regional Administrator, Health Care Financing Administration, to Cesar A. Perales, Commissioner, New York State Department of Social Services, Ref. DPO:SOB:3 (November 5, 1986) (on file with Westchester Prepaid Health Services Plan, Inc.).
13. New York State's 1115(b) waiver request, known as the "Partnership Plan," was submitted to the Health Care Financing Administration in March 1995. The plan, which billed itself as "a public-private initiative ensuring healthcare for needy New Yorkers," made a great deal of the fact that it was going to rationalize the health care delivery system, cut costs and improve access for recipients through a competitive bidding process and the entry of large, commercial insurers into the public sector market.
14. "Managed Care Enrollment Trends, October 2000." A report by the Coalition of New York Prepaid Health Services Plans. Kalkines, Arky, Zall & Bernstein, PC.
15. 7th edition (1999).
16. *Id.* at 640.
17. Indeed, the American Medical Association, in its 1934 principles entitled "Sickness Insurance Problems in the United States," lauds the fiduciary role of the physician, stating that "[no] third party must be permitted to come between the patient and his physician in any medical relation . . . The method of giving the service must retain a permanent, confidential relation between the patient and [the physician]." Cited in Rand E. Rosenblatt, et al., Law and the American Health Care System 24, Foundation (1997).
18. 29 U.S.C. § 1001 *et seq.*
19. 29 U.S.C. § 1104(a)(1).
20. 29 U.S.C. § 1104(a)(1)(a).
21. *Pegram v. Herdrich*, 120 S. Ct. 2143 (2001). In this case brought by an HMO enrollee against her health plan, Justice Souter, writing for the majority, stated, "The fiduciary is, of course, obliged to act exclusively in the interest of the beneficiary, but this translates into no rule readily applicable to HMO decisions or those of any other variety of medical practice."
22. *See, e.g.*, PHL § 4408-1 (grievance procedure), §§ 4900-4908 (utilization review and right to appeal adverse determinations), §§ 4909-4916 (right to external appeal).
23. After large losses by most Medicaid MCOs in the mid-1990s, one result of which was the withdrawal of several commercial insurers from the program, the NYS Department of Health has returned to a method of determining premiums that takes into account MCOs' historical experience and real costs.
24. Actually, there is little meaningful distinction between Medicaid and commercial plans, with respect to conflicting duties resulting from the fact the payer is not the enrollee; most commercial insurance in the US is paid for by the employer, and not the individual beneficiary.
25. PHL §§ 2510, 2511.
26. New York State Department of Health enrollment statistics, December 2001.
27. For example, the mission statement of HealthSource/Hudson Health Plan, a provider-sponsored MCO operating in Westchester and other counties in the Hudson Valley is "To Promote and Provide Access to Health Services for All People."

28. Medicaid Managed Care Model Contract, 1999, § 13.5.

29. *Id.* App. E-2.

30. *Id.* § 12.2. In Westchester County, written material for enrollees must be prepared in both English and Spanish.

31. *Id.* §§ 25.3, 26.1, and App. F-3.

32. *Id.* § 10.20.

33. *Id.* § 10.21.

34. *Id.* App. C.

35. *Id.* § 10.19c.

36. This process and the various programs it encompasses are referred to collectively as "Access NY Health Care." The application packet, DOH-4220-I 8/01, is available from the New York State Department of Health and from participating facilitated enrollers or MCOs.

37. Even under Federal law, however, courts have consistently found no constitutional right to governmental aid—including health benefits. *See, e.g., De Shaney v. Winnebago County Department of Social Services*, 489 U.S. 189, 196 (1989) (holding that the "Due Process Clauses generally confer no affirmative right to governmental aid, even where such aid might be necessary"). *See also Dandridge v. Williams*, 397 U.S. 471 (1970) (upholding a Maryland law that imposed a ceiling on welfare grants to families, regardless of the number of children in that family, and stating that programs limiting the right to welfare benefits are subject to review only on a rational basis—rather than strict or intermediate scrutiny—standard).

38. *See Kelly v. Wing*, 237 A.D.2d 976, 654 N.Y.S.2d 535 (1997), holding that DSS may suspend Home Relief and Medicaid benefits of a client who fails to attend a work experience interview; *Casid v. Prinzo*, 232 A.D.2d 860, 649 N.Y.S.2d 64 (1996), finding that the discontinuance of public assistance benefits was appropriate for a Home Relief client who failed to participate in Albany County's "Work Through Independence" program, and failed to submit to a psychiatric examination despite his contention that his psychological problems rendered him unable to work.

39. For a determination in favor of the client, see *Bryan v. Hammons*, 173 Misc. 2d 894, 662 N.Y.S.2d 691 (1997), where benefits were ordered restored because their termination was found to be arbitrary, capricious and contrary to law, given that recipient was never designated or assigned to a work experience program

40. 11 N.Y.C.R.R. § 420 (Reg. 169 - Privacy of Consumer Financial and Health Information) (effective Nov. 2000).

41. Health Insurance Portability and Accountability Act of 1996 (HIPAA), Title 11, Subtitle F, §§ 261-264, Public Law 104-191 (Aug. 21, 1996); The final HIPAA privacy regulations (45 C.F.R. §§ 164.506–164.512: published December 28, 2000, effective April 14, 2001; full compliance due by April 14, 2003).

42. *See, e.g.*, N.Y. Mental Hygiene Law §§ 22.05(b), 33.13.

43. 42 U.S.C § 290dd-2. *See* related regulations at 42 C.F.R. §§ 2.1 *et. seq.* Note that although Home Relief is not federally subsidized, all treatment facilities that accept Medicaid or Medicare payments—i.e., virtually every substance abuse treatment plan to which a Home Relief client would be referred—are covered under this law.

44. Consent is not required, if certain specific conditions are met, in the following situations: medical emergencies (42 C.F.R. § 2.5); court orders (42 C.F.R. § 2.61(b)); research, audit or evaluation (42 C.F.R. §§ 2.52, 2.53); internal program communications (42 C.F.R. § 2.12(c)(3)); communications that do not disclose patient identity (42 C.F.R. § 2.12(a)); patient crimes on the premises of the program (42 C.F.R. § 2.12(c)(5)); child abuse and neglect reporting (42 C.F.R. § 2.12(c)(6)); release to qualified service organizations (42 C.F.R. § 2.12(c)(4)).

45. Coverage Gaps: The Problem of Enrollee Churning in Medicaid Managed Care and Child Health Plus: A Report of the New York State Coalition of Prepaid Health Services Plans, Kalkines, Arky, Zall & Bernstein LLP (2000).

46. K.J. Brower, et al., *Treatment Implications of Chemical Dependency Models: An Integrative Approach*, 6 J. Substance Abuse Treatment 147 (1989), discussed in Arthur J. Anderson, *Therapeutic Program Models for Mentally Ill Chemical Abusers*, 1 Int'l J. Psychosocial Rehabilitation 21 (1997), *available at* http://www.psychosocial.com/dualdx/rehabpub.html.

47. The National Alliance for the Mentally Ill (NAMI) uses the phrase "brain disorder" to refer to all mental illness.

48. Interview with Pat Doyle, Director of Alcohol and Substance Abuse Services, Westchester Department of Community Mental Health, January 2, 2002.

49. Anderson, *supra* note 46.

50. Dual diagnoses would result in the designation of many substance abusers as "disabled," providing them with a far more extensive set of rights, although federal law explicitly excludes users of illegal drugs from being considered "disabled"; *see* 42 U.S.C. § 12210(a) and the Rehabilitation Act Amendments of 1992, Pub. L. No. 102-569, 106 Stat. 4344 (1992). Furthermore, New York's Medical Assistance law actually builds treatment (i.e., behavioral conformance) requirements into statute: "No disabled person will be categorically eligible for MA if he/she is medically determined to be a drug addict or alcoholic, unless he/she is undergoing treatment that is appropriate for his/her condition as a drug addict or alcoholic, so long as such treatment is available and the person demonstrates that he/she is complying with the terms, conditions and requirements of such treatment." N.Y.C.R.R. tit. 18, § 360-5.10 (b).

51. Of course, access to any given service, such as detoxification or rehabilitation for substance abusers is, *ipso facto*, limited by the system's capacity. One of the strongest criticisms with regard to drug enforcement efforts in this country has been based on the shortage of treatment programs. In Westchester County, MCOs have frequently been unable to find appropriate treatment within a reasonable geographic distance, and on a timely basis (various interviews with Elena Ruiz-Diaz, CSW, Clinical Case Manager, Beacon Health Services and HealthSource/Hudson Health Plan, Dec. 2001).

52. 42 U.S.C. § 290dd-1.

53. 8 U.S.C. § 1611(b). This policy clearly exists for the benefit of providers, not patients.

54. Interviews with officials from the Departments of Social Services and Community Mental Health in Westchester County, as well as with behavioral health case management staff at HealthSource/Hudson Health Plan.

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Outsourcing Non-Clinical Services in Health Care

By Edward A. Pisacreta, Jill C. Alvarez and Leslie J. Levinson

Over the past decade, health care organizations (HCOs) across the entire spectrum of the health care industry have increasingly come to view outsourcing as a powerful management device. But more than that, they view outsourcing as critical to the ability of an HCO to successfully navigate the difficulties of providing quality care within the confines of an era of fiscal constraint.

Why Outsourcing?

Outsourcing is the agreement between an HCO as buyer, and a third-party provider of services as vendor (the "Vendor") pursuant to which the Vendor provides to the HCO certain defined services formerly performed by the HCO itself. A broad variety of services and functions can be and have been outsourced by HCOs, including the outsourcing of the human resources functions and other management support services; internal accounting; claims processing; capital projects management; non-professional patient-related services such as appointment scheduling, kitchen and catering services, and laundry services.

HCOs may also opt to outsource significant clinical functions, raising special regulatory and liability issues. This article, however, focuses on the outsourcing of functions that are non-clinical, but nonetheless essential to the operation of the HCO.

Often, it is the outsourcing of Information Technology (IT) functions and services which is embraced by HCOs as they seek to contain the otherwise significant capital investment required to develop, implement and maintain in-house IT systems; manage the high personnel costs associated with IT employee retention and training; and help control the increasing costs associated with the regulatory compliance imposed on the healthcare industry. Regardless of the functions outsourced, many of the issues facing the HCO are the same. This article will address some of the more significant of these issues.

Outsourcing as a Core Business Strategy

For the HCO, outsourcing has the potential to become a core business strategy. By leveraging the outsourcers' core abilities, the HCO is able to maximize its options to, for example, enter into new markets, by gaining access to state-of-the-art technologies without investing directly in development of such technologies, thereby limiting risk to the HCO. Thus, by allowing the outsourcer to deal with services that are the core competency of that outsourcer, the HCO is able to focus its efforts on its own core competencies.

Outsourcing allows the HCO to leverage the Vendor's knowledge repository of services and abilities. It also provides the HCO with access to individuals with specialized skills who might otherwise be expensive and difficult for the HCO to attract and retain, particularly in IT where the skill development of employees is costly and complicated. By outsourcing the IT functions or a part thereof, an HCO does not have to invest in the constant training and development of employees, nor does it have to keep up with the rapidly accelerating rate of technology advancement on its own.

Through outsourcing, the HCO gains access to the experience of the Vendor which may, through its provision of the outsourced services, improve the work patterns or processes of the HCO, which may in turn improve services provided by the HCO itself as well favorably impact the HCO's profitability. It also allows an HCO to benefit from the ability of the Vendor to provide these services at rates that reflect economies of scale.

The Importance of Outsourcing

While outsourcing functions to comply with the Health Insurance Portability and Accountability Act (HIPAA) provides significant incentive for certain HCOs, there are other factors that HCOs must consider. Although outsourcing by its nature involves the delegation, and to some extent, loss of control and management over some aspects of systems and services, significant numbers of HCOs have determined that there are still substantial advantages to outsourcing, particularly to the outsourcing of IT, and through a carefully constructed outsourcing agreement, issues of loss of control and problems arising therefrom can be addressed. Ultimately, whether the outsourcing arrangement proves beneficial to the HCO and the Vendor will depend, to a large degree, on the underlying outsourcing agreement.

The Importance of the Outsourcing Contract

Logically, as outsourcing continues to take hold as a powerful business management tool, and the scope of services outsourced increases, the contract between the

HCO and the Vendor grows more important and more sophisticated than ever. The negotiation of the outsourcing agreement is an intensive process during which the HCO and the Vendor determine the terms of the engagement, such as scope, value, risk, reward and the structure of the outsourcing relationship itself. If handled properly, however, the process of drafting the contract, and the contract itself, will set the stage for successful and beneficial outsourcing.

The outsourcing contract should embody and represent the parties' understanding of what was agreed to and what is expected to happen during the outsourcing engagement. It is essential to the success of the engagement that the parties put the requisite time and effort into crafting, understanding and negotiating the document, and provide for adequate follow-up and management during the life of the contract.

Goals of the Contracting Process

The first step is for the HCO, in its role as buyer, to understand the reasons why it is seeking an outsourcing relationship. Is the goal financially driven, or is the HCO looking to accomplish certain strategic objectives with technology, or is the industry being transformed by technology, or a combination of these and other factors? Likewise, the Vendor needs to know and understand what it does best and what services it can provide and agreements it can enter and successfully fulfill.

It is also important to have executive support for outsourcing. Having strong leaders who are determined to come to an agreement and work together is a powerful force that can help when hitting "rough spots in the road" during the negotiation process. An attorney who is knowledgeable about the ins and outs of the outsourcing contract and the negotiation process is also a critical asset. Without a skilled negotiator—one who understands both sides of the negotiation and the thoughtful process of taking strategic objectives and the related agreements and putting them into legal terms—the contractual framework may not support the intended agreement of the parties.

Furthermore, even if the goals and objectives of the transaction appear to be unambiguous during negotiations, a prudent HCO should always incorporate such goals and objectives into the final agreement. An HCO may accomplish this by explicitly incorporating various documents into the agreement that contain the parties' goals and objectives, such as the Vendor's proposal or the HCO's request for proposals. The negotiating parties should even include the obvious in the final agreement to avoid confusion and disappointment later on if the parties disagree on exactly what was said at the bargaining table.

Addressing Risk

When an HCO enters into an outsourcing contract, putting substantial assets and business processes into the hands of the Vendor, the HCO assumes certain risks including loss of control, loss of flexibility, the failure by the Vendor to improve the performance of the HCO, and/or failure to achieve the projected financial benefits, and/or the inability to respond appropriately and effectively to changes in the marketplace. Likewise, the Vendor undertakes significant risk when it contracts to provide the outsourced IT services, including the risk that it will fail to meet financial benchmarks, fail to provide the agreed-upon levels of services, or fail to stay abreast of trends in the marketplace, to the extent that it has such obligations under the agreement.

Typically, outsourcing agreements allocate the risk assumed by each party under the agreement. With each party assuming some but not all of the risk, a failure of performance by either party can substantially affect both the HCO and the Vendor. It therefore becomes essential that the underlying risk in the outsourcing arrangement be effectively managed by both parties throughout the term of the relationship.

The agreement needs to recognize and provide for circumstances under which the agreement may be terminated, or when issues need to be resolved by third-party mediators and/or consultants.

Scope, Performance and Pricing

The outsourcing agreement is the only deliverable from the outsourcing negotiating process. It therefore becomes essential that the agreement fully and clearly reflects a meeting of the minds of both parties regarding all issues. Critical to this understanding are the issues of scope, performance and pricing.

Consequently, the outsourcing agreement must contain a detailed description of services to be performed, often set forth in separate services schedules or statements of work. In the absence of a complete agreement, disputes may arise as to whether a particular request is outside the scope of the contracted-for services. Therefore, both parties should strive to document a complete listing of services, service levels and deliverables, accompanied by further agreement setting out benchmarking and price and/or performance migration milestones and project schedules.

Pricing of services is an area where there can also be a great deal of flexibility woven into the contract that can reward both the HCO and the Vendor. For example, variable pricing can allow for a baseline where a sustained trend above or below can result in renegotiations or adjustments to benefit both parties and reduce the risk to both.

A new trend in outsourcing arrangements, evidenced in the health care and other industries, is "risk-reward" pricing provisions in outsourcing contracts. These provisions are meant to guarantee a Vendor significant financial incentives to improve the business performance of the HCO. While these are difficult to negotiate and require that due consideration be paid to any regulatory issues that might arise (such as fee splitting or kickback issues, for example), these profit-sharing models offer a good deal of flexibility to the HCO as buyer of the outsourcing services.

Addressing Changes in the Contract

A common problem leading to difficulties in an outsourcing engagement is a change in the needs of the HCO, which will invariably occur. Therefore, planning for change during the negotiation process and as part of the agreement is essential to the success of any outsourcing engagement. Today's outsourcing world demands flexibility and continuous improvement. Whether the change is in technology, or in the needs and skills of either party, the contract can and should reflect the mechanisms and procedures needed to plan for and manage the change.

Procedures need to be developed to enable the parties to change the scope of services during the term of the contract, and the agreement must address cost/fee implications for the changes, the personnel authorized to request such changes for the HCO, and the personnel authorized to approve such changes for the Vendor.

Monitoring and Evaluation

The enhancement of value can serve as the trigger mechanism at which the contract contemplates and provides for change in certain provisions, and the range of alternatives for this process is up to the creativity of the parties. Therefore, defining "value" becomes an important part of the negotiating and outsourcing process. For example, value may be defined as the ability of the Vendor to develop initiatives on its own, based on and designed to address the needs of the HCO. Alternatively, value can be tied to the willingness of the Vendor to set, and meet, concrete and measurable service levels or financial targets.

To control the risks and increase the value of outsourcing, organizations need to monitor and evaluate the performance of the other party on an ongoing basis. The goal of building in monitoring and evaluation processes is to develop mutually beneficial arrangements for both the Vendor as supplier of services, and the HCO as buyer. Monitoring and evaluating the performance of the outsourced services environment requires an agreement on performance measures that are easy for the parties to understand, relatively few in number and capable of being put into effect by the people responsible for executing the work.

One such method is to allow user or customer satisfaction ratings to be given by establishing a set of performance criteria, such as a service-level agreement. This type of standard provides an opportunity to evaluate the Vendor's performance at any specific time, as well as over time. Such benchmarking—which often involves third-party evaluation and the use of industry standards—also allows the HCO to provide performance incentives to the Vendor, or to share the benefits of the relationship with the Vendor.

After the employee transition that is typical in an outsourcing arrangement, the Vendor will be providing services using its own employees. The outsourcing entity needs to be able to measure the level of resources that it currently gets in relation to the number of personnel the entity had performing services as employees when those services were under its own control. The HCO should be cautious of metrics proposed by the Vendor that do not permit the HCO to determine the level of personnel resources that it receives for the amount it is asked to pay.

No Loss of Responsibility

Outsourcing does not mean shedding responsibility for outsourced functions. Particularly in the health care industry, responsibility for ensuring the integrity of functions such as claims processing and regulatory compliance, including compliance with HIPAA by Vendors and other third parties, remains with the HCO. Procedures and safeguards to build in compliance-related processes to insure the integrity and propriety of outsourced services is an integral part of the outsourcing agreement, which must be monitored by both the HCO and the Vendor.

The Living Agreement

When the negotiation process is finished and the agreement executed, the outsourcing contract should be the embodiment of the understanding of the parties of what is expected to occur in this relationship. It cannot be put into a drawer. It is, and must remain, a vital document able to reflect and adapt to the changing needs and interests of the parties.

Often the parties are best served when outsourcing contracts attach multiple schedules that, in clear and substantial detail, address the nature and level of the contracted-for services, performance benchmarks and other expectations of the parties.

The outsourcing agreement should also set forth clear service-level agreements and the compensation expected by the Vendor for providing such services. Scope and level of service are often difficult to quantify, but it is well worth putting time and thought into the negotiation and drafting of these issues. The process itself of negotiating the scope of the agreement can prove remarkable in terms of an awakening for both parties as to what the outsourcing arrangement is really about.

The scope of the outsourcing arrangement represents, in essence, what one party retains and what it gives up. For example, in entering into an IT outsourcing arrangement, an HCO not only has to determine whether or not it wants to be involved in the day-to-day management of the IT technology, but also the degree to which it wants to retain responsibility for the architecture, design, management, growth or change of the outsourced systems, if at all.

The ongoing management of the relationship between the HCO and the Vendor is an important issue that needs to be addressed in the agreement. The parties must agree on the level of day-to-day issues to be handled by the Vendor without consultation with or approval by the outsourcing entity. Further, since issues will arise from time to time, it is essential that the agreement contain an agreed-upon method of resolution, be it mediation, arbitration or otherwise.

When the outsourcing agreement terminates or expires, the HCO may not be able to switch Vendors immediately or insource the functions. Therefore, the parties will need to provide for a transition period after such termination or expiration, during which the Vendor shall continue to provide services, in order to allow for an orderly transition from the Vendor back to the HCO or to a new Vendor.

In addition, since as a result of the outsourcing relationship the HCO may have transferred some of its resources, such as its employees, software and equipment to the Vendor, the HCO may require upon termination of the agreement the right to offer employment to Vendor's employees who perform services for the HCO and/or acquire the equipment and software the Vendor uses to provide the services at a predetermined fee set in the agreement.

HIPAA Concerns

The Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §§ 1320d *et seq.*) (HIPAA) and regulations promulgated thereunder, impose requirements and standards that add to the growing impetus for HCOs to outsource IT functions. HCOs, already burdened by the complexities of designing and managing IT systems, are now attempting to meet HIPAA-imposed deadlines concerning the implementation of certain standards. These HIPAA-mandated standards collectively require that an HCO establish procedures and systems to protect against unauthorized access to, or modification of, certain protected health information defined as "individually identifiable health information," whether maintained or transmitted by the HCO on paper or electronically (the "Protected Health Information"), and require the establishment by the HCO of internal audit procedures, incident reporting procedures, termination procedures and data authentication controls to maintain the integrity of the Protected Health Information, and the use of encryption systems. There are mandated privacy standards as well as standards establishing identifiers for providers, payers and beneficiaries, supporting codes, security standards and standards for electronic administrative and financial transactions affecting all health plans, clearing houses, those health care providers conducting certain covered transactions electronically and certain third parties doing business with HCOs. Covered transactions include, for example, claims processing, referrals and determination of eligibility.

The mandated privacy standards also require an HCO to put in place procedures and written agreements to assure that those contractors deemed to be "business associates" under HIPAA use and disclose the Protected Health Information only as permitted under the privacy standards. HIPAA defines a business associate as a person, business or organization that performs services or functions for or on behalf of an HCO subject to HIPAA, and which in the course of what it does for the HCO creates or uses or receives Protected Health Information from such HCO. The concept of a business associate is broadly interpreted and may encompass a contractor performing one or more functions and services that may be outsourced by an HCO, such as IT functions, claims processing, legal or accounting services and office administration and management services.

The agreement with the business associate may be a stand-alone agreement or, if appropriate, incorporated into another agreement between the HCO and the business associate. The business associate must be obligated: (a) not to use or disclose the Protected Health Information other than as permitted under law or the terms of the agreement; (b) to use appropriate safeguards to prevent such unauthorized disclosure or use; (c) to promptly report to the HCO any unauthorized use or disclosure; (d) to ensure that any subcontractors of the business associate to whom Protected Health Information may be disclosed agree to each of the terms of the agreement between the HCO and the business associate; (e) make available to the Secretary of the United

States Health and Human Services ("HHS Secretary") its own internal practices, book and records relating to the use and disclosure of the Protected Health Information for purposes of determining the HCO's compliance with HIPAA; (f) upon the termination of the relationship between the business associate and the HCO, to return to the HCO, or destroy, all copies and forms of the Protected Health Information; and (g) to agree to incorporate into the agreement any amendments to the HIPAA privacy standards.

The HCO has no obligation to actively monitor the compliance of the business associate with the restrictions on the use and disclosure of the Protected Health Information. However, once the HCO has knowledge of a breach, the HCO must have the authority under the agreement with the business associate to terminate the agreement if the business associate fails to cure the breach.

Additional Regulatory Concerns

Outsourcing, arising as it does from a contractual relationship between the HCO and the Vendor, implicates regulatory concerns in addition to HIPAA. For example, if the outsourcing contract will cost the HCO more than $10,000 a year and the HCO plans to report the costs on its Medicare cost reports, section 1861(v)(1)(I) of the Federal Social Security Act requires that the contract include specific language to grant the HHS Secretary and the Comptroller access to the contract and records. Such access must be granted for a period of up to four years after the provision of the services by the Vendor to the HCO.

Moreover, New York Department of Health regulations provide that contracts to perform any services for a licensed medical facility must (a) be in writing; (b) set forth the responsibilities of each party and the financial arrangements between them; (c) require compliance with applicable New York law and regulations; and (d) further expressly provide that despite the outsourcing agreement, the HCO remains responsible for compliance with applicable federal and state laws and regulations.[1]

Outsourcing arrangements may also implicate other federal and state statutes and regulations that restrict or prohibit the ability of physicians and other providers to enter into certain relationships, including referral and financial relationships. For example, these restrictions or prohibitions include, but are not limited to, the making of certain referrals between entities in which the provider has an interest and that provide what are known as designated health services (the so-called "Stark laws"), enter into financial arrangements deemed to be fee-splitting arrangements that give the Vendor an interest in the revenues of the HCO, and the making of certain payments deemed to constitute prohibited payment for referral of patients for treatments or services. A careful analysis of the outsourcing arrangement and its compliance with each of these state and federal laws and regulations must be carefully undertaken by each of the parties and its counsel.

Conclusion

The success of health care outsourcing arrangements starts with the contracting process, which must seek to develop and foster clear channels of communication to encourage new ideas, reward those ideas and create revenue opportunities for both parties. The contracting process—an integral part of the education of both parties—must bring the Vendor to a clear understanding of and respect for the particular complexities and interrelationships inherent in the HCO, and the technical and financial issues with which the Vendor must contend. Ultimately, and if it is negotiated and administered correctly, the outsourcing contract provides a road map for the HCO and the Vendor, to accurately and clearly describe where the parties seek to go in this arrangement, and how they can best arrive there.

Endnote

1. 10 N.Y.C.R.R. § 400.4.

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Genetic Testing and Screening in the Age of Genomic Medicine

Executive Summary

New York State Task Force on Life and the Law

Editor's Note: *This is the Executive Summary of the Task Force's November 2000 Report. The full Report is available and can be purchased from: Health Education Services, P.O. Box 7126, Albany, NY 12224 (518) 439-7286.*

Genes and Chromosomes

- Genes are the blueprints of heredity. Genes are made of hundreds of thousands of DNA bases.
- Each gene directs cells to produce one or more specific proteins, including enzymes and structural proteins.
- The human genome is the complete set of genes that every person inherits from his or her parents. It is present in virtually every cell of the body.
- The human genome consists of tens of thousands of pairs of genes. Each person inherits one copy of each gene from each parent.
- Genes are organized along string-like structures called chromosomes. Each individual inherits two sets of twenty-three chromosomes, one from each parent: two sets of twenty-two autosomes and one set of sex chromosomes (X, X or X, Y).

Genetic Variations, Mutations and Human Disease

- The DNA base sequence of human genes is about 99.9 percent identical among individuals. About 1 of every 1,000 DNA bases varies among individuals, accounting for inherited differences in traits and disease susceptibility.
- Changes in a DNA base sequence, called mutations, account for inherited gene variations. Mutations may be harmful if they prevent a gene from making a normal copy of its specific protein. These mutations can cause, or increase susceptibility to, specific diseases.
- Single-gene diseases are relatively rare diseases that result when a person inherits one gene with a harmful mutation or a pair of genes in which each has a harmful mutation. Inheritance of these mutated genes generally results in a 100-percent chance of developing a specific disease. Single-gene diseases include autosomal dominant diseases (e.g., Huntington disease), autosomal recessive diseases (e.g., sickle cell disease), and X-linked diseases (e.g., Duchenne muscular dystrophy).
- Most diseases result from a complex set of both genetic and environmental causes. Inheritance of some harmful gene mutations increases the chance, although it does not ensure, that a person will develop a specific disease. These mutations are called inherited susceptibility mutations.

The Human Genome Project and Health Care

- The Human Genome Project, an international research project, has now deciphered the more than three billion DNA letters of the human genome. Follow-up research is expected to discover the structure and function of thousands of new genes.
- Genetics research will lead to the development of new predictive and diagnostic genetic tests. It also will lead to the development of new preventive and treatment interventions. Generally, the development of interventions lags years, even decades, behind gene discovery and genetic test development.

Genetic Testing

- Genetic testing for inherited genetic variants is performed for several purposes: diagnosis of individuals with symptoms, determination of future disease risks in asymptomatic individuals, determination of genetic risks for progeny, guidance of medical treatment, research, and individual identification.
- Genetic testing for inherited genetic disease risks is an analysis of DNA, chromosomes, or gene products to provide specific information about variations in the number or form of genes or chromosomes in an individual or his or her progeny.
- Genetic information is information about specific variations in genes or chromosomes learned by genetic testing or by other means.
- DNA-based testing directly analyzes the DNA base sequence of a gene.
- Phenotypic testing identifies specific inherited gene variations indirectly, by detecting specific variations in the structure of a protein encoded by a gene or variations in a protein's enzyme activity.

- Karyotype analysis and fluorescent in situ hybridization analysis detect variation in form or number of chromosomes.
- New testing technologies that will promote genetic testing in health care include DNA chip technology and tandem mass spectrometry.

Assessing the Accuracy and Usefulness of Genetic Tests

- Analytical validity of a genetic laboratory test is a measure of how well the test detects what it is designed to detect. It encompasses analytical sensitivity (the probability that the test will detect a gene variant it is designed to detect when present in a sample) and analytical specificity (the probability that the test will be negative when a specific variant tested for is not present in a sample).
- Clinical validity measures the extent to which an analytically valid test result can diagnose a disease or predict future disease. For predictive genetic tests, it includes positive predictive value (the ability to predict that an individual will develop a disease) and negative predictive value (the ability to predict that an individual will not develop a disease).
- For DNA-based testing, clinical validity is limited by genetic heterogeneity and incomplete penetrance. Genetic heterogeneity means that different mutations in a specific gene, or mutations in different genes, are associated with the same disease. Incomplete penetrance means that within a population, not everyone who tests positive for a specific gene mutation will develop the associated disorder.
- Utility of a test is a measure of how useful test results are to the person tested. Clinical utility is a measure of how a test may guide clinical decisions. In some circumstances, predictive genetic testing may not provide medical preventive or treatment options but may help reduce anxiety and/or aid planning for the future.

Predictive Genetic Testing to Assess Reproductive Risks

- Reproductive genetic tests detect heritable genetic variations that are associated with disease. This type of testing includes carrier testing, prenatal testing of fetal cells, and pre-implantation testing of embryos formed by in vitro fertilization.
- Reproductive genetic tests generally are offered to individuals and couples who are at increased genetic risk for a specific disorder based on family history or membership in a racial or ethnic group that has identified genetic variants that increase risk for a specific disease.
- Carrier testing generally is performed to determine the risk of a healthy individual or couple of having a child with a recessive disorder. It may be performed before or after conception.
- Prenatal testing of fetal cells includes amniocentesis and chorionic villus sampling.
- Pre-implantation testing of embryos formed by in vitro fertilization is performed using single cells removed from individual embryos to detect specific gene mutations or chromosomal anomalies.

Predictive Genetic Testing to Assess Future Disease Risks in Healthy Adults

- Presymptomatic genetic testing is predictive testing of apparently healthy adults to determine whether they are at risk for a single-gene disorder. These disorders occur with virtually 100 percent incidence in persons who have inherited a specific gene mutation.
- Susceptibility (predispositional) testing is predictive genetic testing of apparently healthy adults to determine whether they are at increased risk, relative to the general population, for a specific future disease. A positive test result (finding a mutation) does not necessarily mean that a person will develop a future disease.
- For susceptibility testing, establishing a test's clinical predictive value may require years of research.
- Pharmacogenetic testing is genetic testing of individuals to guide their pharmaceutical or other medical treatment. Pharmacogenetic testing seeks to promote a favorable response and to prevent an adverse response to a drug or other treatment based on genetic predisposition.

Misunderstandings of and Misperceptions about Genetics

- Throughout human history, people have understood that physical and behavioral traits have a genetic component. Proponents of a centuries-long debate, referred to as the "nature-nurture" debate, have disagreed about the relative contribution of genetic and environmental factors to human behavioral and cognitive (intelligence) traits.
- Scientific evidence, including evidence from molecular genetics research, shows that genes may influence complex behavioral and cognitive traits and mental illness. Generally, however, behavioral and

cognitive traits and mental illnesses result from a complex and cumulative interplay of many genetic and environmental factors.

- Many commentators express concern that the general public and the popular press overemphasize the role of genetic inheritance for health as well as for the development of behavioral and cognitive characteristics, taking an overly deterministic view of genetics. These views may lead people to overestimate the meaning of genetic testing and to misconstrue genetic test results.
- Throughout the past century, some countries, including the United States, have promoted and/or endorsed eugenic policies that aim to promote the births of certain types of individuals and to discourage births of other types of individuals.
- In the first half of the twentieth century, eugenic attitudes contributed to the passage of federal legislation to limit immigration of people into the United States based on country of origin. Eugenic attitudes also were a cause of federal and state court decisions and state legislation that prevented or discouraged marriages of people from different racial groups and promoted involuntary sterilization of individuals who were deemed "unfit." Included among the "unfit" were the mentally ill, the "feebleminded," and habitual criminals.
- "Genetic exceptionalism" is the belief that medical genetics is sufficiently different from other areas of medicine to warrant special protections. Commentators disagree on whether genetic testing should be treated differently from other forms of medical testing.
- Genetic testing shares characteristics with other forms of medical testing. However, some forms of predictive genetic testing, notably DNA-based testing of inherited genetic variants, differ from other medical testing in important ways. For example, predictive DNA-based genetic testing has exceptionally long-range predictive powers; it can predict disease, or increased risk for disease, in the absence of clinical signs or symptoms; it reveals the sharing of genetic variants within families at precise and calculable rates; and, at least theoretically, it has the potential to generate a unique identifier profile for individuals.

Genetic Screening for Adult Health and Reproductive Risks

- Genetic screening differs from genetic testing in that it targets populations rather than at-risk individuals. Genetic screening generally is performed to detect future disease risks in individuals or their progeny for which established preventive interventions exist. Examples of genetic screening include newborn screening for phenylketonuria, carrier screening for sickle cell disease, and prenatal screening of fetal cells to detect chromosomal or other congenital abnormalities.
- Although predictive genetic screening to detect future disease risks in adults has not yet been offered, commentators predict that predictive genetic screening for hemochromatosis and other adult-onset diseases will be offered in the next decade.
- Some commentators express concern that if screening tests become routine practice, individuals may be pressured to undergo testing that they would not choose to undergo in a different context. Commentators also express concern about possible discrimination and/or stigmatization against individuals and groups who are the subjects of genetic screening because of their racial, ethnic, or geographic origin.
- Commentators maintain that a number of factors should be evaluated in determining whether a particular screening test should be implemented, including the purpose of the screening test, the test's analytical validity, clinical validity, and clinical utility, and the cost of the screening test.
- Multiplex genetic testing is genetic testing for two or more completely different conditions in a single testing session. Some commentators oppose multiplex genetic testing if it is performed only because it is technologically possible. Other commentators maintain that multiplex genetic testing is generally inappropriate unless the tests provide clear and useful options to the persons being tested. A key issue for both reproductive and late-onset multiplex testing is how to bundle tests together to allow for appropriate pretest education, counseling, and consent.

Conclusions and Recommendations of the Task Force

Purpose of Predictive Genetic Screening

- The purpose of predictive genetic screening should be to benefit the individual or couple tested. Screening tests offered to healthy individuals who do not perceive themselves or their offspring to be at increased risk for disease based on family and/or personal history should provide clear medical benefits or expanded reproductive options.

Predictive Value of Screening Tests

- Predictive genetic screening tests should have a sufficient level of confirmed predictive value in healthy

populations to justify their use for individuals who are not known to be at increased disease risk.

How to Offer Predictive Genetic Screening Tests

- Predictive genetic screening tests should be voluntary and should be offered only when accompanied by adequate education, counseling, informed consent, test follow-up, and efforts to ensure confidentiality.

Special Concerns about Offering Genetic Screening to Determine Risks for Late-Onset Disorders

- Genetic screening tests to determine future risk for late-onset disorders should have confirmed clinical utility, and screening should be offered on an age-appropriate basis to ensure maximum medical benefit and minimal risks.

Special Concerns about Offering Genetic Screening to Determine Reproductive Risks

- Genetic screening tests to predict reproductive risks should provide individuals and couples with useful options. Providers should make clear that despite the routine offering of tests, some individuals may wish to decline if they think that the test will not be useful to them. Providers should offer screening tests in a timely manner to maximize the reproductive options of tested individuals.

Federal and State Governments Should Not Require Genetic Screening by Law

- It is generally inappropriate for federal or state governments to mandate population genetic screening. New York State should repeal legislation that mandates sickle cell carrier screening for some couples seeking a marriage license.

Role of Study Panels and Professional Guidelines

- Study panels that include national experts, community representatives, and others, as well as professional medical societies such as the American College of Obstetricians and Gynecologists and the American College of Medical Genetics, should determine the appropriateness of offering specific genetic screening tests based on the test's validity and utility. For reproductive screening tests, for which follow-up options may include decisions about pregnancy termination, professional guidelines should consider the seriousness of the disorder tested for, its penetrance, its age of onset, and the variability of disease symptoms.

Genetic Screening of Minors

- Generally, minors should not be offered genetic screening tests to determine future health or reproductive risks, unless screening provides a clear and timely medical benefit and has minimal psychosocial risks.

Multiplex Genetic Testing Panels

- Genetic tests that provide information about future risks for unrelated disorders should be included in multiplex testing panels only when they meet all criteria for genetic screening tests. Tests should be grouped based on similar issues and implications to allow for adequate counseling and consent. For tests to determine risks for late-onset diseases, tests placed in multiplex panels should provide a demonstrated, significant medical benefit and should be offered on an age-appropriate basis. For reproductive carrier testing, tests placed on a multiplex panel should be for diseases of similar seriousness.

Newborn Screening

- Newborn screening is the most widely performed type of genetic testing in the United States today. Newborn screening programs exist in all fifty states, the District of Columbia, Puerto Rico, and the Virgin Islands. The goal of newborn screening is to detect infants affected by conditions for which prompt application of confirmed interventions can prevent or reduce disease, disability, and/or death.

- As a result of the Human Genome Project, the discovery of the genetic variations that underlie inherited disorders and the technology to detect them are expanding rapidly. These developments will present state screening programs with new testing methods and expanded lists of disorders for which testing is possible.

- Most states, including New York, have added tests to their newborn screening panels without formal criteria or processes to guide them. Many commentators recommend that newborn screening programs form advisory committees composed of medical and laboratory professionals and community participants to establish criteria for screening tests and to review screening test panels and program outcomes.

- Most states, including New York, mandate newborn screening and do not require parental consent. New York and other states exempt from newborn screening children whose parents have religious objections to it. Commentators disagree over whether parental consent to newborn screening should be required.

- Some benefits of newborn screening are reduced morbidity and mortality of children and cost savings to society through early prevention and treatment of childhood disease. Some of the risks of newborn screening include parental anxiety about false positive results; harm that can be caused to the parent-child relationship by parental misperceptions about the meaning of a child's carrier status; and the possibility that children will be subjected to needless, and potentially risky, medical interventions or monitoring.
- Most newborn screening programs, including New York's program, store residual newborn blood samples (bloodspots) and use them for research. Some commentators maintain that it is appropriate to use residual screening samples for research if the samples are anonymized. Others contend that ethical concerns about the use of residual newborn blood samples may be greater than for other tissue samples obtained in the clinical context because the collection of newborn screening samples is mandated by law. Commentators also have discussed the appropriate research uses of identified and coded newborn samples and whether parental consent for and / or notification about the research use of residual newborn screening samples should be required.

Conclusions and Recommendations of the Task Force

Basic Requirements for Newborn Screening Tests

- New York's Newborn Screening Program panel should be restricted to tests that detect congenital disorders characterized by serious and irreparable harm that can be avoided or minimized only by prompt application of confirmed medical interventions. The analytical and clinical validity of the screening tests also must be confirmed.

Statutory Authorization for New York's Newborn Screening Program

- New York Public Health Law § 2500-a should be amended to delete the names of individual disorders screened for by the Newborn Screening Program. The law should designate the Commissioner of Health to specify in regulations those congenital disorders for which screening should be performed.

Informing Parents about Newborn Screening

- The Commissioner of Health should promulgate regulations to require the Newborn Screening Program to provide educational materials about screening to prenatal care providers, as well as to hospitals and institutions of birth. Prenatal care providers should be required to provide and be available to discuss these materials during the course of prenatal visits. Program materials should be multilingual and at appropriate reading levels for a general audience. They should explain the purpose of screening and provide a description of the disorders screened for, their population incidence, and the follow-up process for infants with a positive screen test result.

Mandatory Newborn Screening

- New York's Newborn Screening Program should be mandatory for all infants born within the state, provided that several conditions are met: (1) all screening tests must meet the criteria described above in the recommendation concerning the basic requirements for newborn screening tests; (2) parents must be informed and receive educational materials about the program, its goals, and the screening process; and (3) the state must ensure that newborns identified as positive in screening tests are promptly diagnosed and that identified newborns and their families have access to follow-up medical care and counseling related to the disorder, regardless of their ability to pay. New York Public Health Law § 2500-a should be amended to remove the right of parents to assert religious objections to screening.

Follow-up Evaluation and Diagnosis of Screen-Positive Newborns

- The Newborn Screening Program should ensure that follow-up testing and diagnostic evaluation of newborns who test positive on a screening test is rapid and readily accessible, to maximize treatment benefits for affected newborns and to minimize potential anxiety associated with an initial false positive test result.

Follow-up Medical Care for Confirmed Positive Newborns

- New York State should ensure that newborns detected to have a congenital condition by newborn screening receive necessary long-term medical and preventive care, into and through adulthood, regardless of ability to pay. The Newborn Screening Program should facilitate efforts to ensure that affected newborns identified by the program obtain necessary and appropriate medical care. The program should assist treatment centers in locating and treating children who are lost to follow-up.

Establishment of a Newborn Screening Advisory Committee

- New York's public health regulations should establish a newborn screening advisory committee to act in an advisory capacity to the Commissioner of

Health and the Newborn Screening Program. The committee should include outside professional and community representatives and should be independent from the screening program. It should meet at least annually to consider new screening tests, solicit community input, and evaluate program infrastructure, policies, and outcomes.

Review and Implementation of Newborn Screening Tests

- A newborn screening advisory committee, and ad hoc specialty subcommittees established by it, should review all tests currently on or under review for New York's screening panel, as well as potentially valuable new tests, and make recommendations to the Commissioner. For tests for which a confirmed medical benefit has not been sufficiently demonstrated, tests should be viewed as human subject research and should require parental informed consent. These tests should be subject to review by an institutional review board to determine the information that should be provided as part of obtaining parental informed consent. All new screening tests should be subject to periodic follow-up evaluation to determine test accuracy and effectiveness of medical interventions.

Universal Performance of Newborn Screening

- Newborn screening tests should be performed for all newborns, rather than targeted to specific minority populations perceived to be at higher-than-average risk for a particular disorder.

Financing of the Newborn Screening Program

- A permanent, stable funding source is needed to enable the program to consider additional tests, implement new tests as needed, consider changes in testing technologies, improve processes and follow-up evaluation, and support the activities of the advisory committee.

Research Use of Anonymized Newborn Bloodspots

- The Newborn Screening Program, consistent with the recommendations in Chapter 7 concerning research use of samples obtained in the clinical context, should permit the use of anonymized samples for research. The program should inform parents that residual bloodspots may be anonymized and used for quality assurance activities or research. Parents should be informed of the potential research value of the samples and of the impossibility of linking research results to any individual newborn.

Research Use of Identified Newborn Bloodspots

- Research use of identified newborn bloodspots should be permitted in accord with recommendations in Chapter 7 concerning the research use of identified samples obtained in the clinical context. In addition, investigators who seek to use identified newborn blood samples for research should demonstrate why unidentified samples or alternate sample sources would not suffice. The use of identified samples should require recontact by the New York State Department of Health and informed consent of parents for each research use. The New York State Department of Health should not release samples that retain identifying data to researchers outside the department except for rare circumstances in which the research is directly relevant to the health of a specific newborn.

Research Use of Coded Newborn Bloodspots

- Research use of coded newborn bloodspots should be permitted in accord with recommendations in Chapter 7 concerning the research use of coded samples obtained in the clinical context. The use of coded samples should require recontact by the New York State Department of Health to obtain the consent of parents for the future research use of the samples.

Policies for Storage of Newborn Bloodspots

- The Newborn Screening Program should establish a formal policy for the storage of residual identified and anonymized bloodspots. The policy should specify potential uses for stored bloodspots and a maximum period of time for which samples may be maintained with personal identifiers.

Notification of Parents of Newborn Carrier Status

- When carrier status for a recessive genetic disease is determined as an incidental finding of a newborn screening test, New York's Newborn Screening Program should report that finding to the authorized physician. Ideally, parents of carrier newborns should be informed of that result and offered appropriate education, counseling, and testing by appropriately trained and credentialed professionals.

Informed Consent

- Informed consent to a medical procedure is an agreement to allow a medical procedure to go forward after having been advised of relevant facts necessary to make that agreement an intelligent one. Relevant facts include the patient's diagnosis, the

nature and purpose of the proposed procedure, and the risks and benefits of, and the alternatives to, the procedure.

- Obtaining a patient's informed consent to medical procedures is both a legal necessity and a basic requirement of medical ethics, and most commentators maintain that the requirement of informed consent applies to decisions about predictive genetic testing. Some of the issues that commentators recommend that health care providers should discuss with their patients as part of obtaining informed consent to predictive genetic testing include: (1) the purpose of the test; (2) a description of the testing process; (3) the accuracy of the genetic test and the meaning of its results; (4) the risks and benefits of, and alternatives to, genetic testing; and (5) confidentiality issues.
- It is unclear whether New York's general law on informed consent to medical procedures covers predictive genetic testing. However, in 1996 and 1997, New York enacted laws that require persons performing predictive genetic tests to obtain the individual's written informed consent prior to testing. The laws require the consent form to contain some, but not all, of the information commentators have recommended for informed consent to predictive genetic testing.
- Multiplex genetic testing is predictive genetic testing for more than one condition in a single testing session. Some commentators argue that health care providers should obtain full informed consent from patients for each test in a multiplex testing panel. Others contend that a patient's generic consent to all of the tests in the panel would be sufficient if the consent process highlights broad concepts and common-denominator issues for all of the tests.
- Commentators disagree about the proper method for obtaining informed consent to predictive genetic tests for gene variants that have been identified as having multiple, seemingly unrelated health effects (pleiotropic genetic tests). One contends that health care providers have an obligation to disclose to patients the risks associated with learning information about all of the conditions detected by the tests and must provide counseling and other support services as required by testing protocols for each individual condition. Another maintains that outside of the reproductive genetic testing context and situations where there are "special concerns" about the psychological state of a patient to be tested, health care providers need only inform their patients about the different clinical uses of the test and need not provide any special counseling or support services.
- Stored tissue samples, which today number at about 282 million in the United States, are used by medical researchers as their principal source of human biological materials. These tissues are most commonly collected during clinical medical procedures, and many of the patients from whom they are collected are not informed that their tissues will be stored and used for research.
- In some circumstances, federal regulations governing research involving human subjects require researchers to obtain a subject's informed consent before performing research on the subject's identified or coded tissue samples removed in the clinical context. These regulations do not require informed consent if the tissue samples have been anonymized. New York's statutes concerning research involving human subjects specifically exempt tissues removed in the clinical context from the statutes' coverage.
- Although most commentators agree that researchers should obtain a subject's informed consent before performing research on the subject's identified tissue sample, commentators disagree about whether, or what type of, consent is necessary before researchers may perform research on a subject's coded or anonymized tissue samples.

Conclusions and Recommendations of the Task Force

Necessity of Informed Consent for Predictive Genetic Testing in the Clinical Context

- Predictive genetic testing should not be performed without the informed consent of the subject of the test, except in the limited circumstances described below.

Power of the Commissioner of Health

- Those sections of New York's genetic testing statutes that list specific elements of informed consent should be replaced with an authorization for the Commissioner of Health to issue regulations on the process and content of informed consent to predictive genetic testing.

Content of Informed Consent to Predictive Genetic Testing in the Clinical Context

- Assuming that New York law is amended to authorize the Commissioner of Health to regulate informed consent to predictive genetic testing, the Commissioner should require the following information to be provided to the patient before obtaining the patient's consent (elements currently not required by New York law are italicized):

1. The purpose of the test
2. A general description of the testing process
3. A description of the diseases or conditions tested for, *including their ranges of severity*
4. *The risks and benefits of, and alternatives to, the predictive genetic test*
5. Confidentiality issues, *including confidentiality protections, the circumstances under which results of tests may be disclosed without the patient's consent*, and the names of persons and / or organizations to whom the patient has consented to disclose the results
6. *Protections against adverse uses of genetic information*
7. *The chances of false positive and false negative results*
8. The meaning of both positive *and negative* results
9. *The ability, or lack thereof, of the test to predict a disease's severity and age of onset*
10. *The possibility that no additional risk information will be obtained at the completion of the test*
11. *Available medical surveillance, treatment, and/or reproductive options following testing*
12. A statement that, prior to providing informed consent to genetic testing and after receiving the results, the individual may wish to obtain professional genetic counseling
13. *The risks of transmitting the relevant mutation to children and that the mutation may be present in other blood relatives*
14. A statement that no tests other than those authorized will be performed on the biological sample and that the sample will be destroyed at the end of the testing process, or not more than a specific period of time after the sample was taken, unless the subject consents to a longer period of storage
15. *That the test is voluntary*
16. *An offer to answer inquiries*
17. *The fees charged for the laboratory tests and pre- and post test counseling*

Sufficiency of Signed Informed Consent Form as Evidence of Informed Consent

- Assuming that New York law is amended to authorize the Commissioner of Health to regulate informed consent to predictive genetic testing, the Commissioner should require that health care providers disclose the information described above in a manner that will enable the patient to make a knowledgeable evaluation. A signed informed consent form is not necessarily sufficient evidence that this goal has been achieved.

Use of Decision Aids in the Informed Consent Process

- Health care providers are encouraged to use decision aids, such as written materials, videos, group discussions, and CD-ROMs, as part of the informed consent process to predictive genetic testing. However, health care providers should not use decision aids as a substitute for discussing predictive genetic testing issues with their patients.

Persons Required to Obtain Informed Consent

- Assuming that New York law is amended to authorize the Commissioner of Health to regulate informed consent to predictive genetic testing, the Commissioner should require that the person who orders a predictive genetic test has the obligation to ensure that the subject's informed consent is obtained.

Responsibility of Testing Laboratories

- The New York State Department of Health should permit clinical laboratories to perform predictive genetic tests on biological samples only if the laboratories receive assurances that the subjects provided informed consent for the tests.

Professional Guidelines on the Process and Content of Informed Consent for Predictive Genetic Tests

- Professional organizations should issue guidelines on the process and content of informed consent for specific predictive genetic tests and should create model consent forms that are consistent with existing law and contain the information necessary for patients to make informed decisions about undergoing predictive genetic testing.

Health Care Providers Qualified to Order Predictive Genetic Tests

- Health care providers should order predictive genetic tests only when (1) they know the circumstances under which it is appropriate to order them and the

meaning of their results, (2) they are capable of providing their patients with sufficient information to make informed decisions about undergoing the tests, and (3) they are able to provide their patients with comprehensive pre- and post test counseling or can refer their patients to professionals who are able to do so.

Informed Consent to Multiplex Genetic Testing

- Ideally, a patient's full informed consent should be obtained to each test on a multiplex panel prior to testing. However, assuming that New York law is amended to authorize the Commissioner of Health to regulate informed consent to predictive genetic testing, generic consent to multiplex testing should be permitted if (1) the number of tests on the panel is so high or the information about the tests is so complicated that attempting to obtain full informed consent from the patient to each test would be confusing or otherwise burdensome to the patient; (2) the tests on the panel meet all of the criteria described in Chapter 5 for inclusion in a multiplex panel; (3) the patients are informed, prior to testing, that more detailed information about each test is available; and (4) the patients are given an opportunity to obtain that information prior to testing either from the health care provider offering the multiplex panel or from another health care professional.

Special Issues Related to Pleiotropic Information

- Before offering a predictive genetic test to a patient, providers should give the patient all information necessary for the patient to provide informed consent to the intended use of the test, that is, information relevant to any condition about which the patient intends to receive test results. If the test also may reveal confirmed, clinically valid information about conditions for which the patient has not sought testing, the provider should inform the patient of this fact, specifying (1) the condition(s) about which the test may reveal information; (2) the consequences of having this additional information in his or her medical record; and (3) opportunities, including genetic counseling, for the patient to obtain further information about aspects of the test unrelated to its intended use. If the patient expresses an interest in learning how his or her test results relate to conditions for which testing was not originally sought, the provider should ensure that the patient provides informed consent to obtaining this additional information. Providers should respect patients' right not to learn pleiotropic information revealed by genetic tests.

Court Orders for Predictive Genetic Testing

- New York law should be amended to permit courts to order predictive genetic testing without the subject's consent only when (1) absent the testing, there would be a clear and imminent danger to the public health; (2) such testing is authorized by federal and/or New York State statutes or regulations; or (3) in a civil or criminal litigation, the subject affirmatively places his or her physical or mental condition at issue and the genetic testing directly relates to that physical or mental condition.

Remedies for the Performance of Genetic Testing without Informed Consent

- New York law should be amended to expressly authorize private lawsuits by subjects of unconsented-to predictive genetic tests against persons who order and/or perform the tests.
- New York law should be amended to authorize the Attorney General to bring lawsuits on behalf of individuals who have undergone predictive genetic testing without informed consent.
- Persons and organizations licensed by New York State should be subject to professional discipline and/or other sanctions, including fines and license suspension and revocation, for performing or ordering predictive genetic testing without informed consent.

Research on Tissue Samples Obtained in the Clinical Setting

- New York's law on the protection of human research subjects should be amended to cover research on tissue samples obtained in the clinical context. The amendment should apply only to tissue obtained after the amendment's effective date.
- Research on identified tissue samples obtained in the clinical context should be permitted only after the subjects have provided full informed consent to the research and an institutional review board has reviewed and approved the research protocol.
- Research on anonymized tissue samples obtained in the clinical context should be permitted only after an institutional review board has reviewed and approved the research protocol. The institutional review board review should ensure that the samples are or will be truly anonymized and should determine whether the research is of such a sensitive nature that it is inappropriate to use anonymized samples without having obtained the subjects' specific consent to the research.

- Research on coded tissue samples obtained in the clinical context should be permitted only if (1) the patients have agreed to the storage and research use of their coded samples; (2) the patients have been told about the operation, tissue release policies, and confidentiality protections of the tissue repository; and (3) an institutional review board has reviewed and approved the protocols for the research. The institutional review board review should ensure that the samples are or will be truly coded and should determine whether the research is of such a sensitive nature that it is inappropriate to use coded samples without having obtained the subjects' specific consent to the research. The coding of the samples should be performed by a person who is not connected to the research and who will not learn the individual results of the testing.
- Patients should be informed that their decision about whether to consent to the research use of their coded and/or identified tissue samples is wholly voluntary and that their decision will not affect their access to, or quality of, care.
- Institutions should encourage clinicians to ask patients to consider authorizing the use of their tissue for research purposes, and clinicians should do so when they deem it appropriate.

Predictive Genetic Testing of Children

- When susceptibility to a genetic disorder is discovered within a family, parents may seek predictive genetic testing of their children to obtain a medical benefit for the child, to reduce the child's future disease risk, and/or to make life planning decisions. Adolescents also may initiate requests for predictive genetic testing to determine future disease or reproductive risks.
- Parents generally have the legal authority to control their children's medical care, and children may generally not obtain medical care without their parents' consent.
- Benefits of testing children for late-onset disorders can include parental recognition of the need for clinical surveillance and/or preventive measures available for their asymptomatic children and enhanced parental ability to make life planning decisions for their children. Possible risks include the use of unconfirmed clinical interventions on the children that may be unnecessary and/or harmful, discrimination against the children, and psychological harms to the children and family.
- There are generally no benefits to genetic carrier testing of minors, except when adolescents are contemplating marriage or having children in the near future. Risks of such testing include stigmatization, discrimination, and parental misunderstanding of the meaning of the test results.
- Most commentators contend that the primary determinant of whether a child should undergo genetic testing is the best interests of the child. In the absence of a clear medical benefit to the child, these commentators opine that avoidance of potential testing-associated harms and the preservation of the minor's future autonomy should be the overriding considerations. Accordingly, these commentators maintain that children generally should not undergo genetic testing for late-onset disorders in the absence of a medical benefit and should not undergo genetic carrier testing for recessive disorders.
- Most commentators agree that health care providers play an important role in assessing the benefits and risks of testing a child to the child and family.

Adoption

- New York mandates that adoption agencies disclose to prospective adoptive parents the "available" medical histories of the prospective adoptee and the child's biological parents. These histories must include all available information about diseases or conditions believed to be hereditary. New York law does not require parties to an adoption to exercise reasonable efforts to collect this information if it is not already available.
- Commentators stress that the best interests of the prospective adoptees should be the guiding principle in determining whether they should undergo genetic testing. Some commentators contend that prospective adoptees should undergo genetic testing only in situations where it would be appropriate to test other children.

Conclusions and Recommendations of the Task Force

Predictive Genetic Testing to Determine Adult-Onset Disease and Reproductive Risks

- The best interests of the child, including respect for the child's future autonomy, should be the primary consideration in decisions about predictive genetic testing of children. Predictive genetic testing of children is clearly appropriate when test results will provide information relevant to current decisions about the child's care, such as decisions to institute prophylactic treatment. Where the benefits to the child are less clear, however, predictive genetic test-

ing should be approached with caution, given that testing can also lead to significant harms.

Predictive Genetic Testing to Determine Risks for Pediatric-Onset Disease

- When a healthy child is at risk for a pediatric-onset disorder, predictive genetic testing to confirm or allay disease risks may be in the best interests of the child, even if preventive or therapeutic interventions are not available.

The Role of Health Care Providers in Guiding Predictive Genetic Testing Decisions

- Health care providers play a critical role in guiding decisions about predictive genetic testing of children. When faced with a parent's request for predictive genetic testing of a healthy child or with a request initiated by a healthy adolescent, providers should counsel the parents and the child, commensurate with the child's maturity, and help families balance potential benefits and risks of testing. When the balance of potential risks and benefits is uncertain, providers should generally respect the decisions of parents.

Conflicts between Parents and Adolescents

- Ideally, predictive genetic testing of children will be performed with both the consent of the parents and either the assent or consent of the child, depending on the child's maturity. The Task Force members hold differing views about cases where parents and adolescents disagree about genetic testing decisions. Where the balance of benefits and risks is uncertain, some members believe that providers should generally defer to the wishes of the parent, even over the objection of a mature adolescent. Others would defer to the adolescent's decision in at least some cases, particularly when an adolescent opposes testing.

Disclosure of Test Results to Minors

- If a child or adolescent has provided assent or consent for predictive genetic testing, he or she also should be informed of test results and their meaning, commensurate with his or her maturity and with his or her desire to have this information.

Genetic Testing of Prospective Adoptees by Their Current Caregivers

- Caregivers of prospective adoptive children should ensure that the children undergo genetic testing when such testing is necessary for the children's current health care.

Genetic Testing of Prospective Adoptees at the Request of Prospective Adoptive Parents

- Genetic testing should be performed on a prospective adoptee at the request of prospective adoptive parents only when (1) the testing is medically indicated and can reveal that a child is highly likely to develop extraordinary health care needs during childhood, (2) the testing will help ensure that the child is placed with a family who is capable of dealing with those needs, and (3) the prospective parents are otherwise committed to adopting the child.

Collection and Disclosure of Prospective Adoptees' Medical Histories

- New York law should be amended to require that parties placing a child for adoption make reasonable efforts to collect a complete medical and genetic history of the child and provide it to the prospective adoptive parents. New York law also should be amended to require the parties to make reasonable efforts to collect the medical and genetic histories of the birth parents and close blood relatives of the prospective adoptee and disclose them to the prospective adoptive parents. The parties should collect and disclose this information in a manner that respects the privacy of the persons from whom it is obtained and the subjects of the information. For example, the medical and genetic histories of the prospective adoptees' relatives should be disclosed to prospective adoptive parents with all identifying information removed.

Confidentiality

- Numerous persons and organizations, including insurance companies and the government, have access to individuals' health and genetic information.
- Although legal protections for health and genetic information confidentiality exist on both the federal and state levels, they are often limited in scope and do not provide adequate safeguards.
- Some commentators maintain that genetic information is more sensitive than other health information and should receive special confidentiality protections because it has been used in the past to discriminate and perpetrate terrible horrors against those deemed to be genetically unfit and because it reveals not only personal health information but also information that has implications for one's family. Other commentators contend that genetic information and nongenetic health information should receive the same levels of confidentiality protections because

nongenetic health information can be just as sensitive as genetic information and it is impractical to provide varying levels of protection to different categories of health information.

- New York passed laws in 1996 and 1997 that provide greater confidentiality protections for predictive genetic information than for other health information. However, the laws do not protect the confidentiality of all genetic information, and they do not protect as confidential the fact that an individual has used or inquired about genetic services. The laws also do not provide individuals with legal remedies against those who violate the laws' provisions, do not appear to prohibit waiver of its confidentiality protections, and do not make clear whether anonymous genetic testing is permissible.
- Commentators disagree about whether health care providers ever have the obligation to disclose to a patient's relatives, over the patient's objection, the medical ramifications to the relatives of the patient's genetic information. Some commentators maintain that health care providers should not make such disclosures over the patient's objection and that health care providers should fulfill any obligations they might have vis-à-vis the patient's family by informing the patient of these ramifications and, when appropriate, advising the patient to disclose the information to the patient's family. Other commentators contend that health care providers should disclose the information directly to the patient's family, over the patient's objection, if the patient refuses to do so and if doing so would avert serious harm that is highly likely to occur absent such a disclosure.
- Some commentators have recommended that, to encourage individuals to take genetic tests and to prevent unconsented-to acquisition of genetic information by insurers, employers, and others, patients should be permitted to take certain types of genetic tests anonymously. Others believe that anonymous genetic testing is generally inappropriate because it interferes with proper pre- and post test genetic counseling.

Conclusions and Recommendations of the Task Force

Confidentiality Protections for Genetic Information and Other Medical Information

- All personal medical information, including genetic information, should receive a uniform, high level of confidentiality protection. Absent new, comprehensive federal legislation or regulation that provides such protection, New York should enact comprehensive medical confidentiality legislation that does so.
- Assuming that comprehensive medical confidentiality protections are not adopted, New York's genetic confidentiality statutes should be amended to protect the confidentiality of all genetic information.

Confidentiality Protections for the Use of Genetic Services

- Assuming that comprehensive medical confidentiality protections are not adopted, New York's genetic confidentiality statutes should be amended to protect the confidentiality of the fact that an individual has obtained and / or inquired about genetic testing and / or counseling. The statutes also should be amended to protect the confidentiality of the content of the inquiries and / or counseling.

Scope of Consented-to Disclosure of Genetic by Persons Other Than the Subject of the Information

- Assuming that comprehensive medical confidentiality protections are not adopted, New York's genetic confidentiality statutes should be amended to limit the disclosure of genetic information by persons other than the subject of the information to the amount necessary in light of the reason for the disclosure. The statutes also should be amended to limit such disclosures to those persons who have a need for the information in light of the reason for the disclosures.

Permissible Third-Party Disclosures of Genetic Information without the Subject's Consent

- Assuming that comprehensive medical confidentiality protections are not adopted, the legislature should review and, if appropriate, amend the genetic confidentiality statutes in light of the recommendations of the Special Committee on Medical Information Confidentiality of the New York State Public Health Council about legitimate disclosures of medical information without patient consent.

Waivers of Genetic Confidentiality Protections

- Assuming that comprehensive medical confidentiality protections are not adopted, New York's genetic confidentiality statutes should be amended to render nonwaivable all of the confidentiality rights they provide.

Disclosure of Genetic Information to Relatives

- Health care providers should discuss with their patients the medical ramifications of the patient's genetic information for the patient's relatives. Health care providers should encourage their patients to disclose genetic information to relatives when the

disclosure is likely to help the relatives avert or treat disease or to make reproductive decisions. Health care providers should not disclose their patient's genetic information to the patient's relatives without the patient's consent or a court order. Courts should be authorized to permit health care providers to make such disclosures only when (1) the patient refuses to disclose the information to an identified relative despite attempts by the health care provider to convince him or her to do so; (2) without disclosure, serious harm to the relative is highly likely to occur; (3) with disclosure, the harm can be averted or its chances of occurring significantly minimized; and (4) the harm that may result from failure to disclose outweighs the harm that may result from the disclosure.

Court Orders for Disclosure of Genetic Information

- Other than court orders for the disclosure of genetic information to a patient's relatives, New York law should be amended to permit court orders for the disclosure of genetic information to third parties without the subject's consent only when (1) absent the disclosure, there is or would be a clear and imminent danger to the public health; (2) the third party is entitled to the disclosure under federal and/or New York statutes or regulations; or (3) in a civil or criminal litigation, the subject of the information affirmatively places his or her physical or mental condition at issue and the genetic information to be disclosed directly relates to that physical or mental condition.

Remedies for Unlawful Disclosure or Solicitation of Genetic Information

- Assuming that comprehensive medical confidentiality protections are not adopted, New York law should be amended to (1) expressly authorize private lawsuits by victims of unlawful disclosures or solicitations of genetic information against persons who make such disclosures or solicitations and (2) authorize the Attorney General to bring lawsuits on behalf of individuals whose genetic information has been or will be unlawfully disclosed or solicited. In addition, persons and organizations licensed by New York State should be subject to professional discipline for unlawfully disclosing or soliciting genetic information.
- Private and public institutions that deal with genetic information should create their own internal sanctions against persons who unlawfully disclose or solicit genetic information.

Anonymous Genetic Testing

- Although anonymous genetic testing has significant drawbacks, it should be an option available to those who desire it. New York law should be amended to eliminate potential barriers to anonymous genetic testing.

Insurance and Employment

Insurance

- Currently, insurers do not require applicants to take predictive genetic tests because the tests are very expensive and reveal only a limited number of serious genetic abnormalities. Commentators disagree about whether insurers use genetic information to make adverse insurance decisions. Insurers maintain that they may wish to use genetic information for insurance underwriting in the future.
- Some commentators argue that insurers should be prohibited from using genetic information for insurance underwriting because otherwise individuals, who could potentially benefit from genetic testing, may refrain from undergoing it and thereby endanger their health. Insurers argue that prohibiting the use of genetic information in underwriting could lead to adverse selection and would unfairly favor people who have genetic conditions or identifiable predispositions.
- Some commentators contend that although most Americans appear to consider access to health care a basic right, public attitudes concerning access to life, disability, and long-term care insurance are less clear. These forms of insurance can be seen as means to protect assets rather than as providing access to an important social good, such as medical care. Therefore, according to these commentators, the justifications for prohibiting insurance companies from underwriting using genetic information for these forms of insurance may be less compelling.
- Federal law and the New York Insurance Law prohibit group health insurance plans from making adverse insurance decisions against individuals based on their health status, medical history, and genetic information or from treating genetic information as a pre-existing condition. New York's community rating, open enrollment, and other insurance laws prohibit individual and small group health insurers from making adverse insurance decisions based on genetic information or from treating genetic information as a pre-existing condition.

- Federal law and the New York Insurance Law do not prohibit life, disability, and long-term care insurers from making adverse insurance decisions based on genetic information. However, New York law requires the insurers' decision to be actuarially justified and requires insurers to notify individuals in writing if it charges a higher-than-standard premium or denies an individual insurance based on genetic test results. New York law also prohibits insurers from placing an individual's genetic test results into a nonconsenting relative's records and from drawing, using, or communicating an adverse inference about the relative's genetic status based on these results.

Employment

- Commentators disagree over whether employers make adverse employment decisions based on genetic predispositions to disease. Most commentators agree, however, that it is generally inappropriate for employers to fire, refuse to hire, or otherwise discriminate against qualified individuals in the terms and conditions of employment because they have a genetic predisposition to disease.
- Although federal protections against adverse employment decisions based on genetic predispositions to disease are limited, New York law generally prohibits such decisions.

The Impact of the Americans with Disabilities Act

- Because it is unlikely that genetic predispositions to disease are "disabilities" within the meaning of the Americans with Disabilities Act, the Act's protections against adverse employment and insurance decisions based on such predispositions are limited.

Conclusions and Recommendations of the Task Force

Health Insurance and Individual Medical Underwriting

- Access to health care is a necessity for all Americans, and for most Americans, health insurance provides such access. By limiting individual medical underwriting in health insurance, New York's community rating and open enrollment laws appropriately seek to make access to medical care more equitable.

Current Protections against Adverse Insurance Decisions by Health Insurers Based on Genetic Information

- The combination of New York and federal laws currently protects New Yorkers from adverse insurance decisions by health insurers based on genetic information.

Use of Genetic Test Results by Life, Disability, and Long-Term Care Insurers

- New York Insurance Law should be amended to require a moratorium on requests for genetic test results and the use of genetic test results in underwriting, by life, disability, and long-term care insurers. Insurers should be permitted to use these results for underwriting only when (1) the subjects of the tests voluntarily provide the results to the insurer and (2) the insurers will use the results for the subjects' benefit.

Use of Genetic Information by Employers

- New York law provides significant protections against adverse use of genetic information by employers. As a result of these protections, it is not necessary to consider further legislation in New York prohibiting the use of genetic information by employers.

Public Health Role in Genetic Services

- As opposed to clinical medical practice, which focuses on the health of individual patients, public health focuses on disease prevention for whole populations. Public health's core functions include assessment (the systematic collection, assembly, analysis, and dissemination of information about the health of a community), policy development, and assurance of the safety and reliability of, and access to, health services.
- Public health assessment activities in the genetic context include population surveillance and molecular genetic epidemiology research. Policy development activities include the translation of scientific and medical discoveries about genetics into guidelines, regulations, and legislation to promote the public's health. Assurance activities include oversight by the federal government and New York State of genetic testing laboratories.
- New York State has the most far-reaching requirements for genetic test approval and laboratory oversight in the United States. New York State mandates genetic testing laboratories to engage in quality assurance and to employ personnel that meet certain standards. New York also reviews clinical genetic tests for their analytical and clinical validity and requires all laboratories that are located in New York State or test specimens from New York State to obtain a permit for the testing from the New York State Department of Health.

- Commentators have expressed concern about the oversight of predictive genetic testing. They note the current limited degree of federal oversight, the rapid expansion of genetic technologies and clinical genetic tests, and the complexity of genetic test performance and interpretation. Concerns about New York's program of oversight of genetic testing laboratories include disincentives to out-of-state laboratories to participate, timeliness of the program's responses to genetic test approval requests, difficulty locating information about laboratories with New York State permits, and the program's lack of clear criteria for assessing a predictive test's clinical validity.
- The federal and New York State governments, as well as some other states and nongovernmental organizations, promote genetics education for the public and have established and are continuing to establish genetics education programs. The federal and New York State governments also have developed programs to help ensure access to genetic services.

Conclusions and Recommendations of the Task Force

Oversight of Genetic Testing by Federal and State Government Agencies

- Federal government agencies should strengthen their oversight of clinical laboratory genetic tests, including tests provided as services, to ensure that tests have adequate analytical and clinical validity. New York State should continue its oversight of clinical genetic testing laboratories and should re-examine its criteria and processes for test approval and laboratory oversight.

Approval Process for Genetic Tests

- The New York State Department of Health's Laboratory Reference System, and its Clinical Testing Review Panel, should review proposed genetic tests expeditiously, within a specified time period. Approval decisions for individual genetic tests should be made on a case-by-case basis, based on analytical validity and clinical validity data for the test's intended use. The program also should require testing laboratories to provide educational materials to providers ordering the test.

Establishment of Criteria for Genetic Test Approval

- The New York State Department of Health should develop clear guidelines to delineate the assessment criteria the Laboratory Reference System will use for approval of genetic tests. The guidelines document should be open for public comment by interested parties, including genetic testing laboratories and clinical geneticists practicing in New York State, prior to adoption by the department.

State Oversight of Laboratory Quality Assurance

- The New York Laboratory Reference System should continue to require that permitted genetic testing laboratories meet specified certification, performance, and personnel standards and participate in quality assurance programs.

Establishment of a Genetic Testing Advisory Committee

- The New York State Department of Health should create a genetic testing advisory committee, composed of departmental members and representatives of New York's clinical and diagnostic laboratory genetics community, to meet at least annually to review New York's Laboratory Reference System's genetic test approvals, the approval process, and outcomes. The committee also should serve as a sounding board for the clinical genetics and genetic laboratory communities and aid the department in its efforts to disseminate genetic testing information among health care providers.

Categorization of Approved Genetic Tests

- For genetic test approval, the New York Laboratory Reference System should move from its current categories of test approval, "generally accepted" and "investigational," to a single category of approved tests in which test-specific limitations or restrictions that are important to patients, providers, and/or payers are noted. For example, approval should specify, when relevant, the need for ongoing data collection to establish a test's clinical validity for its intended application.

Provider Access to State Oversight Information

- The New York State Department of Health should ensure that an up-to-date database listing of New York State-approved genetic tests and the laboratories authorized to perform them is readily accessible to health care providers in New York State.

Exemption from State Regulations for Laboratory Licensure

- New York's Public Health Law, which requires state licensure for all laboratories performing tests on specimens obtained in New York, should be amended to permit the New York State Department of Health to grant exemptions on a case-by-case basis.

Ongoing Collection, Evaluation, and Dissemination of Clinical Data

- Federal and state health agencies should work with laboratories, providers, and other partners to promote the ongoing collection, evaluation, and dissemination of clinical validity and utility data for predictive genetic tests.

Role of Institutional Review Boards

- Organizations seeking New York State approval for genetic tests that require ongoing collection of clinical data should be required to submit evidence that they have obtained approval of an institutional review board.

Assessment of Population Needs

- Federal and state health agencies play an important role in assessing the population's genetic and environmental risk factors. The New York State Department of Health should continue its activities in statewide assessment of the population's genetic health and genetic epidemiology research.

Public and Provider Education

- Federal and state health agencies play an important role in educating the public about genetics generally and about particular genetics services that are available to the public. They also should support production and dissemination of genetics educational materials to health care providers.

Coordination of State Agency Genetics Activities

- The New York State Department of Health should assure coordination of activities of departmental personnel and programs that promote genetics health and research activities throughout the department. The department also should promote coordination of its efforts with those of other partners outside the department.

Integrating Genetics Services into Clinical Care

- Clinical genetics services encompass the application of genetics technology in a wide array of clinical contexts, including treatment and management of genetic disorders and genetic testing for diagnostic and predictive purposes. Genetics services providers include physicians and nurses with special training in genetics, genetic counselors, and others.
- Studies indicate that primary care physicians, who will be utilized for genetic services more frequently as the demands for such services grow, have limited training in genetics and often do not have the knowledge to integrate genetics into primary care services. Commentators have recommended a number of ways to increase genetics knowledge among physicians, including a greater emphasis on genetics in medical and postgraduate medical training programs, continuing medical education in genetics, and the creation of clinical guidelines for genetic medicine.
- Genetic counselors provide patients with counseling services regarding the occurrence or risk of occurrence of genetic conditions or birth defects. Although no state currently requires genetic counselors to be licensed or certified in order to practice or use the title genetic counselor, genetic counselors can receive board certification from the American Board of Genetic Counseling. In the mid-1990s, about 66 to 75 percent of New York's approximately 150 genetics counselors were board certified.
- Most genetic counselors work in institutional settings as part of a genetics services delivery team and under the supervision of a physician. Under New York law, genetic counselors may not independently order genetic tests for patients. Because there are no specific medical billing codes (CPT codes) for genetic counseling, genetic counselors cannot directly bill third-party payers for the counseling services they provide. Third-party payers do not consider genetic counselors as reimbursable providers in part because the states do not license or certify genetic counselors.
- Increasingly, insurers are covering the costs of predictive genetic testing and counseling for individuals who are at risk for adult-onset disorders or disorders in future offspring. In general, insurers will cover counseling by medical geneticists with M.D. or D.O. degrees, although some insurers will cover counseling by Ph.D. geneticists or nongeneticist physicians.

Conclusions and Recommendations of the Task Force

State Licensure or Certification of Genetic Counselors

- To ensure an adequate level of competency of genetic counselors and to support the viability of the profession of genetic counseling, New York State should create a process for state certification of genetic counselors who are certified by the American Board of Genetic Counseling or American Board of Medical Genetics.

Scope of Genetic Counseling Practice

- Ideally, all genetic counselors should work within a team of health care providers, which may include medical geneticists, Ph.D. geneticists, primary care physicians, and physician specialists, such as oncologists, obstetrician-gynecologists, and neonatologists, to provide genetic counseling as an integrated component of the patient's health care. If genetic counselors practice independently, they should maintain the same level of professional standards as genetic counselors who work within institutional settings and should strive to achieve the benefits of working in an integrated health care team by consulting with other genetics and nongenetics professionals.

Authorization to Order Genetic Tests

- Under New York law, genetic counselors can order genetic testing for their patients only through licensed physicians or other persons who are authorized by law to do so, such as dentists, podiatrists, and nurse practitioners. The Task Force does not recommend any changes to the current law.

Direct Billing by Genetic Counselors

- The Task Force encourages the American Medical Association to adopt changes to the CPT codes that would allow nonphysician genetic counselors to bill directly for genetic counseling services.

Training Genetic Counselors about Legal and Ethical Issues

- All genetic counselors should receive training in and be knowledgeable about legal and ethical issues relevant to genetic counseling, such as confidentiality and medical privacy. Professional societies of genetic counselors should develop standards and guidelines for educating and training genetic counselors about legal and ethical issues.

Genetics Training in Medical School and Postgraduate Education

- Medical schools should incorporate genetics education into their core curriculum. Medical schools and postgraduate training programs should integrate genetics into clinical practice training to teach the necessary skills and attitudes for recognition and assessment of the genetic component of disease.

Physician Licensure Examinations with Genetics Requirements

- Physician licensing examinations should assess knowledge of basic genetics issues.

Genetics Education through Clinical Guidelines

- Professional medical associations should promote development of comprehensive and up-to-date clinical guidelines to help physicians recognize appropriate genetic testing opportunities, provide a source of continuing genetics education, and ensure that patients receive adequate counseling and appropriate specialty referrals. National and state health agencies and private partners should support the development, updating, and dissemination of professional guidelines.

Specialty Board Certifications with Genetics Requirements

- The American Board of Medical Specialties and the individual specialty boards should ensure that specialty board certification and recertification examinations adequately assess genetics competencies.

Medical Organization-Based Requirements for Genetics Education

- Managed care and other medical practice organizations should promote genetics education of their member practitioners for the appropriate integration of genetic testing and counseling services and for specialty referrals.

Genetics Education and Training for Nursing and Allied Health Professionals

- Nursing and allied health professionals, working with the genetics community, should continue their efforts to incorporate genetics into all levels of nursing practice and allied health services and to promote research to assess and monitor the integration of genetics into all nursing and allied health practices.

Revised Health Care Proxy Form

New York State Department of Health

***Editor's Note**: In February 2002, the New York State Department of Health (DOH) released a revised Health Care Proxy Form, which individuals may use to appoint a health care agent. The form was revised primarily to include space for individuals to note instructions about organ donation, as authorized by Chapter 540 of the Laws of 2001. But DOH also used the occasion to update and revise the Instructions and Frequently Asked Questions that have long accompanied the form. For example, paragraph (4) of the form now expressly notes that an agent can make decisions about artificial nutrition and hydration if the principal's wishes about such treatments are "reasonably known" to the agent, whether or not those wishes are written on the form. This DOH-approved form, which is available on the DOH Web site <http://www.health.state.ny.us/nysdoh/hospital/healthcareproxy/intro.htm> is optional. Other versions of proxy forms that include the statutorily required elements, and existing signed health care proxies, remain valid. See generally NYS Public Health Law Article 29-C.*

Health Care Proxy

(1) **I,** _____
hereby appoint

_____

(name, home address and telephone number)

_____

_____

(2) as my health care agent to make any and all health care decisions for me, except to the extent that I state otherwise. This proxy shall take effect only when and if I become unable to make my own health care decisions.

Optional: Alternate Agent If the person I appoint is unable, unwilling or unavailable to act as my health care agent, I hereby appoint

_____

(name, home address and telephone number)

_____

_____

(3) as my health care agent to make any and all health care decisions for me, except to the extent that I state otherwise.

Unless I revoke it or state an expiration date or circumstances under which it will expire, this proxy shall remain in effect indefinitely. (*Optional: If you want this proxy to expire, state the date or conditions here.*) This proxy shall expire (*specify date or conditions*):

_____

(4) _____

Optional: I direct my health care agent to make health care decisions according to my wishes and limitations, as he or she knows or as stated below. (*If you want to limit your agent's authority to make health care decisions for you or to give specific instructions, you may state your wishes or limitations here.*) I direct my health care agent to make health care decisions in accordance with the following limitations and / or instructions (*attach additional pages as necessary*):

_____

_____

In order for your agent to make health care decisions for you about artificial nutrition and hydration (*nourishment and water provided by feeding tube and intravenous line*), your agent must reasonably know your wishes. You can either tell your agent what your wishes are or include them in this section. See instructions for sample language that you could use if you choose to include your wishes on this form, including your wishes about artificial nutrition and hydration.

(5) Your Identification (*please print*)

Your Name _____

Your Signature _____ Date _____

Your Address _____

(6) Optional: Organ and/or Tissue Donation

I hereby make an anatomical gift, to be effective upon my death, of: (check any that apply)

___ Any needed organs and / or tissues

___ The following organs and / or tissues _____

_____

___ Limitations _____

If you do not state your wishes or instructions about organ and / or tissue donation on this form, it will not be taken to mean that you do not wish to make a donation or prevent a person, who is otherwise authorized by law, to consent to a donation on your behalf.

Your Signature _____ Date _____

(7) Statement by Witnesses (*Witnesses must be 18 years of age or older and cannot be the health care agent or alternate.*)

I declare that the person who signed this document is personally known to me and appears to be of sound mind and acting of his or her own free will. He or she signed (or asked another to sign for him or her) this document in my presence.

Date _____	Date _____
Name of Witness 1	Name of Witness 2
(print) _____	*(print)* _____
Signature _____	Signature _____
Address _____	Address _____
_____	_____

Health Care Proxy Form Instructions

Item (1)

Write the name, home address and telephone number of the person you are selecting as your agent.

Item (2)

If you want to appoint an alternate agent, write the name, home address and telephone number of the person you are selecting as your alternate agent.

Item (3)

Your Health Care Proxy will remain valid indefinitely unless you set an expiration date or condition for its expiration. This section is optional and should be filled in only if you want your Health Care Proxy to expire.

Item (4)

If you have special instructions for your agent, write them here. Also, if you wish to limit your agent's authority in any way, you may say so here or discuss them with your health care agent. If you do not state any limitations, your agent will be allowed to make all health care decisions that you could have made, including the decision to consent to or refuse life-sustaining treatment.

If you want to give your agent broad authority, you may do so right on the form. Simply write: *I have discussed my wishes with my health care agent and alternate and they know my wishes including those about artificial nutrition and hydration.*

If you wish to make more specific instructions, you could say:

If I become terminally ill, I do/don't want to receive the following types of treatments:. . . .

If I am in a coma or have little conscious understanding, with no hope of recovery, then I do/don't want the following types of treatments:. . . .

If I have brain damage or a brain disease that makes me unable to recognize people or speak and there is no hope that my condition will improve, I do/don't want the following types of treatments:. . . .

I have discussed with my agent my wishes about_____ and I want my agent to make all decisions about these measures.

Examples of medical treatments about which you may wish to give your agent special instructions are listed below. This is not a complete list:

- artificial respiration
- artificial nutrition and hydration (nourishment and water provided by feeding tube)
- cardiopulmonary resuscitation (CPR)
- antipsychotic medication
- electric shock therapy
- antibiotics
- surgical procedures
- dialysis
- transplantation
- blood transfusions
- sterilization

Item (5)

You must date and sign this Health Care Proxy form. If you are unable to sign yourself, you may direct someone else to sign in your presence. Be sure to include your address.

Item (6)

You may state wishes or instructions about organ and/or tissue donation on this form. A health care agent cannot make a decision about organ and/or tissue donation because the agent's authority ends upon your death. The law does provide for certain individuals in order of priority to consent to an organ and/or tissue donation on your behalf: your spouse, a son or daughter 18 years of age or older, either of your parents, a brother or sister 18 years of age or older, a guardian appointed by a court prior to the donor's death, or any other legally authorized person.

Item (7)

Two witnesses 18 years of age or older must sign this Health Care Proxy form. The person who is appointed your agent or alternate agent cannot sign as a witness.

About the Health Care Proxy Form

This is an important legal document. Before signing, you should understand the following facts:

1. This form gives the person you choose as your agent the authority to make all health care decisions for you, including the decision to remove or provide life-sustaining treatment, unless you say otherwise in this form. "Health care" means any treatment, service or procedure to diagnose or treat your physical or mental condition.
2. Unless your agent reasonably knows your wishes about artificial nutrition and hydration (nourishment and water provided by a feeding tube or intravenous line), he or she will not be allowed to refuse or consent to those measures for you.
3. Your agent will start making decisions for you when your doctor determines that you are not able to make health care decisions for yourself.
4. You may write on this form examples of the types of treatments that you would not desire and/or those treatments that you want to make sure you receive. The instructions may be used to limit the decision-making power of the agent. Your agent must follow your instructions when making decisions for you.
5. You do not need a lawyer to fill out this form.
6. You may choose any adult (18 years of age or older), including a family member or close friend, to be your agent. If you select a doctor as your agent, he or she will have to choose between acting as your agent or as your attending doctor because a doctor cannot do both at the same time. Also, if you are a patient or resident of a hospital, nursing home or mental hygiene facility, there are special restrictions about naming someone who works for that facility as your agent. Ask staff at the facility to explain those restrictions.
7. Before appointing someone as your health care agent, discuss it with him or her to make sure that he or she is willing to act as your agent. Tell the person you choose that he or she will be your health care agent. Discuss your health care wishes and this form with your agent. Be sure to give him or her a signed copy. Your agent cannot be sued for health care decisions made in good faith.
8. If you have named your spouse as your health care agent and you later become divorced or legally separated, your former spouse can no longer be your agent by law, unless you state otherwise. If you would like your former spouse to remain your agent, you may note this on your current form and date it or complete a new form naming your former spouse.
9. Even though you have signed this form, you have the right to make health care decisions for yourself as long as you are able to do so, and treatment cannot be given to you or stopped if you object, nor will your agent have any power to object.
10. You may cancel the authority given to your agent by telling him or her or your health care provider orally or in writing.
11. Appointing a health care agent is voluntary. No one can require you to appoint one.
12. You may express your wishes or instructions regarding organ and/or tissue donation on this form.

Frequently Asked Questions

Why should I choose a health care agent?

If you become unable, even temporarily, to make health care decisions, someone else must decide for you. Health care providers often look to family members for guidance. Family members may express what they think your wishes are related to a particular treatment. However, in New York State, only a health care agent you appoint has the legal authority to make treatment decisions if you are unable to decide for yourself. Appointing an agent lets you control your medical treatment by:

- allowing your agent to make health care decisions on your behalf as you would want them decided;
- choosing one person to make health care decisions because you think that person would make the best decisions;
- choosing one person to avoid conflict or confusion among family members and/or significant others. You may also appoint an alternate agent to take over if your first choice cannot make decisions for you.

Who can be a health care agent?

Anyone 18 years of age or older can be a health care agent. The person you are appointing as your agent or your alternate agent cannot sign as a witness on your Health Care Proxy form.

How do I appoint a health care agent?

All competent adults, 18 years of age or older, can appoint a health care agent by signing a form called a Health Care Proxy. You don't need a lawyer or a notary, just two adult witnesses. Your agent cannot sign as a witness. You can use the form printed here, but you don't have to use this form.

When would my health care agent begin to make health care decisions for me?

Your health care agent would begin to make health care decisions after your doctor decides that you are not able to make your own health care decisions. As long as you are able to make health care decisions for yourself, you will have the right to do so.

What decisions can my health care agent make?

Unless you limit your health care agent's authority, your agent will be able to make any health care decision that you could have made if you were able to decide for yourself. Your agent can agree that you should receive treatment, choose among different treatments and decide that treatments should not be provided, in accordance with your wishes and interests. However, your agent can only make decisions about artificial nutrition and hydration (nourishment and water provided by feeding tube or intravenous line) if he or she knows your wishes from what you have said or what you have written. The Health Care Proxy form does not give your agent the power to make non-health care decisions for you, such as financial decisions.

Why do I need to appoint a health care agent if I'm young and healthy?

Appointing a health care agent is a good idea even though you are not elderly or terminally ill. A health care agent can act on your behalf if you become even temporarily unable to make your own health care decisions (such as might occur if you are under general anesthesia or have become comatose because of an accident). When you again become able to make your own health care decisions, your health care agent will no longer be authorized to act.

How will my health care agent make decisions?

Your agent must follow your wishes, as well as your moral and religious beliefs. You may write instructions on your Health Care Proxy form or simply discuss them with your agent.

How will my health care agent know my wishes?

Having an open and frank discussion about your wishes with your health care agent will put him or her in a better position to serve your interests. If your agent does not know your wishes or beliefs, your agent is legally required to act in your best interest. Because this is a major responsibility for the person you appoint as your health care agent, you should have a discussion with the person about what types of treatments you would or would not want under different types of circumstances, such as:

- whether you would want life support initiated/continued/removed if you are in a permanent coma;
- whether you would want treatments initiated/continued/removed if you have a terminal illness;
- whether you would want artificial nutrition and hydration initiated/withheld or continued or withdrawn and under what types of circumstances.

Can my health care agent overrule my wishes or prior treatment instructions?

No. Your agent is obligated to make decisions based on your wishes. If you clearly expressed particular wishes, or gave particular treatment instructions, your agent

has a duty to follow those wishes or instructions unless he or she has a good-faith basis for believing that your wishes changed or do not apply to the circumstances.

Who will pay attention to my agent?

All hospitals, nursing homes, doctors and other health care providers are legally required to provide your health care agent with the same information that would be provided to you and to honor the decisions by your agent as if they were made by you. If a hospital or nursing home objects to some treatment options (such as removing certain treatment) they must tell you or your agent BEFORE or upon admission, if reasonably possible.

What if my health care agent is not available when decisions must be made?

You may appoint an alternate agent to decide for you if your health care agent is unavailable, unable or unwilling to act when decisions must be made. Otherwise, health care providers will make health care decisions for you that follow instructions you gave while you were still able to do so. Any instructions that you write on your Health Care Proxy form will guide health care providers under these circumstances.

What if I change my mind?

It is easy to cancel your Health Care Proxy, to change the person you have chosen as your health care agent or to change any instructions or limitations you have included on the form. Simply fill out a new form. In addition, you may indicate that your Health Care Proxy expires on a specified date or if certain events occur. Otherwise, the Health Care Proxy will be valid indefinitely. If you choose your spouse as your health care agent or as your alternate, and you get divorced or legally separated, the appointment is automatically canceled. However, if you would like your former spouse to remain your agent, you may note this on your current form and date it or complete a new form naming your former spouse.

Can my health care agent be legally liable for decisions made on my behalf?

No. Your health care agent will not be liable for health care decisions made in good faith on your behalf. Also, he or she cannot be held liable for costs of your care, just because he or she is your agent.

Is a Health Care Proxy the same as a living will?

No. A living will is a document that provides specific instructions about health care decisions. You may put such instructions on your Health Care Proxy form. The Health Care Proxy allows you to choose someone you trust to make health care decisions on your behalf. Unlike a living will, a Health Care Proxy does not require that you know in advance all the decisions that may arise. Instead, your health care agent can interpret your wishes as medical circumstances change and can make decisions you could not have known would have to be made.

Where should I keep my Health Care Proxy form after it is signed?

Give a copy to your agent, your doctor, your attorney and any other family members or close friends you want. Keep a copy in your wallet or purse or with other important papers, but not in a location where no one can access it, like a safe deposit box. Bring a copy if you are admitted to the hospital, even for minor surgery, or if you undergo outpatient surgery.

May I use the Health Care Proxy form to express my wishes about organ and/or tissue donation?

Yes. Use the optional organ and tissue donation section on the Health Care Proxy form and be sure to have the section witnessed by two people. You may specify that your organs and/or tissues be used for transplantation, research or educational purposes. Any limitation(s) associated with your wishes should be noted in this section of the proxy.

Failure to include your wishes and instructions on your Health Care Proxy form will not be taken to mean that you do not want to be an organ and/or tissue donor.

Can my health care agent make decisions for me about organ and/or tissue donation?

No. The power of a health care agent to make health care decisions on your behalf ends upon your death. Noting your wishes on your Health Care Proxy form allows you to clearly state your wishes about organ and tissue donation

Who can consent to a donation if I choose not to state my wishes at this time?

It is important to note your wishes about organ and/or tissue donation so that family members who will be approached about donation are aware of your wishes. However, New York law provides a list of individuals who are authorized to consent to organ and/or tissue donation on your behalf. They are listed in order of priority: your spouse, a son or daughter 18 years of age or older, either of your parents, a brother or sister 18 years of age or older, a guardian appointed by a court prior to the donor's death, or any other legally authorized person.

Nathan Littauer Hospital Association v. Spitzer

LITTAUER HOSP. ASSN. v. SPITZER, 89484 [3d Dept 2001] ___ N.Y.S.2d ___

NATHAN LITTAUER HOSPITAL ASSOCIATION et al., Respondents, v. ELIOT L. SPITZER, as Attorney-General of the State of New York, Appellant.

89484

Appellate Division of the Supreme Court of the State of New York, Third Department.

December 20, 2001.

LITTAUER HOSP. ASSN. v. SPITZER, 89484 [3d Dept 2001] ___ N.Y.S.2d ___

NATHAN LITTAUER HOSPITAL ASSOCIATION et al., Respondents, v. ELIOT L. SPITZER, as Attorney-General of the State of New York, Appellant.

89484

Appellate Division of the Supreme Court of the State of New York, Third Department.

December 20, 2001.

Appeal from an order of the Supreme Court (Best, J.), entered March 14, 2001 in Fulton County, which, *inter alia*, granted plaintiffs' motion for summary judgment and made a declaration in their favor.

Eliot Spitzer, Attorney-General (William Josephson of counsel), New York City, for appellant.

Harris Beach L.L.P. (Paul R. Braunsdorf of counsel), Rochester, for Nathan Littauer Hospital Association, respondent.

Tobin & Dempf (Michael L. Costello of counsel), Albany, for St. Mary's Hospital at Amsterdam, respondent.

Arnold & Porter (Genevieve R. Bishop of counsel), New York City, for Save Our Services-Gloversville and others, *amici curiae*.

O'Connell & Aronowitz (Jeffrey J. Sherin of counsel), Albany, for Healthcare Trustees of New York State, *amicus curiae*.

Wilson, Elser, Moskowitz, Edelman & Dicker L.L.P. (Darrell E. Jeffers of counsel), Albany, for Healthcare Association of New York State and others, *amici curiae*.

Before: Cardona, P.J., Crew III, Carpinello, Mugglin and, Rose, JJ.

OPINION AND ORDER

Crew III, J.

Plaintiffs, Nathan Littauer Hospital Association and St. Mary's Hospital at Amsterdam, are not-for-profit hospitals located in the City of Gloversville, Fulton County, and the City of Amsterdam, Montgomery County, respectively. Colonial Healthcare Corporation, a not-for-profit corporation, is the sole member of Littauer, and Carondelet Health Systems Inc., also a not-for-profit corporation, is a corporate member of St. Mary's. Plaintiffs seek to affiliate under a newly created common parent corporation, Tri-County Health System (hereinafter TCH).

To that end, on or about February 26, 1999, Littauer, St. Mary's, Colonial and Carondelet entered into a "Definitive Agreement", pursuant to the terms of which TCH would become the sole member of each plaintiff. Colonial and Carondelet, in turn, would be the only two members of TCH. As the sole corporate member of Littauer and St. Mary's, TCH would assume certain statutory powers under the N-PCL including, *inter alia*, the power to appoint and/or remove directors and approve amendments to the respective certificates of incorporation and bylaws. The proposed affiliation would be accomplished by plaintiffs each filing a restated certificate of incorporation which, in turn, would amend their respective certificates of incorporation to reserve to TCH certain governance and management powers.

During public review of the subject transaction, defendant determined that the proposed affiliation required Littauer to file a petition with Supreme Court pursuant to N-PCL 510 and 511, with notice to defendant. Defendant also took the position that plaintiffs were required to seek court approval of their restated certificates of incorporation in accordance with N-PCL 804 and 805. Plaintiffs disagreed and commenced this declaratory judgment action seeking a declaration that the proposed affiliation does not require Supreme Court's approval pursuant to the cited provisions of the N-PCL. Following joinder of issue, plaintiffs moved for summary judgment and defendant cross-moved for similar relief. Supreme Court granted plaintiffs' motion and denied defendant's cross motion, prompting this appeal.

A Type B not-for-profit corporation is required to obtain the approval of a Justice of the Supreme Court of the judicial district in which the office of the corporation is located, upon 10-days' written notice to defendant, prior to filing an amendment to its certificate of incorporation if such amendment "seeks to change or eliminate a purpose or power enumerated in the corporation's certificate of incorporation, or to add a power or purpose not enumerated therein" (N-PCL 804 [a]

[ii]). This approval process also applies to a restatement of a certificate of incorporation if such document includes an amendment to the powers or purposes enumerated in the corporation's certificate of incorporation (*see*, N-PCL 805 [d]).

Initially, a review of Littauer's current and restated certificates of incorporation reveals that there has been no change to Littauer's underlying corporate purpose. As set forth in the current certificate of incorporation, Littauer's mission is to "erect, establish, maintain and operate a hospital, infirmary or home for the reception, care, maintenance, giving of medical and surgical advice, aid and treatment to persons afflicted with maladies, or physical injuries, or physical weaknesses or infirmities". This statement is repeated verbatim in the restated certificate of incorporation, and careful examination of that document discloses no change to Littauer's overall business purpose. We reach a similar conclusion as to the current and restated certificates of incorporation of St. Mary's.

With regard to whether Littauer's restated certificate of incorporation "seeks to change or eliminate a * * * power enumerated in the corporation's certificate of incorporation, or to add a power * * * not enumerated therein" (N-PCL 804 [a] [ii]), defendant's argument is two-fold. First, seizing upon the word "enumerated", defendant argues that merely reciting the powers to be vested in TCH as Littauer's sole member, which appear to be nothing more than the general and special powers conferred upon all not-for-profit corporations under N-PCL 202 (a), constitutes an addition of corporate powers because Littauer's current certificate of incorporation does not "enumerate" any powers whatsoever. In our view, defendant's interpretation of N-PCL 804 (a) (ii) is both strained and overly simplistic. Plainly, the statute is designed to require prior court approval only in instances where the proposed amendment truly seeks to change the nature, object or powers of a particular corporation. Under the restated certificate of incorporation at issue here, TCH, as Littauer's sole member, would derive no fewer or greater powers than those currently possessed by Littauer. Indeed, the sole difference between the current and restated certificates of incorporation relative to the issue of corporate powers is that the former is silent on that point while the latter delineates such in painstaking detail. In our view, the mere act of delineating powers already validly possessed by a particular corporation does not constitute an "addition" of corporate powers, thereby triggering the review and approval procedures mandated by N-PCL 804 (a) (ii). Nor are we persuaded that the reservation of the enumerated powers contained in Littaurer's restated certificate of incorporation to TCH, as Littauer's sole member, constitutes a change in, elimination of or addition to corporate powers warranting judicial intervention and approval.

We reach a similar conclusion with regard to defendant's argument that there has been a "change" in certain of the powers enumerated in the current certificate of incorporation of St. Mary's. Pursuant to paragraph 7 (e) of the restated certificate of incorporation, TCH, as the sole corporate member of St. Mary's, would possess the power to "approve * * * the entry by [St. Mary's] into a contract to manage all or part of any other entity, or to be managed, in whole or in part, by any other entity" and, pursuant to paragraph 7 (h), the power to "approve the sale, lease, pledge, mortgage or other disposition of any assets of [St. Mary's]" under certain specified circumstances. Although the foregoing provisions indeed constitute a restatement of corporate powers utilizing language somewhat different than that appearing in the current certificate of incorporation of St. Mary's, the general and specific powers enumerated therein have not been altered. And, as was the case with Littauer's restated certificate of incorporation, we are not persuaded that the reservation of enumerated powers contained in the restated certificate of incorporation of St. Mary's to TCH constitutes a change in, elimination of or addition to corporate powers such that judicial approval is required.

In addition to addressing the arguments advanced by defendant as to the need for compliance with the provisions of N-PCL 804 (a) (ii), we need to consider the contentions of Save Our Services-Gloversville, Planned Parenthood Mohawk-Hudson Inc., Family Planning Advocates of New York State and Citizen Action of New York as *amici curiae* in this matter. Littauer's restated certificate of incorporation contains a provision directing that "the provision by [Littauer] of a service which was not offered by [Littauer] as of the day before [TCH] became the sole corporate member of both [Littauer and St. Mary's] be in conformance with the Ethical and Religious Directives for Catholic Health Care Services". The restated certificate of incorporation contains a similar provision requiring that the discontinuance of a service provided by Littauer be in compliance with the aforementioned directives. Because such provisions admittedly affect the ability of Littauer to provide abortion-related services and potentially impact upon Littauer's ability to offer, *inter alia*, contraception services and counseling, *amici curiae* argue that such provisions constitute a change in corporate powers and, as such, review and approval under N-PCL 804 (a) (ii) is mandated.

Although mindful of the perhaps subtle distinction that exists between a corporation's powers and purposes and the services that it actually provides, we nonetheless are not persuaded that the cited provisions

in Littauer's restated certificate of incorporation constitute a curtailment of corporate power. To be sure, under the general and special powers available to all not-for-profit corporations under N-PCL 202 (a), Littauer previously was vested with the power to decide, in an exercise of its business judgment, which services could appropriately and profitably be provided to achieve its overall corporate purpose and mission. In that regard, Littauer no doubt made numerous decisions over the years regarding the provision or discontinuance of various services pursuant to criteria nowhere specified in its certificate of incorporation. Although TCH, as Littauer's sole member, would now be vested with such decision-making authority under the restated certificate of incorporation, and although certain guidelines governing such decisions—namely, that the provision or discontinuance of services be in compliance with the foregoing directives—now appear in the restated certificate of incorporation, the basic power at issue remains unaltered. In other words, the decision to delineate in a restated certificate of incorporation a specific or potential restriction upon the services to be provided by the corporation is not the functional equivalent of altering the corporation's underlying purpose or curtailing its power to achieve its overall objectives. Accordingly, we find the position taken by *amici curiae* to be lacking in merit.

As a final matter, defendant contends that judicial approval of Littauer's restated certificate of incorporation is required pursuant to N-PCL 510 (a) (3) which, in turn, requires that a Type B not-for-profit corporation obtain leave of Supreme Court prior to any "sale, lease, exchange or other disposition" of all, or substantially all, of the assets of the corporation (*see also,* N-PCL 511). Defendant's theory on this point is that the change in membership of Littauer and the corresponding reservation of powers to TCH constitutes an "other disposition" of assets under N-PCL 510 and 511. We cannot agree. Although there indeed will be a change in Littauer's membership if the proposed affiliation is accomplished, defendant has failed to offer any persuasive authority in support of the proposition that a change in the composition of Littauer's membership is the functional equivalent of a sale, lease, exchange or other disposition of corporate assets. Defendant's remaining contentions, to the extent not specifically addressed, have been examined and found to be lacking in merit.

Cardona, P.J., Carpinello, Mugglin and Rose, JJ., concur.

ORDERED that the order is affirmed, without costs.

Editor's Note: *The Attorney General is appealing this decision to the N.Y. State Court of Appeals.*

Legislation Report: Family Health Care Decision Act

Editor's Note: *The Health Law Section approved and issued this report in March 2001. It is reprinted in this issue of the* Health Law Journal *because of the possibility of activity on the proposed Family Health Care Decisions Act in 2002, and the relevance of this report to that debate.*

Health Law Section

Report No. 68 June 25, 2001

A.5523 By: M of A Gottfried

Assembly Committee: Health

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

LAW AND SECTION REFERRED TO: Article 29-C of the public health law

REPORT PREPARED BY THE HEALTH LAW SECTION (#3)

THE BILL IS APPROVED WITH AMENDMENT

The Health Law Section recommends that the Family Health Care Decisions Act (the "Act") should be amended to simplify the legislation and address several key issues that have proven contentious in public consideration of the bill. Specific recommendations for amendments are set forth below. The Health Law Section has proposed these changes in the hope of renewing public deliberation and action on the bill. The Family Health Decisions Act remains critically important to patients, their families, and health care providers in New York State. The Health Law Section urges passage of the amended bill during this legislative session.

The Need for Legislation

The Family Health Care Decisions Act is urgently needed to protect the wishes and best interests of patients in New York State. Under current law, no one, not even a concerned family member, has the right to decide to forgo life-sustaining measures for patients who lack decision-making capacity, unless the patient has signed a health care proxy or left "clear and convincing evidence" of his or her treatment wishes. Most people never sign a proxy or leave this kind of evidence. As a result, incapacitated patients are routinely at risk of receiving burdensome treatments that violate their wishes, values, or religious beliefs. By giving family members and others close to the patient the right to decide about medical treatment for patients who lack capacity, the Family Health Care Decisions Act would bring New York law in line with the law in the vast majority of other states. The Act contains important safeguards to ensure that decisions promote the wishes and best interests of incapacitated patients.

The Act would also remove legal barriers to needed treatment for patients who are too ill to decide for themselves and have no family members or others close to them to decide on their behalf. Under existing law, decisions to provide needed treatment for patients who have no surrogate must be made by a court-appointed guardian or approved by a judge. The Family Health Care Decisions Act establishes a process for health care providers to authorize needed treatment, in accord with the known wishes, if any, or the best interests of patients who have no family members or others to consent on their behalf.

Recommended Changes

The Family Health Care Decisions Act was proposed by the New York State Task Force on Life and the Law in 1992. The Act has the support of over 40 consumer, religious, professional, and civic organizations in New York State, many of whom testified in support of the Act in public hearings held by the Legislature in 1993 and 1996. Despite this exceptionally broad support, the Act has not been passed due to continuing controversy regarding certain provisions and concern that the bill is too complex and may be difficult to implement. The proposed amendments simplify procedures in the bill in key sections and address issues that have been the subject of continuing public discussion. Specific recommendations for changes to the Act are set forth below.

Decisions about life-sustaining treatment for patients without surrogates; role of ethics review committees

As currently drafted, the Act would give "ethics review committees" in hospitals and long-term care facilities the authority to review and approve physicians' recommendations to withhold or withdraw life-sustaining treatment for incapacitated patients with no family member or friend to decide on their behalf. After careful consideration, the Health Law Section concluded that the facility-based decision-making process set forth in the Act should be eliminated. Instead, courts should be authorized to approve decisions to forgo life-sustaining treatment for patients without surrogates in accord with the standards set forth in the Act.

The central premise of the Act is that relying on decisions by family members and others close to the patient is the best way to protect the wishes and best interests of patients too ill to decide about life-sustaining treatment for themselves. Since the Act was first proposed in 1992, patient advocates and others have expressed concern that

facility-based committees cannot adequately protect isolated patients with no one to advocate on their behalf. The Task Force on Life and the Law recognized the vulnerability of this patient population and devised extensive procedural protections for review by ethics committees. The number and complexity of these provisions increased during the process of public comment and revision. In fact, much of the complexity and administrative burden in the Act arises from the grant of authority to ethics review committees to decide about life-sustaining treatment for patients without surrogates. Removing the authority accorded facility-based committees for this vulnerable population and referring those decisions to the courts would simplify and strengthen the legislation.

Judicial review and authorization for decisions to forgo life-sustaining treatment for patients without surrogates would constitute a significant advance for these patients over existing law. Under the amendments, courts would be authorized to approve the withholding or withdrawal of life-sustaining treatment for patients without surrogates in accord with the standards set forth in the Act. By contrast, under existing law, not even a court can decide to withhold or withdraw life-sustaining treatment for an incapacitated patient in the absence of clear and convincing evidence of the patient's wishes, even when the treatment is clearly inconsistent with the patient's best interests. Because the wishes of patients who have no family members or friends are rarely known with such specificity, existing law makes it virtually impossible for courts to make appropriate decisions about the use of life-sustaining treatment for these patients.

Decision-making standard

In the current version of the Act, the decision-making standard for decisions to withhold or withdraw life-sustaining treatment requires that decisions be made on an individualized basis for patients, and further requires the surrogate to consider the patient's preferences, values, and personal circumstances. Inclusion of this language only for decisions about life-sustaining treatment suggests that this standard is somehow unique to this set of decisions. In fact, these requirements should apply to all decisions; decisions about other medical treatments ranging from organ transplantation to elective surgical procedures should also be made in accord with these requirements. The amendments proposed by the Health Law Section therefore incorporate this language into the general decision-making standard.

In addition, decisions for patients who are pregnant have been the subject of extensive public discussion. The Health Law Section recommends the addition of language that expressly requires consideration of the impact of treatment decisions on the course and outcome of the patient's pregnancy. The Section believes that this language reflects a consensus shared by New Yorkers who hold a diversity of perspectives and beliefs.

Record-keeping requirements

The Health Law Section recommends the elimination of several provisions that mandate specific record-keeping requirements for decisions made pursuant to the Act. The Act contains a general provision requiring health care facilities to develop policies to document clinical determinations and decisions by surrogates in accord with accepted medical standards. Implementation of this requirement is best addressed in institutional policies, not in legislation.

Other provisions

The Health Law Section recommends eliminating confusing language that specifies that health care providers are not obligated under the Act to offer or provide a treatment to a surrogate that they would have no obligation to offer or provide to a competent adult. This provision was designed to address the issue of medically futile treatment, but is redundant of the underlying premise of the Act that surrogates would have the same authority as competent adults to make decisions, subject to the standards and limitations set forth in the Act.

The Section proposes that the bill be amended to require health care providers to notify surrogates before relying on a prior decision made by the patient before the loss of decision-making capacity. Because the meaning of the prior decision may be ambiguous, and the applicability of the decision to the current situation may be unclear, those interpreting previous decisions by incapacitated patients should involve the patient's surrogate whenever possible.

The Health Law Section recommends the deletion of language requiring notification of "persons acting as surrogates" when a person higher on the priority list becomes available. The requirement is neither necessary nor likely to have any practical effect. Finally, the Health Law Section recommends deletion of unnecessary language in the section of the Act governing the determination of incapacity.

The recommendations set forth in this memorandum were developed initially by the Section's Special Committee on Treatment Decisions and endorsed by the Executive Committee of the Health Law Section. The members of the Special Committee on Treatment Decisions are as follows:

Special Committee on Treatment Decisions

Carl Coleman, Chairperson
Arthur Levin
Kathryn Meyer
Tracy Miller
Barbara Shack

Testimony on the Professional Medical Conduct Process

New York State Bar Association Health Law Section

Submitted to the New York State Assembly Committees on Health and Higher Education, January 31, 2002

The New York State Bar Association, through its Health Law Section and the many active committees of that Section, has an ongoing interest in the proper and fair administration of professional licensure and discipline in the State of New York. That interest includes the licensing and discipline of attorneys, but also extends to include the licensure and discipline of other professionals, including health care professionals, who are licensed in New York and whose professional practices are subject to scrutiny and regulation by State authorities. As attorneys, the members of our Association's Health Law Section are often called upon as advocates for, and as advocate-opponents of, these licensed professionals and the institutions and employers for which they work and at which they practice their professions. Many of the Health Law Section members also serve directly in the licensure and discipline process, in their role as attorneys or administrative law judges for the New York State Education Department and the New York State Department of Health. For these reasons, in regard to the discipline process for physicians and physician assistants, the members of our Section have broad experience.

The testimony that we offer today does not reflect unanimity within the Association's Health Law Section, although we believe it does reflect the broad, middle range of the thought of Section attorneys. Indeed, the widely differing roles among our Section's members almost guarantee that many of those members will take differing positions regarding the existing disciplinary process within the Office of Professional Medical Conduct (OPMC), some criticizing it vociferously as grossly unfair, others criticizing it as grossly inadequate, and still others defending it as an entirely appropriate compromise among many competing values. The Health Law Section is mindful and vastly supportive, as it must be in light of its own role as part of an association of independent licensed professionals, of the critical need for the State of New York to maintain, foster and protect an effective process for the discipline of physicians. Such a process is required in order to protect the public and to maintain the integrity of the profession itself.

While physicians should be treated fairly and accorded due process, we recognize that patient safety must be the paramount concern. The OPMC has significantly contributed to improving the quality of care in New York by removing bad doctors from practice. The agency should continue to have discretion and the ability to act quickly to protect the public. Strong enforcement power is appropriate given the vital interests at stake and the position of trust held by physicians within the community, yet that position of trust must not be abused and must be limited by clear, consistently applied, and readily understood procedural rules. One of the Section's chief concerns regarding current OPMC practice is that due to the closed nature of the investigatory and hearing processes, evidence regarding OPMC adherence to internal rules—or even the nature and existence of those internal rules—is often anecdotal and ambiguous. Greater clarity of rules, and placing rules into statute or regulation accessible to all and not subject to internal Departmental changes, would be, in general, preferable to the current state of affairs.

For these reasons, the Section believes that it may contribute most valuably to this discussion by suggesting reforms to the existing disciplinary process so that the process itself may be clarified and improved, with fair results for physicians and thus effective results for the public. The Section's goal, in other words, is to elucidate, standardize and improve the process and, insofar as possible, to render its fairness and justice unimpeachable, so that the disciplinary process and OPMC itself are strengthened. An unjust process would be, indeed, unfair to physicians but also ineffective as protection of the public.

Over the past few months, well in advance of the Notice from the Assembly Committees regarding this hearing, two Committees of the Health Law Section of the Association—the Committee on Health Care Providers and the Committee on Hospital In-House Counsel—formed a joint working group to consider the existing disciplinary process within OPMC and methods by which the process might be appropriately reformed. Its process is not yet complete, but its goal is to issue a "white paper" describing any procedural inadequacies and recommending reforms and alternatives. For the purpose of this hearing, however, the Section offers this testimony with our preliminary view of these issues, but does so with the request that when the working group has completed its work, its final product may be submitted to these Assembly Committees for their consideration.

The Health Law Section has several observations and suggestions in regard to OPMC processes and methods of operation. Although all of the observations are readily describable, solutions may be less readily identified in some cases, especially if they involve needed changes in

attitude or informal process. In any case, the Section would make the following observations and suggestions:

1. **The existing OPMC process often fails, in various ways, to give fair notice to physicians of the charges against them. This can result not only in lack of fair process to physicians, but also in inefficiency in the disciplinary process and waste of investigatory and prosecutorial resources.** At the stage of an OPMC investigation when the physician is first notified that he or she may have an interview with an OPMC investigator, OPMC is not obligated to give (and on at least some occasions, does not give) the physician notice of the topic(s) that will be discussed during the interview. Especially given that there is no "statute of limitations" on OPMC charges, the result is that at an interview, a physician may be completely unprepared to discuss issues and topics, and may not even recollect the issues or patients about which or whom he or she is questioned. Gross inefficiency may be the result, even though "surprise" questions may elicit useful information or damaging answers. Further, no transcript is made of these physician interviews; instead, an OPMC investigator routinely takes contemporaneous handwritten notes, and if the case goes to hearing, memoranda based on those notes are often introduced as evidence and used to cross-examine and impeach the credibility of accused physicians. It has been the experience of some Section attorneys that those memoranda are inaccurate. For these reasons, the Health Law Section would propose that before interviews, physicians routinely be given notice of the patient(s) about whom they will be questioned, and at least some idea of the issues involving the patient(s). Further, in order to prevent misunderstandings and misinterpretations of physician statements at these interviews, OPMC should be required to make verbatim transcripts of the interviews themselves, and to make those transcripts available to the physician questioned.

   An additional but related problem is that prior to the interview of the accused physician, OPMC routinely seeks and gains an expert opinion report on the very issues about which the physician is to be questioned. That expert report is not made available to the physician prior to the interview, and in fact, may never be made available to the accused physician until shortly before the commencement of (or even during) an actual hearing. This can result in a gross inefficiency in the process, since the issues raised in an expert opinion may, if closely examined by the physician at that time, be explainable or defensible. Instead of allowing the physician to address the issues raised in that expert report, however, OPMC may continue its investigation, charge the physician and even begin a hearing without providing that report to the accused. If OPMC's expert opinion is in fact flawed in some fundamental way, then under the current process, those flaws may not be uncovered until the middle of a hearing. This is not the best method of assuring a fair and efficient process. The preferable alternative, and one that would not seem to undermine legitimate disciplinary proceedings, would be to have a clear requirement that OPMC provide the accused physician with the OPMC's expert opinion before the interview itself, so that at the interview, the physician may discuss the relevant issues and respond to the expert opinion. Prosecutorial decisions may then be made based on fuller, more informed evidence, with fairer and more efficient results.

   Finally on this issue, charges filed against a physician after an investigation are almost invariably worded in extremely general ways, under what can be extremely vague standards set forth in Section 6530 of the Education Law. The charges themselves need not—just as the investigation process itself need not—provide a physician with full notice of the accusations made. The result is that a physician may, under current rules, proceed to an actual hearing and not become aware of the concrete evidence against him or her until the OPMC attorney presents its witnesses. Although it seems to the Section unduly burdensome to have complete pre-trial discovery available in OPMC proceedings, it seems not unreasonable for OPMC to be obligated to provide some detail regarding accusations and issues prior to interviews, and in any charges filed.

2. **At the outset of the investigation process, physicians are sometimes told by OPMC investigators that legal representation is "their choice" and is not required. When this occurs, it is misleading, and the practice should be remedied.** In some sense, such representations are true, but our Section's members have counseled many physicians who, when they asked about the need for legal representation, have reportedly been told that it is not required, and who then have proceeded to undergo an OPMC interview alone, without representation, and without an understanding of the actual legal defenses that he or she may present. When such a physician is ultimately charged by OPMC, he or she in most cases will retain an attorney, but the attorney must then, at a late date and after the process has ground on for months or even years, finally marshal and present the relevant arguments in the physician's defense. If there are real defenses that have not theretofore been

identified and presented, then the OPMC process has been made less efficient and less fair. There is no reason, in fact, that OPMC should view a physician's legal representation as an obstacle to a sound disciplinary process. Instead, attorney representation should be viewed (and in fact, seems to be viewed by many at OPMC) as a method of assuring that all relevant arguments and facts are presented at an early stage, at a time when efficient prosecutorial and investigatory decisions may be made. Although the Health Law Section does not believe that OPMC investigators should direct or counsel that physicians have legal representation, we do suggest that OPMC adopt a uniform policy that OPMC investigators, when asked by physicians or when inviting physicians to the interview, state the following: that OPMC is a disciplinary body; that it has the ability to discipline physicians for misconduct; that misconduct is a legal definition; that disciplinary action can include loss of medical license; and that physicians are permitted to have legal representation throughout the OPMC process.

3. **OPMC is under no clear statutory or regulatory obligation to provide exculpatory or inculpatory evidence to a physician who has been charged. Internal OPMC policies and procedures that seem to be designed to serve these ends may be inadequate.** The statutes and regulations relating to OPMC in no place provide for any comprehensive, explicit obligation of OPMC staff or attorneys to provide an accused physician with evidence, much less at an early stage of proceedings. Inculpatory evidence therefore often emerges only at hearing or in the days immediately preceding a hearing, long after opportunities for careful examination of the evidence have passed, due to the press of time. Further, there is no statutory or regulatory obligation for OPMC to provide, or alert an accused physician to the existence of, exculpatory evidence. Although OPMC reportedly has an internal policy requiring production of exculpatory evidence to charged physicians, application of that reported internal policy may be inconsistent, and the policy itself could be changed at any time, since it is not based on a clear statutory requirement. Further, recent experience has indicated that in following this internal policy, OPMC may, in fact, not disclose significant exculpatory evidence until very late in the process, during or shortly before a hearing commences, thus reducing its usefulness. The suggestions set forth above (such as clear, specific notice of issues prior to interview) would, if implemented, provide greater notice of inculpatory evidence, but the Section suggests that explicit statutes or regulations also be adopted to require OPMC to turn over exculpatory evidence within a *short* time after that evidence comes into its possession and after a reasonable conclusion may be drawn that the evidence appears exculpatory. Not explicitly to require OPMC to do so seems to the Section directly inimical to the most basic sense of fairness. Indeed, at least one state's highest court has found a state constitutional duty of medical disciplinary bodies to provide exculpatory evidence to accused physicians.

4. **In negotiating possible settlements of charges, OPMC attorneys may open negotiations by an insistent demand that the accused physician agree to surrender his or her license, at least for a significant period of time. This settlement demand may occur even in relatively minor cases. Further, OPMC settlement demands fail to take into account the secondary and tertiary impacts of settlements on physicians, which may be much more far-reaching than licensure discipline itself.** Attorneys who practice before OPMC report that, after making draconian demands for license surrender in some first settlement discussions, OPMC eventually relaxes its settlement demands, but a reduction in the demand may require, even in relatively minor cases, several weeks or months, thus wasting time and effort of both physician and OPMC attorneys. The cause of this approach to many settlement discussions is not clear and may lie in the charging process itself (which is conducted by a committee of the State Board of Professional Medical Conduct), but such a process causes inefficiencies and unfairness, especially if the physician or his or her attorney is not familiar with the settlement process. Further, the Assembly should note that many hospitals, insurers and managed care plans have recently instituted policies that provide for immediate termination of privileges or membership for any physician who has any OPMC order entered against him or her. The result is that even minor OPMC penalties or consent orders can result in a severe or catastrophic reduction in a physician's ability to practice the profession and earn a livelihood. In truly egregious cases of misconduct, this may not be a concern, but for minor infractions of standards, these effects can be unfair. The experience of our Section attorneys has been that OPMC does not take these entirely predictable consequences into account during settlement negotiations; the effect, in reality, is to magnify physician discipline in ways perhaps unintended and unsought by OPMC, but very real for physicians.

5. **OPMC often sets standards in new areas through ground-breaking prosecutions, rather than the Board of Professional Medical Conduct prospectively defining new interpretations of the appli-**

cable disciplinary standards. OPMC enforces standards that are often, as stated above, very broad and vague in their terms. Perhaps this is unavoidable in professional codes, but the result is that in new areas of OPMC enforcement activity—such as research misconduct, "alternative" medicine, inappropriate billing of third party payers, and physician advertising—OPMC prosecutions have the effect of subjecting the unlucky charged physician with a first application of a vague standard to his or her certain category of conduct. In some instances, the violation of professional ethics may be obvious, even if no body of law directly supports OPMC charges, but in other cases—as for example in billing prosecutions and in the practice of "alternative medicine"—OPMC charges may have the effect of applying new standards retrospectively to one or more unlucky physicians. The most appropriate way to avoid this, and to give practicing physicians actual notice of new standards, would be for the State Board of Professional Medical Conduct to issue guidelines or position papers prospectively, not in order to establish specific guidelines for clinical practice, but to define conduct that would violate broadly worded provisions in the statutory definition of misconduct. The Board would then be compelled, in an entirely appropriate way, to express and justify publicly its interpretation of the misconduct standards, and to give physicians fair notice of new standards or interpretations.

6. **The role, duties and powers of administrative law judges should be reviewed carefully by the Assembly Committees, with a view toward enhancing the independence and authority of those judges.** The Association has previously expressed its strong view that administrative law judges should have greater independence from the State agencies whose staff attorneys appear before them. This is no less true in the case of administrative law judges before whom OPMC cases are tried. In the Health Law Section's estimation, strong consideration should be given to increasing the authority of these judges so that they can better control attorneys and proceedings, and can better ensure rapid compliance with orders for the sharing of documents and information according to the existing practices and the new practices suggested above. These judges are able, as is no one else in the existing process, to act as a neutral referee, preventing both physicians' and OPMC attorneys from abusing the process and from delaying proceedings. Among the areas that seem to require attention of these judges is the not uncommon use by OPMC prosecutors of "last-minute" subpoenas for witnesses and medical records, even when the need for such subpoenas can be readily seen months before. Tough prehearing management by qualified administrative law judges can smooth the process, and make it more effective and fairer for all, including for non-party physician witnesses and health care providers required to furnish medical records.

7. **There should be strong consideration of adopting a statute of limitations for OPMC prosecutions.** Presently, there is no statute of limitations on OPMC charges, resulting in situations in which physicians may be charged with conduct that occurred so long ago that memories, evidence, and thus possibilities of defense may be compromised. Strong consideration should be given to adopting a statute of limitations. Six years has been suggested by one Health Law Section member as an appropriate period, presumably since it coincides with the current medical record retention period.

Other concerns recently raised by Section members relate to the composition of hearing panels and the prevalence on panels of a "core" of panel members; the familiarity with which panel members may treat OPMC attorneys; the fact that the Administrative Review Board freely and often increases disciplinary sanctions (unlike most other appellate tribunals); and the failure of OPMC to give post-interview written notice of charges to physicians, as required by statute. The Health Law Section today has no specific recommendations on these issues, but would call the Assembly's attention to these additional areas of concern.

OPMC attorneys, investigators and experts have the difficult, and often undoubtedly unpleasant, task of investigating and prosecuting professional misconduct. No one doubts but that their efforts are conducted in a full spirit of public service. For this, the public and their colleagues owe them gratitude. The suggestions contained in this testimony are not meant as criticisms of OPMC staff, but of OPMC process – of what is and is not clearly, explicitly required by law and regulation. To the extent that new laws and regulations can make physician discipline a "level playing field" and to the extent that the process can have a full appearance and reality of fairness, the daily work of physician discipline will, in the Health Law Section's estimation, ultimately benefit.

The Health Law Section thanks the Assembly Committees, their Chairs and Members, for the opportunity to present this testimony today. The Section fully intends to continue to consider and examine these issues, and stands ready to assist the Assembly in any way that its Committees see fit.

NEWS flash

What's Happening in the Section

Attendance Record for Section's 2002 Annual Meeting

Over 170 health lawyers attended the Section's 2002 Annual Meeting on January 23 at the New York Marriott Marquis in New York City. The featured program, Penalizing Health Care Providers: Enforcement or Exploitation," was chaired by Philip Rosenberg of Wilson, Elser, Moskowitz, Edelman & Dicker, LLP.

In addition to professional education presentations, the program included an engaging panel discussion among regulators and representatives of provider associations.

DOH General Counsel Donald P. Berens, Jr. gives luncheon address.

Chair Robert Abrams presents an award to 2000-01 Chair Tracy Miller.

Committee Chairs Lynn Stansel and Mark Barnes describe a joint project of the In-house Counsel and Health Care Providers Committees.

New Section Officers Elected

At the Annual Meeting, the Section elected the following officers for 2002-03:

Chair:	Salvatore J. Russo	NYC Health and Hospitals Corporation
Chair-Elect:	James W. Lytle	Kalkines, Arky, Zall and Bernstein
Vice-Chair:	Philip Rosenberg	Wilson, Elser, Moskowitz, Edelman & Dicker, LLP
Secretary:	Lynn Stansel	Montefiore Medical Center
Treasurer:	Mark Barnes	Ropes & Gray

Section Committees and Chairs

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

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Health Law Section

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____ Consumer / Patient Rights (HLS1200)

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

____ Fraud, Abuse and Compliance (HLS2400)

____ Health Care Internet (HLS2700)

____ Health Care Providers (HLS1400)

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